



U.S. Department of Commerce  
International Trade Administration

# Healthcare Technologies Resource Guide

**A Reference for U.S. Exporters to World Markets**

Prepared by:  
U.S. Commercial Service  
Global Healthcare Technologies Team  
2011-2012 Edition



# Global Healthcare Technologies Team

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# What Can The Healthcare Technologies Team Do For You?

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Across the world healthcare is consistently a strong and growing industry. With private and public spending on an upwards trend in many countries, we urge you to take advantage of the U.S. Commercial Service to develop your international strategy.

## What Can the Healthcare Technologies Team Do for You?

Whether you are a new exporter or experienced global company, the U.S. Commercial Service global **Healthcare Technologies Team** is your primary export resource and should be your first point of contact when selling overseas.

Our members are domestic and international Trade Specialists who focus on helping U.S. healthcare companies sell their products and services internationally. Our Team members are located throughout the United States and in the U.S. Embassies and Consulates overseas and help you identify markets of opportunity and connect you with qualified distributors and partners in foreign markets

- We provide up-to-date market research produced by our overseas specialists on market conditions, industry-specific information, areas of growth and opportunity, local competition, distribution channels, and more.
- We disseminate trade leads at the request of foreign buyers
- We are present at a most large international trade shows across the globe in an effort to maximize your time at these events through matchmaking and pre-show promotional campaigns to foreign buyers
- We offer market and issue-specific webinars with industry experts that you can participate in without leaving your desk
- We organize trade missions to markets that hold great opportunities
- We maintain and build partnerships with industry associations to jointly promote your interests

We look forward to helping your business achieve its international goals!

**For more information** on how the CS Healthcare Technologies Team can help your business increase its international sales, please contact:

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# How To Use This Guide

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While our economy may be taking a downturn, exports are booming. Many U.S. healthcare firms, both small and large, have been able to continue their success by looking at foreign buyers and overseas partners. Through this Resource Guide, the U.S. Commercial Service is encouraging more U.S. firms to take advantage of a weak dollar and a global demand for American expertise in the healthcare sector to explore foreign markets.

The Resource Guide is divided into three main sections, a healthcare sub-sector matrix, certification matrix, and a market research section for each country. In the back of this book you will find a reference section that is designed to provide additional sources of information for exporting generally. The sub-sector matrix provides ratings for countries in each of 15 healthcare sub-sectors. It is intended to provide the reader with a quick reference in understanding which of 15 healthcare sub-sectors have the most potential for success in a given market. Each sub-sector and market has a 1-4 rating according to the opinion of our healthcare commercial specialist.

The numbers refer to the following.

- 1 A U.S. exporter has little or no probability of success in this market
- 2 There are more challenges than opportunities for a U.S. exporter in this market
- 3 There are more opportunities than challenges for a U.S. exporter in this market
- 4 A U.S. exporter has a very high probability of success in this market

Following the subsector matrix is a matrix that includes the certification requirements for the countries in the guide. It explains whether or not a county requires or accepts FDA certification, and or CE Mark certification. The matrix also provides information about the certifying bodies in the country.

A short market research section follows, authored by each healthcare commercial specialist that further explains opportunities or barriers within the markets indicated in the matrix.

The ratings in the sub-sector matrix, the certification matrix, and the market research represent the opinions of the commercial specialists responsible for the healthcare sector at U.S. embassies and consulates worldwide. You will notice that the sub-sector categories are still quite broad and may not be applicable to specific products within those sub-sectors. We encourage you to do further research to confirm that there is a market for your product or service. There may be additional barriers to entry once a market is further explored, such as political turmoil or a change in import duties since the date of this publication. While we encourage you to use our expertise and services, there are other sources of information to help decide if you are prepared to enter a foreign market. See our reference section for more information.

The U.S. Commercial Service is present in 80 countries; however we are not in all markets. Not all countries are represented in the matrix or the market research section. Therefore, you should not assume that there is no market for U.S. healthcare products in countries not included in this guide. If you are interested in a market that is not represented in the Resource Guide, contact the nearest local U.S. trade specialist in one of our 102 offices in the U.S.

*Disclaimer: The information provided in this report is intended to be of assistance to U.S. exporters. While we make every effort to ensure its accuracy, neither the United States government nor any of its employees make any representation as to the accuracy or completeness of information in this or any other United States government document. Readers are advised to independently verify any information prior to reliance thereon. The information provided in this report does not constitute legal advice. International copyright, U.S. Department of Commerce, 2008. All rights reserved outside of the United States.*

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## European Union

**Capital:** Brussels  
**Population:** 501 Million  
**GDP:** US \$14.793 Trillion  
**Currency:** Euro  
**Language:** 23 different languages



### Summary

As the European Union (EU) does not have a Food and Drugs Administration (FDA), the task of harmonizing requirements and regulating medical devices is handled by the European Commission in close cooperation with Member State's Health Authorities. The purpose of the EU harmonization effort is to merge the differing national requirements into one law which can be applied throughout the European Union. Legislation adopted through this process covers implantable, non-implantable and in vitro diagnostics medical devices in three separate directives that provide manufacturers the basics to certify their compliance with EU-wide safety requirements.

### Adopted Legislation

The following EU directives are in force throughout the European Union consisting of 27 Member States (Austria, Belgium, Czech Republic, Cyprus, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxemburg, Malta, the Netherlands, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Romania, Bulgaria and the United Kingdom):

- **Active implantable medical devices (90/385/EEC):** Active implantable medical devices (AIMD), such as heart pacemakers or defibrillators are defined as “any active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure”. Considering the potentially high risk factor of such devices for the patient, manufacturers cannot self-certify and have to rely on the services of an accredited test laboratory to complete the process of compliance.
- **Medical devices (93/42/EEC):** Medical devices are broadly defined as “any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings” for several purposes such as diagnosis, treatment, alleviation of disease and more. As the range of this directive is broad and leaves room for interpretation, the Commission has written guidance for manufacturers. Medical devices include syringes, bandages, wheelchairs, endoscopes, prescription glasses and contact lens solution among others. As the range of devices covers minimal risk as well as higher risk devices, the classification of the product will determine whether a manufacturer can self-certify or needs to involve the services of an accredited test laboratory.
- **In vitro medical devices (98/79/EC):** An in vitro diagnostic device (IVD) is a “reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system whether used alone or in combination intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body solely or principally for the purpose of providing information”. It covers items such as pregnancy test kits and blood analysis machines. While manufacturers of simple IVD test kits such as for diabetes can self-certify compliance with the requirements, more high risk test kits such as HIV will require the services of a notified body.

The directives have been supplemented over time by six modifying and implementing directives, including the last technical revision brought about by [Directive 2007/47/EC](#) which entered into force on March 21<sup>st</sup>, 2010. The main changes introduced by this directive impact medical devices and active implantable medical devices. New elements are among others:

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- *The conformity assessment procedures and classification of devices as well as the essential requirements for active implantable medical devices (AIMDs) and medical devices (MDs) have been somewhat simplified, harmonized and enhanced.*
  - Software with an intended medical purpose is now a medical device in its own right.
  - All certificates issued by notified bodies are limited to a maximum validity of 5 years.
  - With the emphasis on clinical data for all devices in the new directive, the European Commission published [guidance](#) on the clinical evaluation dossier in December 2009.
  - Use of PVC softeners in certain types of devices will require labeling. Following a mandate from the European Commission for medical devices, CEN, the European standards organization, has developed a [draft standard pr EN 15986](#) which includes a symbol to show the presence of phthalates in medical devices.
  - Custom-made devices will be subject to a post-market review system.

Since directive 2007/47/EC is not easy to read, the changes have been merged with the original directives to create a single, readable text which is up-to-date. The consolidated versions as well as guidance can be downloaded here:

[Directive 90/385/EEC on active implantable medical devices](#)

[Directive 93/42/EEC on medical devices](#)

[Directive 98/79/EC on in vitro diagnostics](#)

[Guidance document from the Commission on Interpreting Directive 2007/47/EC](#)

## CE Marking

Known as “new approach” directives, these directives outline a set of “essential requirements”, rely on use of voluntary EU wide harmonized standards, and offer a choice of conformity assessment modules. The distinguishing feature of new approach directives is CE marking, which is a conformity mark, affixed to the product, the instructions for use and the packaging, an indication to inspection authorities that the product complies with the directives. The steps for compliance with EU medical device legislation are described in the following paragraphs.

## Exception to CE Marking

While CE marking is generally required on all medical devices, there are a few exceptions. All custom made implantable and non-implantable devices and devices for clinical investigations are subject to a different conformity assessment module which does not require CE marking at the end of the process. In vitro diagnostics for performance evaluation or research purposes only are not subject to the IVD directive although they may be subject to national requirements. In general, devices shown at trade fairs, exhibits, for demonstrations etc do not need to have CE marking. However, it is recommended to indicate clearly that non-CE marked devices are for demonstration purposes only.

## Classification

Manufacturers should note that the differences in regulatory approach between the EU and the U.S. mean differences in classification and compliance verification. It would be wrong to assume that meeting the requirements for the U.S. market would satisfy the EU requirements. To illustrate this point, hospital beds including accessories, according to FDA guidance, are either Class I or II depending on the type of bed. In the EU, hospital beds and accessories are classified as Class I devices, allowing self-certification. In addition, the beds and their accessories would have to be considered separately, each as medical devices in their own right, especially when such items are sold separately.

The AIMD directive has but one class and does not allow self-certification. The medical device directive covers four classes, ranging from Class I, II a and b to Class III. Only Class I devices can be self-certified.

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Manufacturers have to involve the services of a notified body in all other cases, and sterile Class I devices or those with a measuring function must also use a notified body. The IVD does not distinguish classes but rather groups: general tests, self-testing kits, and Annex II lists A and B. For simple tests, self certification is usually an option. To help with classification in case the annexes in EU directives are difficult to interpret, the Commission has published new guidance on its website - [Guidance on the classification of medical devices](#).

### **Borderline Products**

For the majority of medical devices, the purpose is obvious: pacemakers, endoscopes, syringes and wound dressing are clearly to be used for medical purposes. Products where the intended purpose is not so clear are known as borderline products and they may be subject to several directives. For example, a scale to weigh patients in a hospital would be subject to both the non-automatic weighing scale and the medical device directives. Disinfectants for exclusive use with a medical device may be classified as an accessory to a medical device because the intended purpose is medical rather than general. The intended purpose is usually supported by appropriate statements on the company's website or in promotional literature. It is possible to get an official interpretation to clarify borderline products but manufacturers should be able to make the determination in most cases themselves by using the guidance provided by the Commission.

The Commission released new guidance on borderline products in March 2011: [Manual on borderline and classification of medical devices](#).

### **Compliance with “Essential Requirements”**

The “essential requirements” for the protection of health, safety and environmental concerns form the core of the directives. They cover risks and hazards that may occur at the design, production and handling stages. The manufacturer has to address the essential requirements which apply to a product and identify relevant risks for the patient. Non-relevant essential requirements do not have to be considered. As an example, manufacturers of arm braces made of stretch fabric would have to consider the essential requirements related to “compatibility between the materials used and biological tissues”, in other words, the fabric's potential to cause skin allergies. A non-relevant requirement for arm braces would be “protection against radiation”. Choice of packaging is an essential requirement for prepackaged devices, as damage resulting from mishandling could have an adverse impact on the device making it harmful for the patient upon use. These are just examples, bearing in mind that there are many other elements to verify and that the manufacturer should carefully review the complete list of essential requirements.

### **Use of EU-wide Harmonized Standards**

The task of complying with essential requirements can be simplified by voluntarily using EU (EN) harmonized standards. The risk assessment management standard which facilitates the initial checking of the relevant essential requirements is ISO/EN 14971. Manufacturers may also establish their own checklists for risk assessment of medical devices.

Other than the risk assessment standard mentioned above, the Commission has listed over hundred EU wide harmonized medical device standards addressing various essential requirements. These standards have been developed and/or identified by the European standards organizations. They are often based on international standards. References to EN standards are published in the Official Journal (the EU equivalent of the U.S. Federal Register). As a result, the standards are uniquely linked to EU legislation and are known as harmonized standards. Use of EU harmonized standards gives “presumption of conformity”. When a manufacturer opts not to use an EU harmonized standard or prefers to design/manufacture to other standards, then the manufacturer has to show in great detail how their

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medical device meets the essential requirements in EU medical device legislation. All other existing standards not published in the Official Journal are either national or industry standards.

## **Modules of Conformity Assessment**

To facilitate acceptance of the final product as meeting the requirements of the EU directive, the manufacturer will have to choose a conformity assessment module as described in the annexes of EU medical device legislation. The choice of the module is determined by the classification and the preference of the manufacturer for a given module. As there may be several options, the Commission created flow charts to facilitate the task of selection. The flow charts can be found in [Annex 8 of the Guide to New and Global Approach](#).

The conformity assessment modules address the design and production stages. For design, the manufacturer must provide the evidence of how the device meets the essential requirements. For production, the manufacturer has to put in place and document a quality system to ensure continuity in complying with the essential requirements.

Low risk products, such as Class I medical devices or self-test kits, generally allow self-certification based on conformity assessment module A which consists of establishing a Declaration of Conformity and compiling a technical file. All modules between B and H combine design and production compliance such as type examination and verification of manufacturing to type based on technical file inspection (modules B and F) or full quality assurance (module H). As these are conformity assessment modules for higher risk products, the services of an EU notified body or U.S. based subcontractor will be required to some degree depending on the classification.

## **Roles of a Notified Body**

All active implantable medical devices and certain types of IVDs as well as medical devices belonging to Class II a or b or higher require the involvement of a notified body, the official term for accredited test laboratory based in the EU. Only notified bodies in the European Union can make the final assessment of conformity certification in accordance with EU directive(s). A U.S. based subcontractor of an EU notified body, such as UL or Intertek Testing Services, can also handle the tests for certification, but the certificate of conformity will still have to be supplied by the EU based notified body.

## **Technical File**

The technical file contains all relevant information to support the claims of compliance with EU requirements such as a general description of the product, documentation of the quality system, design information, list of standards used, result of design calculations/inspections, test reports, performance evaluation data, sample of label and instructions for use, and Declaration of Conformity. It is to be kept either by the manufacturer or his/her authorized representative with the understanding that it should be quickly accessible upon request from an official national inspection authority.

## **Declaration of Conformity**

Among the final steps in the CE marking process of medical devices is the drawing up of a Declaration of Conformity which consists of name and address of the manufacturer and/or authorized representative, product name, type, model number and any relevant supplementary information, the reference numbers of standards, the date, a signature with title and a statement regarding responsibility of manufacturer or authorized representative. By applying the CE marking on the product, packaging and on the instructions for use, which can be done either by the manufacturer or his importer/distributor, the manufacturer has completed the CE marking process.

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## Authorized Representative

Manufacturers outside the EU have to identify an EU-based authorized representative unless they have a registered business in the European Union. The primary task of the authorized representative is to be the point of contact for the national health authorities of the Member States. The representative will have to notify the national authority in the country of residence whenever a new Class I device is brought on the EU market. Some national authorities have standardized forms on their website. In addition, the authorized representative's name must be mentioned on the Declaration of Conformity.

The arrangement between the authorized representative and the manufacturer is purely administrative and subject to a commercial contract specifying the role that can be limited (authorized representative only) or broader (importer/distributor). Details about the responsibilities of manufacturers and authorized representatives can be found in the [new legislative framework](#) which covers all CE marking legislation.

Other than single notification, authorized representatives or manufacturers typically also register devices in individual member states. In the future, registration will become easier. With the Commission's 2010 Decision to enforce use of [Eudamed](#) - the EU-wide database for devices on the market - registration of in vitro diagnostics in each country became redundant. The system for medical devices, however, will remain unchanged for the time being. Exporters/authorized representatives will still have to register their devices nationally until and when the Commission decides to move to a centralized registration for manufacturers of devices. In the meantime, Eudamed will be of use to member states for internal communications and for post-market surveillance purposes. To facilitate registration, the EU encourages use of the Global Medical Device Nomenclature (GMDN) based on EN/ISO standard 15225.

## Post-market Surveillance

As the EU regulator allows manufacturers to self declare conformity, with or without involvement of an accredited test laboratory, verification of compliance to ensure safety of consumers is left to the Member States after the products have been brought on the market. As Member States each have their own system, it is possible that some countries grant extensive inspection powers to their national customs service where others may focus their resources in local inspections. When caught in an infraction, the measures imposed on manufacturers may vary from a simple warning to a hefty fine or complete withdrawal from the market, depending on the type of infraction.

EU medical device legislation requires that Member States put in place safeguard procedures. In case of an incident involving injury or death, the Commission will be notified, thereby triggering an EU-wide rapid alert system as described in the EU's general product safety legislation. The Commission has been putting more emphasis on post-market surveillance, with a goal to strengthen the infrastructure of cooperation among national inspection authorities.

## Coming Soon: New Regulatory Framework for Medical Devices

The existing medical device directives (MD and AIMD) are currently being reviewed following the 2008 public consultation. The purpose is to recast the regulatory framework. A proposal for a new framework is expected in 2012. The review focuses on extending the scope, possibly creating a Medical Device Committee within the European Medicines Agency (EMA), improving the vigilance and post-market surveillance system, updating the regulatory framework after the revision of the New Approach and further aligning the EU system with the international regulatory principles of the Global Harmonization Task Force for medical devices (GHTF).

In June 2010, the Commission launched a separate public consultation to review in vitro diagnostic device legislation. The review focuses on scope, classification and conformity assessment methods of IVDs, among others.

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For more information about the consultations:

[http://ec.europa.eu/consumers/sectors/medical-devices/documents/revision/index\\_en.htm](http://ec.europa.eu/consumers/sectors/medical-devices/documents/revision/index_en.htm)

## Medical Devices and Machines

Overlap with the new machinery safety directive 2006/42/EC has been clarified for medical devices that are also machinery. Only one single conformity assessment is required under the medical device directives 93/42/EEC and 90/385/EEC. The risk assessment to be carried out is the risk/benefit analysis as set out in the essential requirements of the directives concerning medical devices. Harmonized standards for medical devices which are also machinery should cover in their scope any requirements of the machinery directive that are applicable to the devices. Such standards will be reviewed and amended or revised if needed.

[Interpretation of the relation between the revised Directives 90/385/EEC and 93/42/EEC concerning \(active implantable\) medical devices and Directive 2006/42/EC on machinery](#)

## MRI Equipment

The European Commission is reviewing directive 2004/40/EC on electromagnetic fields. This directive impacts manufacturers of MRI (magnetic resonance imaging) equipment because it sets exposure limits for workers. Stakeholders affected by this directive lobbied the EU and Member States in order to obtain an exemption for MRI equipment. The European Commission published its proposal for a revised EMF Directive in June 2011. MRI equipment manufacturers were successful in obtaining an exemption for MRI from the binding exposure limits proposed in the Directive. However, the proposal will be scrutinized in the months to come by the EU legislator and may be modified.

## Packaging/Labeling

The amended EU directive on units of measurement (the so-called “metrics” directive 80/181/EC) entered into force on January 1<sup>st</sup>, 2010, which means products must bear metric units of measurement. Use of supplementary units, such as U.S. customary inch-pound, are also allowed. Specific requirements for labels are included in medical device directives. As for choice of language on labels, EU medical device legislation defers to Member States. Please read [our market research report on language requirements](#) and/or contact our CS posts in other countries for more details.

## Medical Devices Using Animal By-Products

The occurrence of bovine spongiform encephalopathy (BSE) in the European Union led to stringent measures regarding traceability of tissues of animal origin for use in medical devices. Risk assessment was addressed in guidance and standardization. The Commission adopted an animal by-product regulation in 2002, repealed in 2009 by Regulation 1069/2009, which covers use of raw material of animal origin for non-food use. Medical devices are subject to specific transport and labeling requirements. The material has to be sourced from approved plants and the process has to be documented. For more information, we suggest you contact the [Foreign Agricultural Service](#) at the U.S. Mission to the European Union.

## Environmental Requirements

Growing mountains of waste of electrical and electronic equipment have forced the EU to consider ways to reduce, recover and recycle packaging and appliances. Also, the use of hazardous substances has led

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to environmental damages; therefore certain substances such as lead or mercury have been banned. Those issues have been tackled by the Waste of Electrical and Electronic Equipment Directive (WEEE) and the Restriction of Hazardous Substances in Electrical and Electronic Equipment Directive (RoHS).

Medical devices are not covered today by the RoHS directive but the text is undergoing revision and medical devices will fall under its scope in the future (3 years after entry into force of the text for medical devices, 5 years after entry into force of the text for IVDs). Other laws such as the Waste Electrical and Electronic Equipment (WEEE) directive require OEMs to dispose of products they manufacture in an environmentally responsible way once the equipment reaches end of life. Medical devices are covered by this directive but with a specific exemption today for “implanted and infected medical devices”.

<http://www.buyusa.gov/europeanunion/weee.html>

## Chemical Substances and Mixtures in Medical Devices

Medical devices containing or consisting of chemical substances and mixtures are subject to specific requirements under the Registration, Evaluation, Authorization and Restrictions of Chemicals (REACH) [Regulation](#) and the Classification, Labeling and Packaging of substances and mixtures (CLP) [Regulation](#). REACH entered into force on June 1<sup>st</sup>, 2007. It changes the former legislative framework for chemicals to ensure a high level of protection of human health and the environment. REACH makes industry responsible for assessing and managing the risks posed by chemicals and providing appropriate safety information to their users. Under REACH, the EU can also take measures to ban the use of highly dangerous substances. CLP aligns previous EU legislation on classification, labeling and packaging of chemicals to the UN GHS (Globally Harmonized System of Classification and Labeling of Chemicals).

## Weblinks

[European Commission](#)

[National health authorities](#)

Finding/buying harmonized standards:

[www.newapproach.org](http://www.newapproach.org)

[www.ansi.org](http://www.ansi.org)

[www.cen.eu](http://www.cen.eu)

[www.cenelec.eu](http://www.cenelec.eu)

Associations:

AdvaMed, Advanced Medical Technology Association: [www.advamed.org](http://www.advamed.org)

Eucomed, Medical Technology: <http://www.eucomed.org/>

Edma, European Diagnostics Manufacturers Association: [www.edma-ivd.be](http://www.edma-ivd.be)

COCIR, European Radiological, Electromedical and Healthcare IT Industry: [www.cocir.org](http://www.cocir.org)

Notified Bodies/Conformity Assessment Bodies:

<http://ec.europa.eu/enterprise/newapproach/nando/>

Consultants/Authorized Representatives:

[http://export.gov/cemark/eg\\_main\\_017270.asp](http://export.gov/cemark/eg_main_017270.asp)

[www.eaarmed.org](http://www.eaarmed.org)

Guidance:

[European Commission guidance on medical devices](#)

Please note that those guidance documents only reflect the views of the European Commission. They are not legally binding like decisions of the European Court of Justice and can be challenged by Member

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States authorities or competitors.

CE marking: [www.export.gov/cemark](http://www.export.gov/cemark)

Original Equipment Manufacturer (OEM): [http://ec.europa.eu/consumers/sectors/medicaldevices/files/guide-stds-directives/interpretative\\_fiche\\_obl\\_en.pdf](http://ec.europa.eu/consumers/sectors/medicaldevices/files/guide-stds-directives/interpretative_fiche_obl_en.pdf)

### **For More Information:**

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## Austria

*Capital:* Vienna  
*Population:* 8.4 Million  
*GDP:* US \$377 Billion  
*Currency:* Euro  
*Language:* German



### Summary

Austria is a dynamic EU member country with an affluent population of 8.4 million German speakers. Austria's manageable size and stable business environment make it an attractive market for U.S. exporters, as well as an attractive test market for U.S. firms with an eye toward expansion into neighboring Germany. Austria's historical and economic ties to the strong growth markets of Eastern and Southeastern Europe also make it a logical base for serving those markets. Currently, 333 U.S. firms have subsidiaries, affiliates, franchisees, and licensees in Austria, of which about 220 have regional responsibilities for Central European, Eastern European, or Balkan countries. U.S. products and services maintain a good reputation in Austria.

Austria is currently at the end of an extraordinarily strong population growth phase. Since the mid-eighties, the population has grown by half a million inhabitants to the current 8.4 million, due to the unexpectedly high level of immigration. Since 1996, this dramatic increase in immigration has stabilized. The population will therefore only grow slightly in the coming decades. The Central Austrian Statistics Office estimates that in the year 2020, approximately 8.5 million people will be living in Austria – a 4.3 percent increase from 1994 levels. After that, the population figure is expected to go down due to decreasing birth rates. One of the major socio-political health challenges of the coming years is the rapid growth of the elderly population. The number of people over 75 years of age is currently approximately 600,000. This figure will have reached at least 800,000 by the year 2021. At the present time, 20 percent of Austrians have reached retirement age, and it is projected that 33 percent of the total population will be retired in the year 2021.

In 2009, Austrian imports of medical equipment were \$1,604.1 million. We expect the 2010 imports, once published, to show an increase to \$1,682.0 million. Total demand for medical devices in Austria added up to \$1,134.4 million, while exports of this equipment amounted to \$1,331.2 million. Austria is a transit-trade country with strong trade relationships with Central, Eastern and Southeastern Europe, as well as the Middle East. The re-exportation of products is quite common here; hence the volume of imports exceeds the total market. Taking into consideration these re-exports, imports are expected to increase at an average annual real growth rate of 3%. The Austrian size of the market for medical equipment should also increase about 3% annually over the next three years.

### Market Entry

U.S. firms should plan their market entry very carefully. Given its location in the center of Europe and the size of its market, small enough to allow a quick overview, Austria stands out as a desirable, affluent pilot market for advanced U.S. products. The best strategy is to screen potential distributors and select a qualified local distributor. Austrian distributors are usually knowledgeable and experienced. They regularly call on hospitals, clinics, laboratories, and medical doctors with practices. The majority of distributors are fluent in English. They are also knowledgeable about EU approval procedures and will obtain approval for U.S. suppliers if needed.

The successful U.S. supplier should discuss and agree on a marketing strategy with a prospective distributor. Once the agent or distributor is selected, it is preferable to maintain this relationship for a number of years. Abrupt changes in distribution patterns distract users from trusted suppliers and have

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been detrimental to U.S. suppliers who have taken such action in the past. It may take up to two years to introduce a new product, owing to the conservative and complex nature of the Austrian market.

The metric system of weights and measures is standard in Austria. The electric power supply is 230/400 volt, AC 50, 1 or 3 phases.

In addition to complying with standards and regulations, U.S. firms should seek to meet some additional criteria to assure product acceptance, recognition, and marketability when trying to enter the Austrian market:

- Supply product information and trade literature in German. At a minimum, catalog inserts should be in German;
- Provide operational and instructional manuals in German to ensure proper understanding and usage of equipment;
- Provide reliable after-sales servicing and product support, or select qualified agents or distributors who are capable of providing quality service;
- U.S. firms should maintain close contact and good feedback with agents in Austria in order to stay informed about market developments, trade issues, regulations, and laws concerning their products.

### **Current Market Trends**

U.S.-made products that are on the cutting-edge will have great potential, as Austrians expect hospitals to have the latest technology. The trend, however, is to reduce the number of hospital beds and to close down some hospitals altogether. Therefore, American companies that are interested in hospital construction or in the sale of "routine" hospital equipment and supplies may find their prospects reduced over the next few years.

Projected growth rates for different imaging products vary considerably. The Austrian market for medical equipment is constantly evolving and utilizing increasingly sophisticated products.

Scanning units have benefited from technological improvements since their introduction about 25 years ago. Most suppliers now offer user-friendly features like image networking, which enable the user to digitally store and project high-quality images. These products should have very good prospects in the future.

Austria is an interesting market for echographic units. This ultrasound technique continues to gain popularity as the industry discovers new applications for it. Recent technological advances have enabled manufacturers to implement Doppler technology and sophisticated probes within their designs.

Sales of conventional radiology apparatus (traditionally, the most popular type of equipment) have declined over the last several years. The recent ability to digitalize this out-dated equipment, however, has sparked new interest in traditional radiology.

Interventionism radiology is the most recent development in the medical imagery field. A combination of radiology and surgery, interventionism radiology has resulted from advances in vascular radiology, digitalization techniques and catheter performance. It promises to have a strong future.

There is also an increasing demand for all kinds of in-vitro products in Austria.

### **Main Competitors**

The great majority of medical equipment used in Austria is imported. U.S. manufacturers have seized a substantial share of the market and are now the second-largest supplier group, following German

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companies. German competition enjoys the advantages of geographic proximity, a common language, and products with the same standards, no exchange rate problems, and duty-free access through Austria's membership in the EU.

The Austrian market for medical equipment is sophisticated and well-served. Industry giants such as Siemens, Philips, Hitachi, and Toshiba are well entrenched. General Electric GmbH, Agilent Technologies Oesterreich GmbH, Nova Biomedical GesmbH, and Tyco Healthcare Austria GmbH are only a few of the Austrian subsidiaries of U.S. medical device suppliers. Against the heavy German competition in this market, American products can usually compete well on the basis of price and innovation.

## Current Demand

The following high-quality products and devices are currently in demand in Austria:

- Nuclear medical instruments (nuclear magnetic resonance scanners)
- Diagnostic apparatus including cardiology instruments, echocardiography systems, advanced electrocardiograph equipment, monitoring systems, ultrasound equipment, gynecology and urology
- diagnostic systems and endoscopes
- Scanners, computer tomography imaging systems, magnetic resonance imaging
- Dialysis equipment
- Pacemakers
- Sophisticated digitalized x-ray equipment
- Clinical laboratory equipment including blood cell counters, and blood gas analyzers
- In-vitro diagnostic products

The trend is moving toward miniaturization of electro-medical devices and nano-technology products.

## Barriers

Austria is a highly developed open market with relatively liberal policies and sharp competition. The import climate is favorable towards U.S. products. American exporters, like domestic and European firms, are subject to packaging and other collection, recycling, and reprocessing laws. There are no significant trade barriers or limitations on U.S. medical devices.

## Trade Events

At the present time, there is no general medical fair taking place in Austria. Some smaller specialized medical exhibitions are organized in connection with medical conventions. The great majority of Austrian medical importers/distributors are regularly attending the most important European medical fair:

**Name of event:** MEDICA

**Location:** Messe Duesseldorf GmbH, Duesseldorf, Germany

**Date:** Nov. 16 – 19, 2011 and Nov. 14 – 16, 2012

**Website:** <http://www.medica.de> or <http://www.messe-duesseldorf.de>

**Description:** Participation in a leading German trade fair – and for this industry MEDICA is the right choice – is one of the most cost-effective ways of testing the receptivity of the European market to a U.S. product, of evaluating competitors and of finding customers or potential agents and distributors. German trade fairs, because they are so internationally important and draw such a large attendance, are an excellent vehicle for introducing new technologies and products and offer a gateway to world markets. Unlike many North American trade shows, the typical German fair is very large, represents virtually the entire industry and is an excellent place to conduct sales. German trade shows attract serious attention from buyers worldwide. U.S. firms that are still on a waiting list for exhibit space at a particular fair, or that

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are not interested in exhibiting but do need qualified assistance and meeting rooms, should consider the Corporate Executive Office ("CEO") program offered by the U.S. Commercial Service at the American Embassies in Europe. Considered the world's most important and largest international fair for medical equipment, the annual MEDICA draws 137,000 trade visitors from 85 countries. Over 4,500 exhibitors from 60 foreign countries exhibit over 1.2 million square feet in 17 halls. Products include medical equipment and services, hospital equipment and supplies, laboratory technology and pharmaceuticals, diagnostics, building engineering, communication technology, therapeutics and orthopedics. As the largest foreign contingent, the United States features roughly 400 companies as official exhibitors, 200 of which are in two U.S. Pavilions, and 15-25 of which are new-to-market/increase-to-market U.S. firms participating in CS Germany's "USDOC Business Center" program as part of the Showcase Global initiative.

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### Available Market Research

Austria – Market for Medical Devices 2010  
Austria – Dental Industry Market Brief 2011  
Austria – In-Vitro Diagnostics 2011

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## Belgium

*Capital:* Brussels  
*Population:* 10.8 Million  
*GDP:* US \$466 Billion  
*Currency:* Euro  
*Language:* Dutch, French, German



### Summary

Belgium produces less than 10 percent of its overall needs for medical equipment. This leaves the market open for heavy competition among suppliers from the U.S., Germany, France and Great Britain. The United States currently has a 20 percent share of total medical equipment imports into Belgium.

In 2009, the Belgian market for medical equipment was estimated at \$6 billion and employed 5,800 people. Belgium imported approx. \$1.9 billion worth of medical equipment from the U.S. in 2009. Over the past 5 years, this sector has seen an annual growth of approximately 3 to 4 percent. The Belgian Social Security System, which includes the Health Care System, is considered among the most extensive and efficient in Europe. It covers nearly 100 percent of the population of 10.8 million inhabitants. In 2009, total healthcare expenditure was estimated at \$45 billion.

### Market Entry

Belgium is an effective starting point for marketing medical equipment to the rest of Europe due to its geographical location, its effective healthcare system, and its relatively open attitude regarding procurement. Belgium is a distribution center for many multinationals: products are imported into Belgium and exported to other European countries.

In order to enter the medical equipment market in Belgium American suppliers should be familiar with the EU directives concerning the registration, marketing, and health/safety standards required throughout Europe as well as regulations specific to Belgium. It is therefore advisable to work with a local partner/distributor.

### Current Market Trends

Belgium's healthcare system is currently facing several challenges. Belgium's growing aging population and the higher health expectations will have an important impact on healthcare expenditures in the coming years. The GOB is therefore looking at various cost-saving measures. Thus, innovative technologies and equipment offering cost savings will have a strong market potential. Orthopedic products, homecare products, obesity and diabetes products are as a consequence in high demand. Furthermore, there is trend towards miniaturization of medical devices, allowing more minimally-invasive and non-invasive procedures. E-Health is also closely looked at but is still facing some legal obstacles such as data protection and privacy.

Belgian hospitals, especially those managed by medical schools and known as "University Hospitals", are always seeking to acquire the latest technology. In addition, all graduating physicians, whether they are specialists or general practitioners, perform their internships in one or several of these hospitals. Therefore, university hospitals are trendsetters and should be considered as prime marketing targets by any supplier of innovative medical equipment or products. American suppliers of medical equipment enjoy a strong position in university hospitals.

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## Main Competitors

Belgium is home to many subsidiaries of American companies such as GE Medical Systems, 3M, Abbott Vascular, Bausch & Lomb, Baxter, Johnson & Johnson medical, Medtronic, Becton Dickinson, Boston Scientific, Cyberonics and St. Jude Medical. Siemens and Philips also have a strong presence in Belgium.

Belgium has approximately 250 companies distributing medical products. The majority of these firms are small or medium-sized, employing an average of 20 to 50 people.

## Current Demand

Best prospects: innovative technologies, minimally invasive and non-invasive equipment, user friendly homecare products, e-Health, telemetry, consumables, orthopaedic and implantable products.

## Barriers

There are no significant barriers on U.S. medical devices.

## Trade Events

The U.S. Commercial Service Belgium supports U.S. exhibitors at the Medica trade show held in Germany in November.

**Name of event:** Healthcare 2012

**Website:** <http://www.health-care.be/>

**Description:** Trade show for home healthcare products

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## Bulgaria

*Capital:* Sofia  
*Population:* 7.5 Million  
*GDP:* US \$47.63 Billion  
*Currency:* Bulgarian Lev  
*Language:* Bulgarian



### Summary

The Government of Bulgaria implements a fundamental reform of its healthcare sector. The health sector reform project has several components, the first one being reform and sustainability of the primary and ambulatory care sector. It provides practice equipment for primary health care, funds physicians' office information systems, provides training in general practitioner (GP) practice management, funds an information campaign, finances a health reform investment program to provide low-interest loans to physicians, and funds a labor adjustment strategy. The second component targets reform of the hospital system, including: introduction of Disease Related Groups (DRG), assigning critical-diseases' tenders to be run by hospitals instead of Ministry of Healthcare; funding hospital information systems, financing a health reform investment program, reduction in number of hospitals; optimizing their functionality and funding a labor adjustment strategy. The third component aims at assisting the National Health Insurance Fund (NHIF) in establishing the technological infrastructure for efficient functioning of the insurance system, including necessary hardware and software systems, as well as training and technical assistance required. The fourth component is aiming at strengthening the management and institutional capacity of the Ministry of Health, the NHIF, and the health system in general.

Healthcare budget for 2009 and 2010 amounted to 1.573 billion EUR and 1.329 billion EUR respectively. Healthcare budget for 2011 is estimated at 1.659 billion EUR (4.2% of GDP), while budget for the mandatory dental care remains 4% out of it. For the long-term period 2001 through 2011 the healthcare budget ranged between 3.8 to 4.4% of GDP.

The health sector reform strategy urges increasing demand for all subsectors' modernization and upgrade, which in general translates into:

- Demand of invasive and noninvasive surgery equipment, oncology, ultrasound equipment, in-vitro diagnostic equipment, urology equipment, laboratory and testing equipment, diagnostic imaging equipment, equipment for haemodialysis, tissue and blood bank related equipment, veterinary turnkey project equipment, hospital care equipment, information systems, modern patient monitoring systems, hospital management systems, new high tech products such as laser instruments, MRI and computerized systems for cosmetic, dental, aesthetic and restorative medicine.
- X-ray systems, dental mechanical tools and instruments, dental surgery services, surgical tools, chairs, ultrasound equipment, photopolymer equipment, physiotherapy equipment, abrasive tools, maxillary surgery, anesthetics, sterilizing equipment, fittings, appliances, metal workplaces, ceramic work places and plastic workplaces
- Telemedicine and introduction of healthcare portal to be based on unified healthcare database files for every Bulgarian citizen fully compatible with EU standards.

### Market Entry

There are no specific challenges to the business environment which could be considered a serious threat. The institutions responsible for regulatory monitoring of market entry rules and laws are Ministry of Healthcare ([www.mh.government.bg](http://www.mh.government.bg)), Bulgarian Drug Agency ([www.bda.bg](http://www.bda.bg)), National Health Insurance Fund ([www.nhif.bg](http://www.nhif.bg)), National Veterinary Institute ([www.vetinst.bg](http://www.vetinst.bg)).

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## Current Market Trends

Being EU member state as of January 2007, Bulgaria is complying to all major EU standard healthcare requirements in terms of legislative framework, structures' upgrading and modernization, licensing, IPR etc.

The Minister of Health Dr. Stefan Konstantinov outlined as his top priorities improving emergency care and prevention in the fields of maternal healthcare, junior dental healthcare, screening and testing for earlier diagnosis of breast and prostate cancer.

Another aspect of healthcare reform is related to the measures, which have to be introduced by the Bulgarian Ministry of Agriculture and its newly established Food Safety Agency concerning sanitation and eradication of pandemic diseases. Being the entry point to the EU veterinary markets, Bulgaria is mandated to carefully and strictly undertake sanitation and eradication measures of any possible veterinary pandemic diseases such as Classic Swine Fever, Foot-and-Mouth disease, Bird Flu.

Beginning of 2011, the Ministry of Healthcare decided to close down 21 hospitals and optimize the scope of work of another 158 hospitals. In times of overall worldwide economic crisis, Bulgarian Ministry of Healthcare is following its long-term labour and reimbursement adjustment policy along with upgrading the other components of its overall operational system.

## Main Competitors

Main competitors are all major EU companies which further more are present on the local market for decades. Some Asian firms are also present on the local healthcare market.

## Current Demand

Best sales prospects are generally outlined in the summary section of present report.

## Barriers

There are no significant barriers on healthcare products in Bulgaria.

Some tariff and non-tariff barriers are reported in the pharmaceutical market sub-segment which are reported by the LAWG in Bulgaria and are included in the National Trade Estimate report.

## Trade Events

**Name of event:** Bulmedica, BaSS (Balkan Stomatological Society), Medicus (International Exhibition of Medicine), Galenia (International Trade Fair for Pharmaceuticals and Balneology), Dento (International Trade Fair for Dental Medicine)

**Location:** Sofia, Varna, Plovdiv

**Website:** [www.bulgarreklama.com](http://www.bulgarreklama.com), [www.bass2009.org](http://www.bass2009.org)

**Description:** Bulmedica (annual international trade show on medical, dental&ophtalmo equipment, consumables and natural products); BaSS (annual congress and exhibition of Balkan Dental Society)

## Available Market Research

Bulgaria Dental Equipment Market Overview, Bulgaria Pharmaceutical Market Overview

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## Czech Republic

*Capital:* Prague  
*Population:* 10.4 Million  
*GDP:* US\$ 195.232 Billion  
*Currency:* Czech Crown (CZK)  
*Language:* Czech



### Summary

The health care sector is very active and prominent in the Czech Republic. Czech healthcare system reform is currently one of the most important political topics. The system is mostly financed by the public sector through mandatory insurance. Approximately 75% of total health expenditures are covered by compulsory health insurance; out-of-pocket payments, general taxes, private voluntary health insurance and other resources represent remaining expenditures. Total expenditure on health amounts to \$14 billion, which represents about 7% of the country's GDP. The market has proved generally resilient to the economic downturn. Although the government is examining ways to reduce healthcare expenses, including limiting purchases of expensive equipment and pharmaceuticals, or adopting e-tenders, which would procure equipment via tenders based solely on the cost of the equipment, the Czech Republic offers strong opportunities for medical device companies. Expected growth in the sector over the next couple years is 7%.

### Market Entry

To import medical devices into the Czech Republic, a foreign producer should have an importer in the Czech Republic. To sell medical devices in the Czech market, several points are important: 1) Medical devices have to obtain the *CE mark* (if required), 2) Medical devices have to have directions for use enclosed in the Czech language, 3) *The Declaration of Conformity* has to be submitted (in the Czech language), 4) The Czech importer has a *notification duty at Ministry of Health*. Medical devices and pharmaceuticals are also subject to a customs duty and a value added tax (VAT).

### Current Market Trends

One of the market trends is an increasing life expectancy. Devices used to monitor symptoms and manage disease are in increasing demand. The most common cause of death is circulatory system problems. Czechs continue to be heavy smokers, and the air in many industrial cities is somewhat polluted. Growing interest in joint Czech-U.S. projects in the health care field could generate new opportunities for U.S. medical equipment providers. The most significant project to date is the International Clinical Research Center (ICRC) at St. Anne's Hospital in Brno, which includes collaboration with the U.S. Mayo Clinic. Other Czech regions are eager to develop similar projects, and U.S. partners are in demand.

### Main Competitors

The Czech Republic has a small but skilled medical device manufacturing sector. Production is at the low to medium end of the technology scale, but is increasingly of good quality. Local producers focus on exports, an estimated 76% of production is exported. Around 80% of the medical device market is supplied by imports. Around one third of the imports are sourced from Germany, other major suppliers include the Netherlands, the USA, and Belgium.

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## Current Demand

In the Czech Republic the best market opportunities exist for cutting-edge, high quality sophisticated medical equipment, especially equipment that increases efficiency and reduces occupancy rates in hospitals. Products, such as the following, have the best sales potential in the Czech market: Mini invasive surgery (MIS), Patient monitoring systems, Video endoscopes, Digital image processing, High end ultrasounds, Home-care equipment, etc.

## Barriers

One of the challenges manufacturers and importers of medical devices and pharmaceuticals will face is getting the product on the reimbursement scheme that is covered by the insurance companies. This can, in some cases, be a time consuming process. Electrical installations in the Czech Republic operate on 50 hertz cycles; power is supplied at the rate of 220V (single phase), and 220V and 380V (triple phase). More than half of Czech company representatives are able to communicate in English or in German.

## Trade Events

**Name of event:** PRAGOMEDICA + NONHANDICAP

**Location:** Prague

**Website:** [www.incheba.cz](http://www.incheba.cz)

**Description:** Pragomedica is one of the two largest medical fairs in the country, traditionally organized in April. It is organized together with a specialized fair of aids for handicapped.

**Name of event:** MEDICAL FAIR + REHAPROTEX

**Location:** Brno

**Website:** [www.bvv.cz](http://www.bvv.cz)

**Description:** Medical Fair Brno is a part of Messe Düsseldorf group (organizer of Medica). The fair takes place in fall.

**Name of event:** OPTA

**Location:** Brno

**Website:** [www.bvv.cz](http://www.bvv.cz)

**Description:** Opta focuses on eye optics and ophthalmology and is taking place in February.

**Name of event:** EXPODENT

**Location:** Prague

**Website:** [www.bvv.cz](http://www.bvv.cz)

**Description:** In fall 2010, a pilot Fair of Dental Medicine and Oral Hygiene Expodent, took place, concurrently with the traditional international congress Prague Dental Days.

**Name of event:** PRAGODENT

**Location:** Prague

**Website:** [www.incheba.cz](http://www.incheba.cz)

**Description:** Traditional fall trade fair focused on dental care, services and hygiene.

## Available Market Research

Healthcare IT (2010)

Eye Care Market (2009)

Dental Market (2009)

Medical Device Market (2008)

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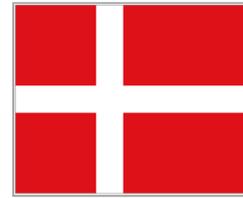
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## Denmark

*Capital:* Copenhagen  
*Population:* 5.5 Million people  
*GDP:* US \$330 Billion (2010)  
*Currency:* Danish Crown  
*Language:* Danish



### Summary

Healthcare is regarded as an important part of the Danish welfare system. A fundamental principle is that all citizens have the right to good health and healthcare on equal terms, regardless of income. About 85 percent of total healthcare costs are financed through taxes.

The healthcare sector has three political and administrative levels: the government, the regions and the municipalities (national, regional and local authorities). Denmark is divided into five regions and 98 municipalities that cover at least 20,000 inhabitants each. The regions are responsible for providing hospital care and they own and run hospitals and prenatal care centers. They allocate finances for GPs, specialists, physiotherapists, dentists and pharmacies. The municipalities are mainly concerned with preventive care and nursing homes/home care etc.

Nearly 5 million Danes, or 90 percent of the population, contact their doctors annually, and approximately 1 million are admitted to the hospital annually. About 1 million people visit the emergency room and 6 million outpatient procedures are conducted. While the number of hospitals in Denmark has decreased in the past decade, the number of hospital visits has increased, bringing facilities near capacity and providing incentives for more efficient methods of treatment.

There are 72 hospital-premises and in 2010 there were 14,335 full time doctors working in public hospitals, 34,330 full time nurses in public hospitals, and 24,348 other full time employed personnel (Interior and Health Ministry 2011).

With a stagnating workforce there will be a general shortage situation in the labor market-despite current unemployment-and hence intense competition for existing and future manpower. By 2015 the shortage will be about 12-14% of the current workforce and around 2020 the shortage will have grown to 15-16%. For 2015 the expected shortage in absolute numbers will be: about 5,700 nursing assistants; about 5,600 nurses; and about 2,600 physicians. There will also most likely be shortages in other areas.

### Market Entry

The Economist Intelligence Unit ranks projects that Denmark will continue to be the best business friendly environment until 2012. This finding was based on Denmark's pro-business policies, structural reforms to enhance labor market stability, and a fiscal policy that preserves the large amount of public services while achieving budget surpluses. Thus, a U.S. company should find Denmark to be a relatively open market. It is recommended that U.S. health care companies work through a local distributor who can guide through the potential maze of import regulations, or establish local presence.

### Current Market Trends

Spending on health care in Denmark will increase in the upcoming years due to the country's ageing population. In 2009, the estimated public health care spending was around USD 33 billion. This figure is expected to be in the USD 35 billion range in 2014. Private healthcare is about 15 percent of total spending. However, another uncertainty that is important to consider is 'health aging.' When life expectancy increases, the terminal costs are postponed, and the increases in health expenditure that

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follow from longer life expectancy are not as large as the increase in the number of elderly persons would suggest; this phenomenon is referred to as “healthy ageing.”

Also, when Denmark takes over the EU Presidency 1 January 2012 the combat against antimicrobial resistance will be a priority and the Danish Minister for the Interior and Health and the Danish Minister for Food aim at a common European surveillance program for antibiotic consumption and a reduced consumption of antibiotics.

Medical devices make up about 6 percent of total public spending, estimated at USD 2 billion in 2009. The market is expected to grow around 9 percent per a year, thus having an overall market value of USD 3 billion by 2014. Best prospect sub-sectors include diagnostics, medical equipment, and ophthalmic instruments. Medtech companies in Denmark and Danish companies abroad have an annual turnover of app. 8 billion USD. Denmark is home to major companies in both the medical technology industry and the biotech and pharmaceutical industries, including Novo Nordisk, Lundbeck, Bavarian Nordic, Coloplast, GN ReSound, Oticon and Widex. Recently, there has been an increase in the sales of disposable products like syringes needle and catheters, and medical supplies.

### **Main Competitors**

Denmark has many local manufacturers that possess fair shares in the global market. They specialize in the production of hearing aids, diagnostics, orthopedic and prosthetic devices. Denmark is home to major companies in both the medical device industry and the biotech and pharmaceutical industries, including Novo Nordisk, Lundbeck, Bavarian Nordic, Coloplast, GN ReSound, Oticon and Widex. About 90 percent of the local production is exported.

### **Current Demand**

The average life-expectancy is 76.3 years for men and 80.7 years for women, which is amongst the lowest in Europe. The low life expectancy may be explained by the fact that Denmark’s medicine expenses per capita is amongst the lowest in Europe.

The most common causes of death are various forms of cancer (28 percent) and cardiovascular diseases (28 percent). Chronic obstructive pulmonary disease, neuropsychiatric conditions (Alzheimer, alcohol abuse, and Parkinson), diabetes, and digestive diseases (peptic ulcer disease and cirrhosis of the liver) are also common causes of death.

It should be noted that since healthcare in Denmark is free, Danes are very reluctant to spend money on healthcare and treatment themselves. Nevertheless, 89% of the Danish population was very or somewhat satisfied with using public services, i.e. consulting a GP, in 2011 (Statens Institut for Folkesundhed, 2011), and Danes are also generally concerned about their health and are willing to spend money on preventive measures including healthy food, dietary supplements and gym memberships.

### **Barriers**

The National Board of Health monitors the overall welfare and use of medical equipment, whereas The Danish Medicines Agency and its sub-unit for medical equipment solve more specific regulatory issues and perform market controls. Danish Standard is a recognized testing body that solves for European and Danish requirements.

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## Trade Events

Lægedage: [www.laegedage.dk](http://www.laegedage.dk)  
ScandMedTech: [www.scandmedtech.dk](http://www.scandmedtech.dk)  
Scandefa: [www.scandefa.dk](http://www.scandefa.dk)  
Biotech Forum + Scanlab: [www.biotechforum.org](http://www.biotechforum.org)

## Available Market Research

Medical Technology; Dental Equipment ; Lab Equipment; Biotechnology with Healthcare Application; Pharmaceuticals; Vitamins and Food Supplements; Healthcare Services; Telemedicine

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## Finland

*Capital:* Helsinki  
*Population:* 5.3 Million  
*GDP:* US \$245.10 Billion  
*Currency:* Euro  
*Language:* Finnish



### Summary

High quality and technically sophisticated medical equipment has market potential in Finland. The United States has a 25 percent share of the total market. Finland also produces high technology medical equipment. Increasing competition in the marketplace is expected as local production expands.

### Market Entry

Finland joined the European Union (EU) in 1995. As a member of the EU, Finland's local legislation concerning medical devices complies with EU directives. Please see [www.valvira.fi/en/licensing/medical\\_devices](http://www.valvira.fi/en/licensing/medical_devices) (National Supervisory Authority for Welfare and Health Valvira) and [www.ec.europa.eu/enterprise/sectors/medical-devices/index\\_en.htm](http://www.ec.europa.eu/enterprise/sectors/medical-devices/index_en.htm) (European Commission, Enterprise and Industry, Medical Devices) for further information.

Medical trade is duty-free within the European Union. Import duties are collected from production coming from non-EU countries. The amount of duty for medical equipment exported from the United States fluctuates according to a specific product, ranging from 5-12 percent.

### Current Market Trends

In Finland, the total market size for medical equipment is estimated at \$900 million in 2011 by the Finnish Healthcare Technology Association. Total local production is estimated at \$1.2 billion in 2011.

The operating costs of Finnish hospitals have been reduced, and major hospital procurement is mainly replacing older equipment and buying some new. However, investments in new medical equipment within the private health care sector are expected to continue.

Finnish hospitals are very eager to try out new technology in the implementation of most modern treatment methods. Implementation of new technologies is effective, as Finnish medical personnel is very technology literate. Local distributors provide the market with equipment packages and maintenance programs.

### Main Competitors

Local production for medical equipment is well known for its quality and high technology. It is concentrated in specialized sectors, such as dental equipment as well as specialized x-ray and IVD equipment. About 90 percent of local production is exported because of the small domestic market size. 82 percent of the medical equipment imported to Finland comes either from or through the European Union. Direct imports from the United States account for 8 percent; however, the total market share is 25 percent. Other important external supplier countries are Germany, the United Kingdom, France, Russia, Japan, and China.

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## Current Demand

High quality and technically sophisticated medical equipment has the best market potential in Finland, especially equipment that increases efficiency and reduces occupancy rates in hospitals. Products, such as the following, have the best sales potential in Finland:

- Patient monitoring systems
- Mini invasive surgery (MIS)
- Day surgery equipment
- Magnetic resonance imaging (MRI) equipment
- Video endoscopes
- Digital image processing
- Picture archiving

## Barriers

There are no restrictions on imports in Finland, as long as they comply with EU qualifications. Although marketing requires thorough knowledge of end user needs, the import climate is receptive to equipment that is new and of good quality. There is keen competition in the market, however.

## Trade Events

**Name of event:** Finnish Dental Congress and Exhibition 2011

**Location:** Helsinki Fair Center

**Website:** <http://web.finnexpo.fi/Sites1/Hammaslaakaripaivat/en/Pages/default.aspx>

**Description:** Finland's leading event for dentistry professionals.

**Name of event:** The Finnish Medical Convention and Exhibition 2012

**Location:** Helsinki Fair Center

**Website:** <http://web.finnexpo.fi/Sites1/Laakaripaivat/en/Pages/default.aspx>

**Description:** Finland's leading event offering further training for doctors and physicians. Finland's biggest medical exhibition is organized at the same time.

## Available Market Research

Dental Industry Overview (2011)

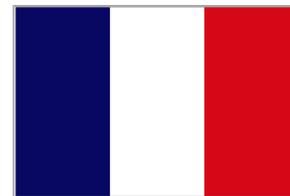
Medical Industry Overview (2010)

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## France

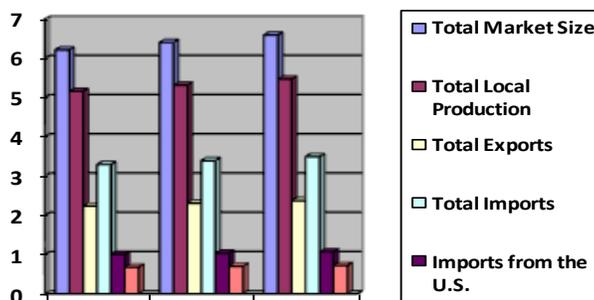
*Capital:* Paris  
*Population:* 65 Million  
*GDP:* US \$ 2.50 Billion  
*Currency:* Euro  
*Language:* French



### Summary

	2009*	2010*	2011*
<b>Total Market Size</b>	6.209	6.40	6.587
<b>Total Local Production</b>	5.155	5.31	5.469
<b>Total Exports</b>	2.234	2.30	2.370
<b>Total Imports</b>	3.288	3.39	3.488
<b>Imports from the U.S.</b>	1.002	1.03	1.063
<b>Exchange rate: USD1.00</b>	0.679	0.699	0.720

(Figures in USD millions. \* indicates unofficial estimates)



Total market demand in France for medical equipment was estimated at USD 6,587 million in 2011, with imports accounting for USD 3,488 million. Imports from the United States were forecast at USD 1,063 million, or 30 percent of total imports. This percentage is expected to remain approximately the same over the next three years, with overall demand growing at 3 percent annually.

France ranks among the top five largest medical device markets in the world. France spends 2.9% of total health expenditure on medical equipment and supplies and 0.3% of GDP, which is average for a West European country.

While the overall market is generally well developed, certain sub-sectors in the more innovative forms of technology still present opportunities for entry.

While the public sector is the largest purchaser of diagnostic, therapeutic and surgical equipment, the private sector is also a very dynamic player.

The continuing deficit of the national health insurance funds has prompted new measures to control spending on medical devices, similar to those already in force for pharmaceuticals.

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## Market Entry

To export medical devices to France, a foreign producer should have an agent/distributor. Medical devices in the French market will be for imported products or domestically manufactured lines are subject to the following requirements:

- Medical devices have to obtain the *CE mark*.
- Medical devices have to have Directions for use enclosed in the French.

## Current Market Trends

The medical market is only likely to see moderate growth, rising from US\$8.3 billion in 2011 to US\$9.8 billion by 2016. The medical manufacturing industry has seen an entry of foreign companies; larger manufacturers are now subsidiaries of multinational groups. With flagging domestic production in several sectors the French medical device market is increasingly reliant upon imports, which now account for around 50% of consumption.

## Main Competitors

France is home to many subsidiaries of American companies such as Alcon, 3M, Baxter, Johnson & Johnson medical, Medtronic, Boston Scientific, Cyberonics and St. Jude Medical.

## Current Demand

### Diagnosis:

The diagnostic sub-sector represents 35 percent of the total medical equipment market. State-of-the-art diagnostic medical imaging systems are in great demand. Applications for this technology already exist for pediatrics, cardio-vascular care, digestion, urology, and spinal/nerve treatment. As it is well accepted and effective, the demand for this type of technology will continue to grow. Health care professionals are very optimistic about a feature of medical imagery equipment known as "image networking." This will dramatically improve diagnostics by providing an image data bank that would enable a specialist to compare the image of a current case to hundreds of previous cases.

### Rehabilitation:

This sub-sector represents 26 percent of the total medical equipment market. It includes all types of disposable medical products. The increasing elderly population reinforces the demand for all kinds of disposable equipment and supplies such as incontinence products and care kits used by nurses and families for home-care.

### Surgery:

The surgery instrument and supplies sub-sectors represent approximately 17 percent of the total sector. Recent developments in the non-invasive surgery field could have a strong impact on everyday hospital practice. These latest advances offer superior results and also present a significantly reduced risk to patients.

### Technical aids:

The French market for medical prosthesis, 8 percent of the total medical equipment market, is characterized by a strong potential for innovative internal prosthesis such as knees, hips, ligaments, and elbows, and with a slightly decreasing market for external prosthesis. Technological evolution, especially in the field of anesthesia, offers the potential for rapid changes in this market.

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### **Intensive care:**

Intensive care equipment such as respiratory monitoring, pumps and incubators represent about 8 percent of the total medical equipment market. Intensive care equipment includes the latest technological advances. Both public and private hospitals show a rising demand for intensive care equipment and supplies.

### **Hygiene:**

The hygiene sub-sector represents approximately 6 percent of the total medical equipment sector. Patient and medical personnel safety is of growing concern to both members of the medical profession and the public. Best sales prospects will certainly focus around assuring stringent personnel safety requirements. This is especially due to the concern regarding AIDS and other contagious diseases. In the future, prevention should receive similar emphasis considering the present focus on protection.

## **Barriers**

There are no significant barriers on healthcare products in France.

## **Trade Events**

**Name of event:** HOPITAL EXPO

**Location:** PARIS / Porte de Versailles

**Date:** May 2012

**Website:** <http://www.hopitalexpo.com/>

**Description:** Hopital and Medical Equipment Exhibition. It is a biennial event.

With 750 exhibitors, an area of over 21,000 square meters, 24,000 visitors throughout Europe and an institutional presence unmatched, HOPITAL EXPO is the largest medical trade show in France.

## **Available Market Research**

- In Vitro Diagnostics (2006)
- Medical Device (2009)

## **U.S. Commercial Service Contact Information**

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**Phone:** +33 (0) 1 43 12 70 14

## Germany

*Capital:* Berlin  
*Population:* 81.8 Million  
*GDP:* US \$3.3 Trillion  
*Currency:* Euro  
*Language:* German



### Summary

Medical technology is set to remain a German domain, at least until 2020. The trend report published by the Association for Electrical, Electronic and Information Technologies (VDE, Frankfurt am Main) for 2011, for which some 1,300 member companies and universities were surveyed, shows that Germany is the most innovative country in this field by a long way. Almost two thirds (64%) of respondents view Germany as having a clear lead on the USA (30%). The general consensus is that Germany will remain largely unchallenged until the end of the current decade, with 57% anticipating that medical technology made in Germany will defend its lead ahead of the USA (26%), the rest of Europe (9%) and emerging countries in Asia. This international comparison reveals the great importance of medical technology in Germany - especially against the backdrop of a dynamic and growing global health market and increasing competition between manufacturers.

Latest OECD Health figures report the healthcare industry as generating 11.6% of GDP (2009) in Germany. Approx. 5.4 million, or 11% of all employees, work in the healthcare sector, ten times more than in the chemical industry, making the healthcare industry the largest employer in Germany. Health expenditures in Germany increased in 2009 by 5.2% to a total of 278.3 billion Euros. Each German incurs healthcare expenditures of 3,400 Euros annually.

According to the German Medical Technology Association (BVMed), the medical devices segment employed 170,000 and generated expenditures of 25 billion Euros in 2009.

### The German Medical Market 2009-2011

(USD million)	2009	2010 (e)	2011 (e)
Total Market Size	26,100	27,530	29,180
Total Local Production	25,600	27,000	28,620
Total Exports	16,000	17,120	18,320
Total Imports	16,500	17,650	18,880
Imports from the U.S.	4,455	4,760	5,100

Major barriers to local market expansion are ongoing health reform efforts and cost-containment measures. Demand will mainly be driven by demographics and a substantial increase in the number of patients; by the need for economies of scale and efficient procedures; and by a major investment backlog estimated at \$31.8 billion in hospitals and \$3.2 billion in doctors' practices.

This backlog especially affected the segments surgery where, according to an employee poll, 56% of the equipment needs to be modernized/replaced, followed by internal medicine with 51%, and radiology with 50%.

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More than two thirds of the German physicians are seeing innovation as the key element in maintaining the high standards of the German health system. Industry experts characterize the medical device market as one with high growth dynamics and continuing consolidation, making it highly attractive for investors, despite of the crisis. It will also continue to provide excellent potential for U.S. suppliers of innovative and price-competitive products. U.S. medical device exporters to Germany continue to hold a 28-30% in import market share, depending on product.

For general statistical information on Germany, cf. "Pocketbook Germany" published by the German Federal Statistics Office, [www.destatis.de](http://www.destatis.de), (type "pocketbook" in search line).

## **Market Entry**

### **Distribution Practices**

Local representation or market presence is essential, when considering differing standards and certifications, warehousing costs, maintenance, accessibility and local marketing/sales preferences/discussions. An agency agreement is often a cost effective mechanism to enter the market but under German law - even if the agent's performance is not satisfactory - it can be difficult and costly to terminate the arrangement. A representation or distributorship agreement may be harder to arrange but the German associate will, in fact, purchase the product which is to be sold, thus sharing the marketing risk.

In addition to complying with standards and regulations, U.S. firms should seek to meet some additional criteria to assure product acceptance recognition and marketability when trying to enter the German market. For example, they should supply product information and trade literature in German. At a minimum, catalog inserts should be in German. Firms should also provide operation and instruction manuals in German to insure proper understanding and usage of equipment, as well as providing reliable after-sales servicing and product support or select qualified agents or distributors who are capable of providing quality service. U.S. firms should maintain close contact and good feedback with agents in Germany in order to stay informed about market developments, trade issues, regulations, and laws concerning their products.

### **Product Standards**

The German market for medical devices is regulated by German and European Union (EU) directives, standards, and safety regulations. The requirements are complex and based on environmental, consumer health, safety and social concerns. Not all standards and regulations are mandatory, but compliance greatly enhances a product's marketability. Advice on the requirements and compliance certification in the case of a specific product should be sought from the sources referenced below.

The German Medical Products Law (MPG) of 1995 underwent a fourth revision in March 2010. It applies to all equipment, instruments, devices, and materials, which are used on or in the human body and is relevant when trying to get permission to enter the German market. Exceptions are those devices, which achieve their intended effect pharmacologically. About 400,000 different medical products fall under this legislation. The MPG implements EU guidelines covering medical and diagnostic products. Devices complying with the MPG or its equivalent directives in other EU countries must carry the CE mark. They have the advantage of being allowed on the market anywhere in the EU without further certification requirements.

### **"CE" Mark**

The CE Mark signifies that a product fulfills all necessary EU requirements. CE marking is now a legal requirement for a wide range of equipment manufacturers in Germany. Certification requirements for use of the CE mark vary depending on the product. For some, such as those in the MPG low risk class I, the manufacturers (or importer/ authorized representative, if the product is manufactured outside the EU) may

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self- certify compliance with EU requirements and affix the mark; for others the certification of a “notified body” (an accredited certification agency such as the TUEV) will be required. For the medical aids sector, the workability and safety of a product is now considered satisfied by CE marking. The CE mark is a visible indication that the manufacturer signed a “Declaration of Conformity” prior to affixing the CE mark, claiming compliance with all relevant CE marking directives in force.

The relevant EU website for more details regarding CE mark/ electrical equipment is [http://ec.europa.eu/enterprise/electr\\_equipment/index\\_en.htm](http://ec.europa.eu/enterprise/electr_equipment/index_en.htm)

[http://ec.europa.eu/enterprise/policies/single-market-goods/cemarking/professionals/manufacturers/directives/index\\_en.htm?filter=14](http://ec.europa.eu/enterprise/policies/single-market-goods/cemarking/professionals/manufacturers/directives/index_en.htm?filter=14)  
(under construction)

### **Packaging and Labeling**

The European Union does not legislate packaging and labeling requirements in general, only in very specific high-risk product related cases. In the absence of any EU-wide rules, the exporter has to consult national rules or inquire about voluntary agreements among forwarders which affect packaging and labeling of containers and outer packaging. The importer or freight forwarder is the first point of contact for shipping documents and outer packaging/labeling. EU customs legislation only regulates administrative procedures, such as type of certificated and the mention of rule of origin on the customs forms and shipping documents.

Product specific packaging and labeling requirements applicable throughout the EU apply to food, medicines, chemicals, pharmaceuticals, and other high-risk items. The purpose of harmonizing such legislation throughout the EU is to minimize the consumer risk. The relevant paragraph from the medical device legislation reads as follows:

13.3. The label must bear the following particulars:

- (a) the name or trade name and address of the manufacturer. For devices imported into the Community, in view of their distribution in the Community, the label, or the outer packaging, or instructions for use, shall contain in addition the name and address of either the person responsible referred to in Article 14 (b) or of the authorized representative of the manufacturer established within the Community or of the importer established within the Community, as appropriate;
- (c) the details strictly necessary for the user to identify the device and the contents of the packaging;
- (d) where appropriate, the word “STERILE”;
- (e) where appropriate, the batch code, preceded by the word “LOT”, or the serial number;
- (f) where appropriate, an indication of the date by which the device should be used, in safety, expressed as the year and month;
- (g) where appropriate, an indication that the device is for single use;
- (h) if the device is custom-made, the words “custom-made device”;
- (i) if the device is intended for clinical investigations, the words “exclusively for clinical investigations”;
- (j) any special storage and/or handling conditions;
- (k) any special operating instructions;
- (l) any warnings and/or precautions to take;
- (m) year of manufacture for active devices other than those covered by (e). This indication may be included in the batch or serial number;
- (n) where applicable, method of sterilization.

### **Payment & Financing Practices**

In Germany the period allowed for payment, is between 30 and 60 days. Early payments are credited with a 3% discount, and supplier credits are common.

Practices regarding finance, availability of capital, and schedules of payment are comparable to those in the United States. There are no restrictions or barriers on the movement of capital, foreign exchange

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earnings, or dividends. Virtually all major U.S. banks are represented in the German market, principally (but not exclusively) in the city of Frankfurt/Main, Germany's financial hub. Similarly, a large number of German banks, including some of the partially state-owned regional banks, maintain subsidiaries, branches and/or branch offices in the United States. Germany is not eligible for support from OPIC, TDA or similar agencies.

### **Tariffs, Import Regulation**

An import duty of 5.1% to 5.3% of the import product value does exist along with a 19% import turnover tax payable at the port entry. For customs clearance, a product description is required describing the use, origin and value of the product. The cost of the import – turnover tax is usually offset by ultimately passing it on to the end-user in later distribution stages in the form of a Value-Added-Tax (VAT), known in Germany as Mehrwertsteuer (MwSt). German customs will provide customs tariff information at:

[http://www.zoll.de/english\\_version/index.html](http://www.zoll.de/english_version/index.html)

Email: [enquiries.english@zoll.de](mailto:enquiries.english@zoll.de)

Ph: 49 (0) 351-44834-530

Fax: 49 (0) 351-44834-590

Or, via the TARIC database of the European Union:

[http://ec.europa.eu/taxation\\_customs/dds/cgi-bin/tarchap?Lang=EN](http://ec.europa.eu/taxation_customs/dds/cgi-bin/tarchap?Lang=EN)

All electro-medical equipment in Germany must be suitable for use with 220 Volt, 50 cycle electrical current, and should have VDE or TUEV approval. A UL approval is not a substitute but is helpful to obtain "GS/VDE", or GS/TUEV" approval in Germany. "GS" stands for "gepruefte Sicherheit" (safety tested). Although "GS" and the "VDE" (or "GS and TUV") marks are not required by law, they are highly recommended for marketing electro-medical goods in Germany. These labels denote high product safety; German consumers look for these labels as Americans do for the "UL" mark.

Contact info for VDE:

Verband Deutscher Elektrotechniker (VDE) e.V.

VDE- Pruefstelle (VDE Testing Division)

<http://www.vde.com/en/Pages/Homepage.aspx>

The U.S. product safety testing institute Underwriters Laboratories (UL), the VDE Testing and Certification Institute, and the TUEV Product Service have formed a strategic alliance for testing of electromagnetic compatibility (EMC) with the result of an EMC test mark recognized worldwide. For manufacturers of electrical and electronic products, this cooperation has led to a substantive simplification of EMC testing. Through a single test carried out by one of these three partners, a product can now be awarded an international EMC mark, which replaces the national test marks in the major world markets of Europe, the USA and Japan.

Contact info for TUEV:

TUEV Rheinland  
(TUEV Rhineland),

<http://www.tuv.com/de/en/index.html>

TUEV Sueddeutschland Holding AG  
(TUEV Bavaria)

[http://www.tuev-sued.de/home\\_en](http://www.tuev-sued.de/home_en),  
[info@tuev-sued.de](mailto:info@tuev-sued.de)

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Key Website for general business practices:  
[www.german-business-portal.info](http://www.german-business-portal.info)

### **Current Market Trends**

Major barriers to local market expansion are ongoing health reform efforts and cost-containment measures. Demand will mainly be driven by demographics and a substantial increase in the number of patients; by the need for economies of scale and efficient procedures; and by a major investment backlog estimated at \$31.8 billion in hospitals and \$3.2 billion in doctors' practices. This backlog especially affected the segments surgery where, according to an employee poll, 56% of the equipment needs to be modernized/replaced, followed by internal medicine with 51%, and radiology with 50%.

More than two thirds of the German physicians are seeing innovation as the key element in maintaining the high standards of the German health system. Industry experts characterize the medical device market as one with high growth dynamics and continuing consolidation, making it highly attractive for investors, despite of the crisis. It will also continue to provide excellent potential for U.S. suppliers of innovative and price-competitive products. U.S. medical device exporters to Germany continue to hold a 28-30% in import market share, depending on product.

### **Main Competitors**

The German market for medical devices is sophisticated and well served. Industry giants such as Siemens (Ger), Fresenius (Ger), Philips (NL), Hitachi (Japan) and Toshiba (Japan) are well entrenched. GE Medical, Agilent, 3M Medica, Hollister, and Johnson & Johnson are only a few of the many German subsidiaries of U.S. medical device suppliers. Despite this, the sector is characterized by small and heterogeneous companies or sub-groups of larger companies and rarely does one company represent more than 2% of the entire sector. In 2009 German manufacturers which produced medical technology ranging from blood volume monitors to dental elevators, in total over 400,000 devices, generated sales of \$34.2 billion with an increase of 2.1% in domestic sales to \$16.30 billion and an increase of 8.1% to \$19.67 billion in export sales.

Germany has to cover almost two-thirds of its demand for electro-medical equipment by imports. Even with a preference for locally produced products, American products can usually compete strongly on the basis of price and innovation. The United States is one of the major suppliers of medical devices to Germany and new and innovative devices are often reported very favorably upon in German media. For example, MA-based Carestream Health (formerly Eastman Kodak), a recipient of the Frost&Sullivan 2010 Medical Imaging Company of the Year Award, and provider of digital medical solutions, recently signed a partnership for a Center of Excellence program with the University of Frankfurt's Department of Diagnostic and Interventional Radiology, widely reported upon in the German medical press.

### **Current Demand**

There is a stable demand for high-quality advanced diagnostic and therapeutic equipment, innovative technologies and minimally invasive equipment, in vascular surgery, urology, gastrology sand gastro-enterology sand gastro-enterology, dermatology, and neuro-surgery. Due to the way German health care tries to face problems coming up with the countries ageing population, there will be an increasing demand for diagnostic equipment, to detect chronic diseases in their early stages in order to prevent higher costs. It will furthermore spur the demand in specialized wound care and easy-to-use home care products, for diabetes; orthopedic appliances; and dialysis equipment.

The trend is toward miniaturization of electro-medical equipment and nanotechnology products. New technologies in emergency care and first responder care and computer-assisted surgery are widely

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discussed among the German medical community. German companies generate about a third of their sales with products not older than 3 years and usually 9% of their sales get reinvested in research.

As public insurance funds (the reimbursers of medical devices) continue to record deficits, cost containment will remain a priority. Thus, price-competitive state-of-the-art technologies and equipment offering proven cost savings will have strong market potential.

## Barriers

Firms exporting medical devices to Germany will not encounter any direct trade barriers or quotas. Non-tariff, indirect trade barriers may be the complex German reimbursement system, the need for additional registration procedures in the case of medical assistive technologies, for example, or products sold in pharmacies, with the requirement to apply for HVM or PZN codes, respectively. For Class 2 medical products, the German medical products law requires manufacturing and distribution control/quality control documentation.

## Trade Events

**Name of Event:** MEDICA with Compamed

**Date:** November 16-19, 2011 and November 14-16, 2012

**Location:** Düsseldorf, Germany

**Website:**

[http://export.gov/germany/TradeShowsEvents/FeaturedGermanTradeShows/eg\\_de\\_030703.asp](http://export.gov/germany/TradeShowsEvents/FeaturedGermanTradeShows/eg_de_030703.asp)

<http://export.gov/industry/health/index.asp>

<http://www.medica.de>

<http://www.compamed-tradefair.com/>

**Description:** Considered the world's most important and largest international fair for medical equipment, the annual MEDICA draws 160,000 trade visitors more than 100 countries. Over 4,500 exhibitors from 80 foreign countries exhibit over 1.5 million square feet in 19 halls. Products include medical equipment and services; hospital equipment and supplies; laboratory technology and pharmaceuticals; diagnostics; building engineering; communication technology; therapeutics and orthopedics. As the largest foreign contingent, the United States features roughly 500 companies as official exhibitors, of which around 200 are in three U.S. Pavilions, and 20 are new-to-market/increase-to-market U.S. firms participating in CS Germany's "USDOC Business Center" program as part of the Showcase Global initiative.

Parallel to Medica and one day shorter, Compamed will take place as the marketplace for suppliers to the medical manufacturing industry, with 600 exhibitors from 40 countries.

**Name of event:** Rehacare

**Date:** October 21-24, 2011 and October 10-13, 2012

**Location:** Düsseldorf, Germany

**Website:** [www.rehacare.de](http://www.rehacare.de)

**Description:** REHACARE International is Europe's premier rehabilitation and care event, taking place annually in the fall in Duesseldorf. It is open to the public and has a great number of end-users sourcing new products and developments. REHACARE International features 50,000 trade visitors and people with special needs and in six halls, 805 exhibitors from 32 countries, showcasing innovative rehabilitation technologies and services and offering advice and information on all aspects of rehabilitation and care. US exporters of rehabilitation and/or personal care equipment should consider REHACARE for attending or exhibiting. For more information, please got to [www.rehacare.de](http://www.rehacare.de) (English version available). There is no U.S. Pavilion, independent exhibits only. The Commercial Service Dusseldorf will attend and support the individual U.S. exhibitors.

**Name of event:** Orthopädie + Rehatechnik

**Date:** May 16-19, 2012 and May 2014 (biennial)

**Location:** Leipzig, Germany

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**Website:** <http://www.ot-forum.de>

**Description:** ORTHOPÄDIE + REHA-TECHNIK is the orthopedic and rehabilitation industry's leading event worldwide with 554 exhibitors from 45 countries. The event takes place every two years and combines the presentation of innovations and new products at the trade fair with further professional training of the highest international quality. One in three visitors to the show is either solely or jointly responsible for purchasing and procurement decisions. 58 % of visitors do not attend another trade show or congress on a related topic. With 21.200 visitors from 108 countries ORTHOPÄDIE + REHA-TECHNIK 2010 reconfirmed its outstanding position worldwide.

**Name of event:** BIOTECHNICA 2010

**Date:** October 11-13, 2011 and October 2012

**Location:** Hanover, Germany

**Website:** [http://www.biotechnica.de/homepage\\_e](http://www.biotechnica.de/homepage_e), <http://regmed.net> (WCRM)

**Description:** BIOTECHNICA in Hannover is the leading event within the European biotech industry. It embraces every segment of biotechnology - from basic biotechnology and equipment, bio-informatics and services to the five major areas of application: pharmaceuticals/medicine, industry, food, agriculture, the chemical industry and the environment. From research and product development, equipment, process technology and services to production and marketing: the exhibition section of BIOTECHNICA charts the biotech industry's value-adding chain from start to finish. This year's Biotechnica will be parallel to the 5<sup>th</sup> World Congress for Preventive and Regenerative Medicine (WCRM) which has previously been hosted in Leipzig and Bangkok. It will take place from October 5<sup>th</sup> till 7<sup>th</sup> at the Hanover Convention Center with about 800 participating scientists.

**Name of event:** A+A 2011 (Safety + Health at the Workplace)

**Date:** October 18-21, 2011 and October 2013 (biennial)

**Location:** Düsseldorf, Germany

**Website:** <http://www.aplusa-online.de>

**Description:** The biennial A+A with roughly 55,800 trade visitors and 1,541 exhibitors in 2009 is the No. 1 international trade fair with congress for Safety and Health at the Workplace and will be held in Düsseldorf from 18 to 21 October 2011.

A+A is the sector's foremost event covering an enormous spectrum of subjects and products: Safety (as in personal safety equipment), Security (corporate security) and Health at Work. Protective Equipment. Following are the main product groups: Protective Clothing, Special-Purpose Clothing, Industrial Health and Safety, Noise Protection, Environmental Engineering, Measuring Systems, Medical Appliances, Industrial Medicine, First-Aid, Corporate Work Ware, Services, Old Sites Redevelopment, Air Purification, Noise Reduction.

**Name of event:** FIBO 2012

**Date:** April 19 – 22, 2012

**Location:** Essen, Germany (as of 2013, will locate in Cologne)

**Website:** <http://www.fibo.de/en>

**Description:** FIBO in Essen is Europe's leading market platform for the fitness and wellness industry. Once every year in Essen, about 500 companies – including all the important key players – from more than 35 countries show products, concepts and solutions for: Fitness studios; health centers, multi-functional facilities; wellness centers, hotels; physiotherapists. FIBO presents training equipment and health-conscious sports nutrition: FIBO's success is based on the unique range and the great variety of products and ideas presented. Every year, approx. 40-45 US companies participate in individual exhibits, among them sports nutrition, nutritional supplement, sports equipment, health and wellness equipment and services providers.

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**Name of event:** 35<sup>th</sup> IDS-International Dental Show

**Date:** March 12-16, 2013 (biennial)

**Location:** Cologne, Germany

**Website:** <http://english.ids-cologne.de/>

**Description:** IDS is the world's leading trade show and sector meeting place for decision-makers from dental practices, dental labs, the specialist dental trade and the dental industry. Some 1,800 exhibitors from 56 countries display their products and technologies to 106,000 visitors from 150 countries on 130,000 m<sup>2</sup> exhibit space. The International Dental Show (IDS), which takes place in Cologne every two years, is organised by the Association of German Dental Manufacturers, Cologne (<http://www.vddi.de/index.php?id=startseite0&L=1>), represented by its Society for the Promotion of the Dental Industry (GFDI). The trade fair is staged by Koelnmesse GmbH, Cologne (<http://www.koelnmesse.com>). The USA Pavilion is organized by the Dental Trade Alliance, <http://www.dentaltradealliance.org> and supported by the U.S. Commercial Service in Germany.

### Available Market Research

IVD Diagnostics 2011

Nursing Care Market 2011

Diabetes Market 2010

Pharmaceuticals 2010

Medical Devices 2010

Biotechnology 2010

BVMED Annual Report 2010/2011

Customized Market Analysis available upon request for a fee

### U.S. Commercial Service Contact Information

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## Greece

*Capital:* Athens  
*Population:* 11 Million  
*GDP:* US \$318.6 Billion  
*Currency:* Euro  
*Languages:* Greek



### Summary

Greece's geographic location makes the country an excellent business gateway into Southeastern Europe. The continuously growing demand for medical equipment in Greece, as well as in many of the developing Balkan states, provides strong prospects for companies in the medical equipment field in Greece, and neighboring Balkan countries. The Greek market for medical equipment has experienced stable annual growth of 12.7 percent over the past several years. One of the prime characteristics of this market is its high level of imports.

Last year's economic developments in Greece, triggered by the recent financial crisis, created a new environment for all sectors. Initially, GDP in Greece was estimated at \$381.3 billion, with a slight decrease of 0.3 percent for 2010. However, due to recent developments related to the upward revision of the deficit and the bail-out of the Greek economy by the E.U., the IMF and the E.C.B. (the "troika") via the implementation of severe austerity measures, the latest GDP estimates show a sharp decline of approximately 4 percent. The new Greek government, elected in October 2009, set as a primary target the reduction of the deficit by cutting waste and government spending. This has also impacted the public healthcare sector that is saddled with large debt accrued over several years. Countering this is an ever-growing private healthcare system that is well represented by U.S. firms and continues to provide opportunities for American companies.

The Greek GDP is expected to be around US\$318.6 billion in 2011, with a 1.6% fall predicted for the coming year. The economy is not predicted to grow until 2013.

According to the Ministry of Health and Social Solidarity, Greece spent over nine percent of its total GDP of \$343.6 billion on healthcare in 2009. This is due to the implementation of a structured plan by the state to further increase the quantity and quality of healthcare services provided, particularly to regional areas of Greece, and the need of the private sector to stay competitive (90 percent of the private sector's expenditures are for high technology medical devices).

Healthcare expenditures as a share of GDP in Greece are about 10 percent or \$3,092 per capita annually. This expenditure is comprised of 52 percent government-provided care and 48 percent private care. Preference for private healthcare is higher in Greece than in most E.U. countries although this may change in the future, given the economic situation and Greek citizens' ability to pay for private care.

### Market Entry

#### *General*

As a member of the E.U., Greece applies the E.U. common tariff schedule on products imported from non-E.U. countries. All products, regardless of origin, are subject to the value-added tax (VAT) which as of July 1, 2010 is 23 percent for most products (compared to the previous 21 percent rate) and 11 percent for pharmaceutical products. A further increase is under debate, as a result of the government's intention to raise more funds to fight the budget deficit.

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### *Medical Equipment & Devices Sectors*

While duties are applied to parts of medical products and disposables, U.S. medical equipment receive duty-free treatment. Within the E.U., medical device legislation has been harmonized through the European Union's Medical Devices Directive 93/42/EEC. This enables a manufacturer who has approval in one E.U. country, to gain access to Europe's entire market without having to obtain approvals from each additional country. All low risk devices, which are in conformity with the requirements of the directive, must carry a CE mark. Higher risk classified products, in addition to the CE mark, must carry the identification number of the certifying organization that performed the conformity assessment and issued the approval. National implementation of the Medical Device Directive requires instructions for use in the national language. However, technical manuals and promotional material may be in English, French or German. Representatives in Greece can assist U.S. companies to meet these standards, if the U.S. firms have not already done so, in an effort to enable them to gain access to E.U.'s entire market.

### *OTC & Dietary Supplements Sectors*

All the details pertaining to the introduction of a new food supplement to the Greek market are outlined in the Greek Government Gazette #935 of November 13-1995 and in the E.U. Directive 2002/46/EC of the European Parliament. An American company interested in entering the Greek market is advised to find a local agent/distributor in order to expedite procedure normally encountered during the registration-approval process.

## **Current Market Trends**

### *Medical Equipment & Devices Sectors*

The Greek market for medical equipment was estimated in 2010 to have increased by 5.4 percent compared to the previous year. It is estimated that the Greek market for medical equipment in 2010 reached \$1,569 million, out of which around 95 percent was supplied by imports. The greater share of the companies' revenues is recorded in their business with the public sector (at around 80 percent) but this is predicted to change due to the revised company focus toward the private healthcare sector, given its ability to pay for the products it buys in a reasonable time frame.

### *Health IT Sector*

Health Information Technologies (e-Health) consists of hardware and software systems used by healthcare professionals to gather, file, classify, have access to, and electronically exchange healthcare information including administrative, clinical and other supportive systems. In terms of e-Health, Greece scores below the E.U. 27 average regarding availability of Information and Communication Technology (ICT) infrastructure (computers and Internet) and the use of ICT for e-Health purposes. Although Greece was lagging behind the E.U. in internet penetration and broadband, the aim of the National Digital Strategy was to reach the E.U. average by 2010, and the recent government efforts through its National Digital Strategy (2006-2013), including related investments of over \$665 million have already led to considerable improvement. In particular, Greece is quickly catching up to the above-mentioned E.U. average (20 percent). As of October 2009, the overall broadband penetration reached 16 percent of the population (almost 2 million broadband connections), which is a 44 percent increase from the previous year and a great improvement compared to the 0.2 percent in 2004.

Although the use of ICT technology for use in healthcare appeared in the 1980's, ICT solutions have not yet been strongly adopted in healthcare practice in Greece. This is mainly due to the rather late development of an e-Health strategy. The national road-map that was drafted in 2006 calls for the creation of a National Health Information System. Pilot programs are planned for the 2007-2015 period. Therefore, the required infrastructure, including standards, a national health portal, insurance smart cards, electronic information systems, etc., will start becoming available in the upcoming years. As a result, there are not many available on-line health services, either public or private. In terms of

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infrastructure, in 2007, 79 percent of general practitioners were using a computer, those with an Internet connection were measured at 66 percent, and 44 percent had a broadband connection. This compares to an average of 87 percent, 87 percent and 79 percent, respectively in the E.U.27 countries. Moreover, in 2009, 79.4 percent of Greek physicians started using computers to create electronic patient records, where the E.U. 27 equivalent percentage is 87.5 percent.

### *OTC & Dietary Supplements Sectors*

The OTC healthcare market in Greece is characterized by consolidation of global supplies, with multiple foreign brands active in the market. This market condition does not seem likely to change, as multinationals are only becoming stronger, and traditional Greek firms are moving towards importing rather than manufacturing medicines. The trend of health and wellness in Greece has favored companies in nutritionals, herbal/traditional products and in OTC healthcare, for example vitamins and dietary supplements.

Local production of pharmaceuticals and vitamins in Greece has been declining for several years, while imports are constantly increasing. However, strong competition among the multinationals makes it difficult for smaller companies to develop and maintain a considerable market share. Financially robust firms rely heavily on advertising to carve out their market share.

The Greek vitamin and dietary supplement market has grown significantly during the last decade, creating investment opportunities. It is indicative that the market for OTC healthcare in Greece increased between 2001 and 2006, growing at an average annual rate of 5.9 percent. There was a decline in market demand in 2010 to be expected based on the recent economic crisis that Greece is experiencing and the decline in purchasing power.

In the last decade, the consumption of vitamins and dietary supplements has increased as people learn of potential beneficial effects through advertisements and their doctors'.

### **Main Competitors**

In the Greek market, there are approximately 300 active companies in the medical device field. These companies are mainly importers and distributors of scientific and medical equipment which also provide after-sales services. Key suppliers of medical equipment to Greece are the United States, Germany, and Italy, and to a smaller degree, the Netherlands, France, United Kingdom, and Luxembourg. The E.U. has acquired a major share of the Greek market due to geographic proximity, product quality, established marketing arrangements and favorable tariff treatments. Domestic manufacturing in this sector is not highly developed. Consequently, the supply capability of Greek companies is largely limited to low-value products such as syringes, bandages, gauze and various small medical devices. The medical equipment market in Greece is highly competitive because of the number of diverse importers. The structure of the public healthcare sector and especially the bureaucratic process of the existing tender system make it imperative for U.S. suppliers to have local partners. Competitive strategies focus mostly on pricing, exchange rates, and payment terms, particularly when dealing with the public hospitals. Leasing is also an option, especially for large, high-tech, expensive equipment. The most active and profitable sub-sectors for foreign suppliers include surgical equipment and supplies, electromedical equipment, IT healthcare systems and telemedicine technology. Specifically for IT healthcare, there is significant demand for products that increase the patient's safety through reduction of medical errors, while improving health information management.

Relevant U.S. company presence in the Greek market includes: 3M, Abbott, Alcon, Bard, Baxter, Becton Dickinson, Boston Scientific Hellas, Carestream, Edwards Lifesciences, GE Medical Systems, Johnson & Johnson, Medtronic, Stryker, and Teleflex Medical. It should be noted that the actual share of U.S. imports was much higher than the estimated 18 percent because a large amount of the medical equipment was produced by the European subsidiaries of U.S. firms and are registered as having originated in the E.U.

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## Current Demand

In the past year alone, private care accounted for up to 48 percent of total health care expenditures, while the European average is around 27 percent. There are two major sources of demand for medical devices: (1) Public Health Institutions (hospitals, health centers, and regional clinics) and (2) Private Health Institutions (hospitals, clinics, diagnostic centers, and professionals). Demand from consumers represents a small but increasing segment of the market. Research shows that demand for medical equipment from public hospitals represents approximately 80 percent of the total demand, making public sector hospital payment delays a serious concern. In the medical equipment market, suppliers claimed delayed payments that amounted to \$1.1 billion. There are ongoing public and private initiatives to reduce the mismanagement of public capital and delay of payments, which the new government claims is at the top of its agenda.

The Government of Greece is evaluating new methods for maximizing public healthcare system efficiency and improving the services offered by public hospitals, while at the same time reducing the relevant budget. There are various plans under consideration by the government such as: the merging of many hospital units, twenty-four hour operation of all public hospitals, greater level of transparency in hospital financial transactions and in hospital procurement, and more efficient allocation of public healthcare system resources and human capital. Additionally the Greek government recently agreed to start paying off debt to hospital suppliers and to maintain the uninterrupted flow of medical supplies and consumables the public hospitals but this is still tentative.

The challenges within the public sector have created an opportunity for the private sector to grow in importance. The involvement of the private sector in health care delivery is extensive and has been growing rapidly since the early 1990s. The current number of private hospitals and clinics is 234 with a total capacity of 15,397 beds, a number that accounts for 26 percent of the total hospital beds in the country. Most of these facilities are general and maternity hospitals.

The market leaders in the private Healthcare Sector in Greece are the Athens Medical Group, Euromedica, Hygeia Group, and IASO Group. These medical business groups have grown tremendously from the past decade. These companies continuously seek to increase their stake in the market, however, because of the current economic situation, operate under financial pressure. Already, they have established facilities in Greece, and some neighboring countries such as Albania and Cyprus. The private health care sector is averaging an annual growth of 13-15 percent. General and diagnostic clinics have averaged 16.8 percent and 8.4 percent annual growth, respectively. In terms of primary health care, there are more than 25,000 private practitioners and laboratories, and approximately 250 diagnostic centers in Greece, most of which are equipped with, "big ticket" medical technology. Private practices, labs and diagnostic centers are also contracted through social insurance funds to provide health care services to their beneficiaries. Remuneration is on a fee-for-service basis. Rehabilitation services and services for the elderly (geriatric homes, etc.) are predominantly offered through the private sector.

## Barriers

There are no real barriers for entry in the Greek market, however, the situation with public sector hospital payment arrears has been an issue, particularly amidst the Greek economic crisis. Many companies have witnessed long delays in the payment of accumulated debts by the Greek public sector. However, the DIRECTIVE 2011/7/E.U. of the European Parliament and of the Council of 16 February 2011 on combating late payment in commercial transactions has placed some increased pressure on the Greek government in proceeding with the normalization of payments in the future.

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## Trade Events

**Name of event:** MedicExpo '11  
**Location:** Athens, EXPO Athens  
**Website:** [www.medicexpo.com](http://www.medicexpo.com)  
**Description:** February 25 – 27

**Name of event:** 6<sup>th</sup> MIRA International Congress, 2011  
**Location:** Athens, Hilton Hotel  
**Website:** [www.mira2011athens.gr](http://www.mira2011athens.gr)  
**Description:** May 11 – 13

## Available Market Research

Medical Equipment Market (2010)  
Health Information Technologies Market (2009)

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## Hungary

*Capital:* Budapest  
*Population:* 9.9 Million  
*GDP:* US \$132 Billion  
*Currency:* Hungarian Forint (HUF)  
*Language:* Hungarian



### Summary

As in most European countries, Hungary's health system is mostly state-funded. Hungary's long-term policy calls for maintaining public financing while increasing private health care services and nonprofit organizations. The public sector accounts for about 70 % of the total health expenditure. In 2009, Hungary spent 4.3 percent of its GDP on public healthcare, representing about USD 3.5 billion, compared to 7.2 percent in 2005. Restructuring of the healthcare systems is currently in process. The government plans to come up with reform plans at the end of July 2011. The new systems is planned to be established by January 1, 2012.

### Market Entry

#### *Medical devices*

In May 2004 Hungary joined the EU, and became part of the External Tariff System. According to Hungarian tax regulations, all products, regardless of origin are subject to a 25 percent value added tax, which is borne by the final customer (hospital or patient).

The EU directives on Medical products have been integrated into Hungarian legislation. Generally, there must be one "Authorized Representative in one of the EU countries, who is responsible for the EU-wide CE marking". Prior to entering the Hungarian market, medical products must have the CE mark. If a medical product has the CE mark issued by an eligible notified body, no further testing is required by any Hungarian authority. If the product has no CE mark, a Hungarian notified body can issue it. According to Hungarian regulations, foreign suppliers must have a "Resident Representative" in the country responsible for the foreign product. This person registers the product with the Authority for Medical Devices (c/o Ministry of National Resources) and provides the necessary information including directions for use and labeling in Hungarian. The resident representative keeps the technical files and is the point of contact for market surveillance.

The Hungarian market is very receptive to high quality U.S. medical equipment. As Hungarian health care is widely felt to be under-financed, foreign companies have a competitive edge if they offer financing. Participation in seminars, medical exhibitions and scientific meetings is an efficient tool of trade promotion. Medical products are marketed in Hungary through authorized distributors. Major foreign companies either have their own subsidiaries or operate through local distributors. Most distributors handle several brands of similar equipment or several lines. Pricing is a key factor in selling a medical product in Hungary, as the market is very price sensitive. When purchasing medical equipment, end-users also look for established companies with reliable after-sales service and customer support.

#### *Drugs*

Registration of all medicines intended for human use including homeopathic preparations, preparations marked with isotopes and immunobiological preparations, vaccines and blood products is carried out by the National Institute of Pharmacy (OGYI) [http://www.ogyi.hu/main\\_page/](http://www.ogyi.hu/main_page/)

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## Current Market Trends

Imports dominate the very competitive Hungarian market for medical supplies and equipment. About 85-90 percent of an estimated USD 727 million (2009) is spent on foreign products. According to the estimates of the Association of Medical Technology in Hungary, some 25 percent is spent on high-value devices, some 30 percent for rehabilitation products and the rest for medical equipment and hospital supplies.

Hungarian companies supply local products for about 10-15 percent of the medical equipment and supply market. There are 150-200 small and medium-sized medical companies in Hungary, most of them specialized in high-tech products for export markets and in R&D activities with a staff of less than 20 people. Electro-medical apparatus are the largest products by export value. Other companies manufacture medium to low-tech products mostly for the local medical market.

U.S. products account for approximately 10-15 percent of total medical product imports. In addition to the official statistics, a number of European subsidiaries of American companies are shipping products to Hungary registered as goods from Germany, the Netherlands, the U.K., etc. A few American companies have their own representative and sales offices in Hungary, while most distribute their products through local firms. Medical products imported from the U.S. in significant amounts include electro-medical instruments; disposables like catheters; ultrasound machines; electro-diagnostic devices; orthopedic appliances and implants, hearing aids and pacemakers.

## Main Competitors

The import of medical products is fully liberalized. American companies face stiff competition from West European companies in Hungary. German, Austrian, Italian and British firms have been present for many years in the market. Germany has been the sales leader for decades with over 20 percent market share in the overall medical market. The proximity of the European firms to the Hungarian market allows them frequent visits to meet end users, to participate in exhibitions and scientific meetings, and to provide prompt after-sales services to buyers. Some of them have established manufacturing units in Hungary for serving their Central-Eastern European markets.

## Current Demand

### Medical Devices

- Funding from EU structural fund (for the period of 2007-2013) will be used for priority healthcare development projects like:
- Development of outpatient clinics (funds for 16 regional outpatient clinics already approved)
- Development of one-day surgery (funds for 7 hospitals already approved)
- "Healthcare Pole Project" – Development of "high priority hospitals" for the regions
- (Funds for 7 hospitals already approved)
- Upgrade of emergency care

Opportunities for U.S. medical equipment suppliers include: ultrasound equipment, digital X-ray, monitoring equipment, MR, CT, nuclear imaging (PET, Gamma camera), laboratory diagnostics, and clinical chemistry.

### Dental Equipment and Supplies

With 5,500 practicing dentists (out of 6,000 registered), Hungary is a market leader in providing dental services for dental tourists. It has a market share of 39 %, closely followed by Poland (32 %), Turkey (15 %), Spain (7%) and Bulgaria (7%). The size of the Hungarian dental equipment and supply market is

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estimated to reach about USD 25 million. It is dominated by German, Scandinavian, Italian, French and Japanese suppliers however it provides market potential for U.S. suppliers of teeth whitening systems, lasers, optical instruments, small equipment for implants and root canal treatment, computer controlled injection devices for anesthetization, and orthodontics devices.

#### E-Health

In the framework of the National Development Plan, European Funds are allocated to various healthcare expenditures including specific IT related projects. Best prospects include the “E-Health Card” project that will require the supply of about 40,000 card readers, a card management system, card application and authentication solutions etc. and the “Electronic authentication database and healthcare portal” project requiring security and authentication SW solutions, secure and scalable database, portal solutions (SW).

#### Drugs & Pharmaceuticals

Drug sales amounted to USD 3 billion in 2008 equal to USD 300 per capita. Imported medicines accounted for 71 percent of sales, worth USD 2.17 billion. As of September 2009, there were 5,800 registered drugs on the Hungarian market, out of which 4,700 were prescription medications. In 2008, the number of subsidized drugs reached 5,713. The number of over-the-counter (OTC) medications rose to 1,100 in September 2009. In terms of total sales, prescription drugs dominate the market with approximately 85 percent of the market share. Three hundred and ninety OTC products can be sold outside pharmacies in gas stations and supermarkets as well. There is no import duty levied on pharmaceutical products, and a 5 percent VAT must be paid by consumers.

#### Barriers

Firms exporting medical devices to Hungary will not encounter any direct trade barriers or quotas. Non-tariff, indirect trade barriers, however, affect the pharmaceutical manufacturers including a 20 percent tax on reimbursed sales of pharmaceutical products, a non-proportional annual fee of HUF 10 million (about USD 54,000) for every pharmaceutical sales representative, and a claw-back, mandating that pharmaceutical manufacturers repay the Government for up to 100 percent of pharmaceutical over-expenditures by the National Health Insurance Fund (NHIF). In order to meet the requirement of the convergence plan and keep the budget deficit under 3 percent, the government plans a HUF 120 billion (USD 645 million) cut in the Pharmaceutical Fund over 3 years that seriously affects innovative pharmaceutical manufacturers in the market.

If there is an overspending in the pharmaceutical budget, the NHIF determines which pharmaceutical manufacturer's market share has increased compared to the base year. Any company whose turnover has exceeded the market share of the baseline year has to pay this claw-back on the basis of a complicated formula.

#### Trade Events

Medical distributors promote their products at specialized medical conferences, scientific meetings organized for one or several medical fields like surgeons, ophthalmologists, cardiologists, oncologists, etc. Hungary has no major medical exhibition except a smaller dental show:

**Name of event:** Dental World Budapest (Dental Show and Conference)

**Location:** SYMA Sports and Event Centre

**Website:** <http://dentalworld.hu/dw-2011/international-information>

**Description:** About 200 Hungarian and foreign exhibitors display in 164 booths.

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## Available Market Research

Hungary: Dietary Supplements and Vitamin Market 12/2010  
Hungary: Dental Equipment and Supplies Market 05/2010  
Hungary: Clinical Trial Market 04/2010  
Hungary: E-Health Market 02/2010  
Hungary: Pharmaceutical Industry 08/2009  
Medical Equipment Market 09/2008

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## Ireland

*Capital:* Dublin  
*Population:* 4.5 Million  
*GDP:* US \$204.26 Billion  
*Currency:* Euro  
*Language:* Irish, English



### Summary

Ireland is ranked as having the 13<sup>th</sup> most consumer-friendly healthcare system in Europe. The market offers American manufacturers of medical equipment and services an opportunity to take advantage of mutual language, business and cultural links and to use the market as a springboard for Europe.

The country has a dual healthcare system, consisting of both private and public healthcare options. The public healthcare system is regulated by the Irish government's Health Service Executive, providing free public health coverage for 1.4 million people with low incomes and those over the age of 65 with modest incomes. Almost 50 percent of people have private health insurance.

Ireland had a total per capita expenditure of \$4,383 in 2010, representing 9.6% of GDP. Public expenditure on healthcare was \$19.6 billion, with health budgets cut by \$885 million year on year. The health budget is likely to be further cut by up to \$1.4 billion over the next four years.

Eleven of the world's top twelve medical device companies are located in Ireland. It is the second largest exporter of medical products in Europe, second only to Germany. Over 160 medical technology companies exported over \$5.78 billion worth of product in 2010, an increase of 11.19% from 2009, 50% of which was exported to the U.S.

A strong relationship is maintained between several Irish and American universities and hospitals, such as the University of Pittsburgh Medical Center which in partnership with the Beacon Medical Group, manages the independent Beacon Hospital in Dublin. The Cleveland Clinic also operates in Ireland in a partnership with the Royal College of Surgeons to research and sell medical devices throughout Europe.

### Market Entry

U.S. medical device products are well regarded in Ireland, with the market being highly receptive to American medical equipment/technologies. Ireland, as a member of the Euro-zone, serves as a natural test market and location from which to begin distribution throughout Europe.

U.S. companies exporting to Ireland should obtain local representation through an agent or distributor, of which there are almost 100 qualified companies in Ireland. CE marking is a legal requirement in Ireland. The Irish Medicines Board is the regulatory authority for medical equipment and healthcare. Medical devices are regulated by EU Directives that set out compliance requirements and procedures including the General Medical Devices Directive (93/42/EEC), the Active Implantable Medical Devices Directive (90/385/EEC), and the In-Vitro Diagnostic Medical Devices Directive (98/79/EC). Irish labeling requirements are similar to those used elsewhere in the EU, except Irish authorities require that the name and the EU address of the manufacturer, distributor or packer also appear on the label.

Ireland applies EU tariffs (customs duties) which are based on the international Harmonized System (HS) of product classification. Duty rates on manufactured goods from the United States generally range from 5-8% and are usually based on the c.i.f. value of the goods at the port of entry.

The standard electricity voltage in the Republic of Ireland is 230V AC, nominal, at 50Hz, with plugs being of the 3-pin IS411 (BS 1363) type. Any electrical item sold on the Irish market should include a 3-pin plug

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attached (molded) to the power cord. Exporters selling electrical products in the EU must conform to the WEEE and RoHS directives.

### **Current Market Trends**

A newly appointed coalition government has published an ambitious healthcare reform program with plans to introduce a Universal Health Insurance Scheme. The government plans to tackle the problems of the dual healthcare system, provide better access to A & E facilities, cut long waiting lists and counteract hospital budget overruns. The government is in favour of primary care centers and is an advocate of preventative medicine focusing on breast, cervical and colon cancer screening.

Cuts in healthcare expenditure have catapulted cost-efficacy and money-for-value products to center stage. Capital spend has diminished with focus primarily on the equipment replacement market. Opportunities exist for products that save time, resources, and produce cost savings in a very price sensitive market.

The Irish government has also identified the medical technology sector as one of the key drivers of future industrial growth and continues to provide support to the manufacturing and R&D sectors.

### **Main Competitors**

U.S. medical device companies include: 3M, Alcon, Baxter, Biomet, Boston-Scientific, Cook Medical, Covidien, GE Healthcare, Hospira, Johnson & Johnson, Medtronic, and Stryker. Foreign competitors include: B. Braun Melsungen, Philips, Siemens and Smith & Nephew.

International brands have local sales and marketing operations or utilize an extensive network of Irish agents and distributors. U.S. Commercial Service Dublin facilitates introductions to this agent/distributor network for U.S. companies interested in serving the Irish and wider European marketplace.

### **Current Demand**

Ireland has a population of 4.5 million people with 192 hospitals, 90% of which have individual purchasing power. Overall government spending on medical devices and technology of 2.5% is below the EU average of 4.5%. Despite the spending cuts, long term demand is expected to continue to grow, with healthcare spending expected to increase to \$50 billion in 2020. Currently 11% of the population is over 65 and as they age, further demand will be placed on healthcare and allow for the emergence of niche markets.

The construction of a new 445-bed Children's Hospital is being planned subject to funding and is due to open in 2016. The private healthcare sector continues to grow with the development of a small number of private hospitals/clinics and state-of-the-art primary care centers. The development of these new projects will provide opportunities for new product and equipment sales.

Distributors are eager to source new products to help them maintain their businesses in a challenging trading environment. Demand for medical equipment exists particularly across the general medical device, diagnostics, hygiene, living assisted and homecare products, bio-medical, dietary supplement, drugs/pharmaceutical, healthcare IT and veterinary sub-sectors.

### **Barriers**

There are no real trade barriers. Industry groups support the development of a national medical device evaluation mechanism to help improve market access. Future cuts in healthcare spending will pose a challenge for American suppliers. U.S. medical device manufacturers should promote the long term cost

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saving and efficacy benefits of their products and equipment at a time when procurement managers are under pressure to achieve short term savings. American companies partnering with distributors should work together to devise creative strategies to bring new products to the market.

## Trade Events

**Name of event:** IMSTA Annual Innovation Showcase

**Location:** Dublin

**Website:** <http://www.imsta.ie/node/426>

**Date:** October 5, 2011

**Description:** Irish Medical and Surgical Trade Association's showcase of the very latest in medical technologies available from medical supply companies in Ireland.

**Name of event:** MEDTEC Ireland 2011

**Location:** Cork

**Website:** <http://www.medtecireland.com>

**Date:** October 5 – 6, 2011

**Description:** MEDTEC 2011 focuses on new manufacturing technologies and techniques, commercial opportunities and clinical and academic research in the medical devices sector.

A large number of Irish distributors attend Medica: <http://www.medica-tradefair.com>

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## Italy

*Capital:* Rome  
*Population:* 61 million  
*GDP:* US \$1.77 trillion  
*Currency:* Euro  
*Language:* Italian



### Summary

The medical device market in Italy was estimated at approximately \$8.9 billion in 2009. Italy is a strong manufacturer of medical devices with over 500 small to medium sized companies and over 30,000 employees.

Italy has a government-funded healthcare system, rated as the second best in the world by the World Health Organization, which makes the Italian government the primary purchaser of medical equipment. Public hospitals account for over 75 percent of medical device sales, while the remaining 25 percent of sales are made to the private sector. Italy's sophisticated health system translates into demand for a broad range of cutting-edge medical equipment. However, due to Italian government budget cuts in healthcare, medical device sales are expected to decline in the coming years.

### Market Entry

The Italian government has implemented various European Union (EU) directives related to medical devices, and U.S. companies must be prepared to comply with Italian and EU legislation.

American companies interested in entering the Italian market should carefully select their potential distributors or agents and should also consider cooperative arrangements or joint venture/licensing agreements with Italian partners.

It is up to the Regional Governments to issue specific regulations governing procurement of medical equipment. Most purchases are made by public tenders open to both domestic and foreign companies. Announcements of tenders on public procurements are monitored by the U.S. Mission to the European Union and can be accessed through the webpage: [www.buyusa.gov/europeanunion](http://www.buyusa.gov/europeanunion).

All medical devices marketed in the EU must bear the CE mark to certify conformity with EU legislation. Member States have appointed certification authorities or "notified" bodies to grant these compliance certificates. Award criteria are normally based either on the lowest price or on the most economically advantageous quotations.

### Current Market Trends

Italy is a strong manufacturer of medical devices, but it also relies heavily on imports, which are valued at \$8 billion in 2009. Italy imports primarily from the United Kingdom, Germany and the Netherlands. Companies producing medical equipment in Italy are primarily small-to-medium sized companies that face increasing competition from foreign firms. The Italian domestic medical market (excluding dental and optical medical devices) was estimated at approximately \$8.9 billion in 2009.

Major medical device suppliers are the United States, Germany, France and Japan. Domestic production is strong in areas such as radiology, cardiology equipment, implantable pacemakers, anesthesia equipment, respiratory apparatus, dialysis equipment and dental products ranging from instruments to dental chairs. Italy's aging population will increase spending on medicines and healthcare in general. Italy

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represents an attractive market for medical devices and equipment. Opportunities exist for innovative products.

### **Main Competitors**

The majority of the third country import market in diagnostic imaging equipment is held by Siemens (Germany), which combines a leading edge in technology with a broad range of products and a very extensive sales and servicing network, along with Toshiba (Japan). Philips (Netherlands) is particularly strong in the sector of digital radiography and angiographies, CT, MR, echography and radiotherapy. Smith & Nephew (U.K.) and Stryker hold a majority of the orthopedic market specializing in orthopedic reconstruction, prosthetics, and surgical navigation systems. Domestic production is strong in radiology, cardiology equipment, implantable pacemakers, anesthesia equipment and respiratory apparatus.

Major multinationals and large companies use their own direct distribution networks and sales organizations for an estimated 67 percent of their business turnover in Italy. The remaining 33 percent is sold through local agents who are becoming increasingly important, particularly in southern Italy. U.S. firms that decide not to have a direct presence in Italy usually operate through locally selected distributors that are well established countrywide. Local distributors offer technical and after-sales service, experience in the different market sectors, and customer relationship management.

With 20 American manufacturing plants, including three research centers in Italy, pharmaceuticals represent an important commercial sector for the United States. There is a strong concentration of non-Italian companies that account for more than 70 percent of production. In addition, the Italian market for nutritional supplements and natural products has grown substantially to make Italy one of the largest markets in Europe. Over nine million Italians have opted for natural medicine as a way to improve their health. Surveys have indicated that 35 percent of Italian consumers are faithful purchasers of natural nutrition products. Forecasts indicate that the sector will continue to grow.

### **Current Demand**

The Italian market for medical equipment and supplies (excluding dental and optical equipment) is in overall decline, with exports falling and imports rising based on Euro values. U.S. medical equipment is traditionally well-received in Italy due to its perceived high quality. Prices are considered to be of primary importance in all purchasing decisions, both by the public and private sectors. Italians are educated consumers and expect state-of-the-art medical treatment, which ensures continuous demand for innovative medical equipment and products.

For U.S. companies to continue to be successful in the Italian market, products should be based on high quality, innovative technology and after-sales service. U.S. subsidiaries operating in the Italian market include: Boston Scientific, Baxter, Johnson & Johnson and St. Jude Medical.

### **Barriers**

Companies interested in participating in public tenders must first qualify by submitting adequate evidence of their business experience and professional expertise. Bidding specifications normally include a detailed technical description of the product, and other requirements such as the CE mark, safety standards, testing procedures, operation manuals and quality assurance. Award criteria are primarily based on the lowest price or the most economically advantageous quotations.

All medical products and equipment imported into Italy require either notification and/or approval from the Italian Ministry of Health (MOH). All new-to-market medical devices must go through an on-line device registration process with the Italian Ministry of Health to be placed in the Italian market. Information on registration procedures is available on the Ministry of Health's website (in English) as follows:

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<http://www.ministerosalute.it/dispositivi/paginainterna.jsp?id=395&menu=registrazione>

There are no other significant trade barriers or limitations on imports of U.S. goods. Technical specifications are essentially those established by the EU, which have been incorporated into Italian law. Official technical norms are issued by UNI, the Italian Standards Institute, and electrical norms are from CEI, the Italian Electro technical Standards Institute. Information on EU standards is available from the Commercial Service Office at the U.S. Mission to the European Union at the following address: 40 Boulevard du Regent, 1000 Brussels, Belgium, tel.: 32 2 5082746; fax: 32 2 5131228.

## Trade Events

Exhibitions are a cost-effective method to enter the Italian market and meet with a wide range of buyers interested in a particular industry sector. Also, trade shows are useful for finding an agent, distributor, or representative.

**Name of event:** EXPOSANITÀ

**Location:** Bologna

**Website:** [http://www.senaf.it/fiera\\_eng.asp?fieraid=107](http://www.senaf.it/fiera_eng.asp?fieraid=107)

**Description:** Exposanità is Italy's unique exhibition and Europe's second largest event dedicated to healthcare. The exposition is held every other year. The next edition will take place May 16 – 19, 2012. This show attracts over 27,103 visitors and has over 1,000 exhibitors.

**Name of event:** SIRM

**Location:** Torino

**Website:** <http://www.congresso.sirm.org/>

**Description:** The SIRM congress is highly specialized and is the recognized forum for diagnostic imaging equipment in general. The exposition is held other year and is sponsored by the Italian Radiological Society. The next show will take place June 1 – 5, 2012.

**Name of event:** SANA

**Location:** Bologna

**Website:** <http://www.sana.it/en/>

**Description:** Sana is a trade show dedicated to herbal, natural and environmentally friendly products. The next edition will take place September 8 – 11, 2011.

## Available Market Research

Italy: Medical Device Industry (June 2010)

Italy: Healthcare Services (December 2009)

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## The Netherlands

*Capital:* Amsterdam  
*Population:* 16.7 Million  
*GDP:* US \$ 680.4 Billion  
*Currency:* Euro  
*Language:* Dutch



### Summary

Public health policy in the Netherlands is aimed at ensuring that the population has access to necessary health care. Approximately \$50 billion is spent on the provision of health care annually. In contrast to the U.S., private health care plays a minimal (but growing) role in the Dutch system. Private companies, however, play an important role in the health care system, and the state is increasingly allowing market forces to increase efficiency and reduce costs.

The domestic market in the Netherlands is relatively small. Imports plus local production far exceed domestic consumption requirements. The country, with its unique geographic position, functions as a distribution center, re-exporting an estimated 20 percent of imported medical equipment. Approximately 75 percent of the companies within this sector market their products outside the Netherlands.

Industry estimates put the value of the annual market for medical equipment and supplies at around \$4.5 billion, of which equipment accounts for 75 percent of sales.

There are more than 500 medical technology companies and over 35 specialized research centers involved in the development and manufacturing of medical instruments and systems, disposables, furniture, consumables, textiles, and supplies.

There are approximately one hundred medical trading companies in the Netherlands, including three or four five large ones. Philips is a major global player. Dutch medical equipment importers are highly specialized, both in terms of product knowledge, and knowledge of the Dutch health care structure. There is a high level of cooperation and communication among importers and medical specialists, user groups, and technicians responsible for maintaining the equipment.

### Market Entry

Local representation or market presence is essential. U.S. exporters should appoint a medical wholesaler/distributor to represent their products. The International Partner Search (IPS), as well as our tailored Gold Key Service, is available through the U.S. Department of Commerce's Export Assistance Centers.

U.S. firms should be prepared to meet some additional criteria to ensure product acceptance, recognition and marketability when entering the Dutch market:

- Product information should be in Dutch. At a minimum, catalog inserts should be in Dutch.
- Operation and instruction manuals should be in Dutch to ensure proper usage of equipment.
- Ensure reliable after-sales servicing and product support, or select a distributor capable of doing so.
- Maintain close contact with distributors to stay informed about market developments, trade issues, regulations and laws concerning products.

Authorized Representative for Class I products: The manufacturer must have an EU-based authorized representative. The primary task of the authorized representative is to be the point of contact for the national health authorities of the member states. The arrangement between the authorized

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representative and the manufacturer is purely administrative and subject to a commercial contract specifying the role of the authorized representative.

### **Current Market Trends**

Trends include: increasing demand for medical services; growing pressure to contain associated costs; an ageing population; shifts from institutional towards out-patient care; a move from curative towards preventative care; and high value placed on innovation and new technologies.

### **Main Competitors**

Manufacturing of medical equipment is characterized by a small number of large companies dominating the domestic market and exporting much of what they manufacture. Dutch manufacturers supply about three percent of the world health care equipment market. Dutch suppliers also do well in specific niche markets, including pacemakers, x-ray equipment and diagnostics. Philips is a major manufacturer of medical equipment in the Netherlands. Major competitors are Toshiba, Siemens, General Electric and Drager. GE is a leading importer of x-ray equipment into the Netherlands. Medtronic Inc. is a major supplier of pacemakers through its Dutch subsidiary. The German company Drager is a leading supplier of patient monitoring systems.

### **Current Demand**

Suppliers in the medical equipment and supplies market serve approximately 220 general hospitals with 44,000 beds, eight university hospitals with 6,000 beds, 69 psychiatric hospitals with 18,750 beds, 15 rehabilitation hospitals with 825 beds, 3 epilepsy hospitals with 1,200 beds, and 16 outpatient hospitals. In addition, there are over 20,000 medical practices, polyclinics, laboratories, and consumers, accounting for 60 percent of sales. Hospital purchases contribute over 40 percent to the total medical equipment and supplies market, with the eight teaching hospitals accounting for the highest proportional share of these purchases.

### **Barriers**

Firms exporting medical devices to the Netherlands will not encounter any trade barriers or quotas. For customs clearance, a product description is required describing the use, origin and value of the product. All electro-medical equipment in the Netherlands must be suitable for use with 220 Volt, 50 cycle electrical current and should have KEMA or similar (TUV) approval.

There are also no restrictions or barriers on the movement of capital, foreign exchange earnings, or dividends.

### **Trade Events**

**Name of event:** European Respiratory Society 2011

**Location:** Amsterdam RAI

**Website:** <http://www.erscongress2011.org/>

**Date:** September 24-28, 2011

**Name of event:** SpineWeek / EuroSpine 2012

**Location:** Amsterdam RAI

**Website:** <http://www.eurospine.org/>

**Date:** May 28-June 1, 2011

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## Available Market Research

ISA Medical Equipment & Supplies 2010  
ISA Nutritional supplements 2009

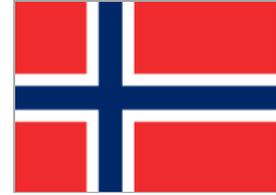
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## Norway

*Capital:* Oslo  
*Population:* 4.9 Million  
*GDP:* US \$370 Billion  
*Currency:* Norwegian Kroner (NOK)  
*Language:* Norwegian



### Summary

Norway is one of the wealthiest countries in the world and this is reflected in its expenditure on medical care for its citizens. With the exception of the U.S. and Switzerland, Norway spends more of its GDP (9% / USD 30 billion) on healthcare than any other country in the world. The state-dominated medical system, covering 84% of total healthcare costs is striving for technological advances and organizational improvements in a climate of increasing demand and an aging population. By 2020, there will be 40% more senior citizens in Norway than today.

U.S. companies are estimated to supply around 25-30 percent of Norwegian purchases of medical equipment. High end, quality products and a tailored marketing approach are key factors for U.S. companies in penetrating the Norwegian market. The perceived reliability and quality of a product, together with information received from health care providers and from relevant certifying bodies and professional associations in Norway constitute the most significant factors in a purchasing decision for Norwegian buyers and end-users of medical equipment. U.S. medical equipment suppliers have attractive opportunities in Norway.

### Market Entry

Finding a local representative with close established contacts with the public authorities and established customers is the key to success for a new-to-market U.S. company. The availability of technical service also plays an important role. Any new product coming into the market must have a support system within the area where the equipment will be used (or in one of the nearest large cities). Also, most internal information is in Norwegian, and it is an advantage to have someone who can stay informed about of the current situation.

### Current Market Trends

Demographically, as in other industrialized countries, Norway has an aging population, and this represents an extra burden for the healthcare system. The government has signaled that nursing and care for the aged must be given higher priority.

In addition, the government of Norway is striving for technological advances and organizational improvements in order to get healthcare costs under control. There is an increasing use of outpatient-based care at hospitals in an effort to rationalize.

### Main Competitors

Norway relies heavily on imports of medical equipment. The major third-country suppliers of medical equipment are Germany, Denmark, Switzerland, Sweden, the United Kingdom, and Japan. The Nordic countries (and to some degree Norway's EFTA partner Switzerland) have traditionally had close contact and cooperation in several healthcare related areas over the last decades. Norwegian companies have also had a preference for participating in and seeking trading partners through European, and in particular German, trade events.

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## Current Demand

High-quality and technically advanced products and a tailored marketing approach are necessary for U.S. companies wishing to penetrate the Norwegian market. An attractive and functional design is also very important in the Nordic countries. The most promising sub-sectors for U.S. suppliers of medical equipment include surgical instruments and equipment, diagnostic apparatus, orthopedic equipment, monitoring instruments and equipment, laboratory/pathology instruments and equipment, digital x-ray systems and customized ICT equipment. Telemedicine is seen as an important part of future acute medical care.

## Barriers

Through the EEA Agreement (European Economic Area), Norway participates fully in the EU internal market and thus in efforts to establish common product requirements and methods of conformity assessment. A CE marking will confirm conformity with the essential requirements of EU/EEA directives, Medical Device Directive (93/42/EEC) and Active Implantable Medical Devices (90/385/EEC). Norway has the same rights and obligations as EU member states in regulation of medical devices. So, all medical products must have pre-marketing approval and bear the CE marking. This marking must be used in order for the product to be placed on the internal EEA market.

## Trade Events

**Name of event:** Lab '11 (October 25-27, 2011)

**Location:** Oslo

**Website:** [www.messe.no](http://www.messe.no)

**Description:** Trade show, laboratory equipment.

## Available Market Research

The Norwegian Clinical Lab. Market  
The Norwegian Medical Equipment Market  
The Norwegian Rehab and Home Care Market  
The Norwegian Dental Market

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## Poland

*Capital:* Warsaw  
*Population:* 38 Million  
*GDP:* US \$488 Million  
*Currency:* Zloty (PLN)  
*Language:* Polish



### Summary

Poland, the sixth largest country in the European Union with a population of 38 million people, represents one of the biggest health care markets in Central/Eastern Europe. That stated, the health care sector in Poland has been in a somewhat challenging financial condition of late, and the short-term outlook remains tentative. However, the current government is finally taking the official position that the health care system in Poland must be restructured to represent a mixture of both public and private initiatives. Plans are also in the works to introduce new laws regarding private health care insurance. The main concerns are in the areas of restructuring, privatization, transparency in treatment standards, and control of the reimbursement system. The traditional public health care sector needs investment and management skills to meet the growing demand from patients and at the same time remain within cost controls. These continuing issues heavily influence the purchase of medical supplies in general. Once the new laws become the legal basis as established legislative reform, the new Polish health care market should present American companies in this sector with good opportunities.

American suppliers of medical products have a good reputation for high quality products. However, technological advantage is not the only factor determining success in the Polish market. American companies should focus on educating end-users and other players in the health care sector. Participation at conferences and seminars is a very effective avenue for promotion in Poland.

### Market Entry

Marketing strategies in Poland are heavily based on market demand. In Poland, medical specialists recommend products, so a good marketing strategy is to keep doctors well informed about new products. This means that a successful importer will need to have a representative/distributor that promotes awareness of new products, attends trade shows, seminars and conferences, and keeps doctors informed by direct campaigns. Price is a more important factor than quality in Poland's health care market. The second factor is local availability of service and spare parts. Another sale-making factor is quick delivery. U.S. companies are encouraged to identify agents/representatives that can provide the necessary assistance and important and timely information often not readily available through public sources. To locate an appropriate agent/distributor, American companies can take advantage of Commercial Service Warsaw's International Partner Search or Gold Key Service.

### Current Market Trends

The most common causes of death in Poland are cardiovascular disease (45%), cancer (26%), injuries and accidents (7%). Also, contagious diseases, especially hepatitis and sepsis, are an important concern. In addition, there is a growing concern with health problems associated with the aging population. About 7.5 million of the population is in retirement, 1.2 million are pensioners, and another 5.4 million are considered handicapped. In Poland, only 24% of handicapped people are employed comparing to 50% in other European countries.

There are 730 hospitals operating in Poland with the total number of available beds at about 183,600 including 546 public hospitals and approximately 186 non-public hospitals. Based on official statistics from the Central Statistical Office (GUS), there are 318,900 people in Poland registered as medical staff

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including doctors, dentists, pharmacists, nurses, and midwives. Nurses represent the largest group (57.3%), followed by doctors (24.5%) and pharmacists (7.4%).

Many experts believe that a significant amount of money is wasted in the Polish health care system by the public sector. There is an extreme inefficiency of work performed by medical personnel, ineffective use of medical equipment, and irresponsibility of management staff, and a vast number of hospitalized patients should be treated on an outpatient basis.

### **Main Competitors**

About 70% of all medical equipment used in Poland is imported. The range of medical equipment produced in Poland is quite limited. Polish manufacturers are not very competitive because they lack the latest technology, efficient production methods, investment capital, and appropriate marketing resources. Therefore, medical equipment represents a good prospect for foreign suppliers. U.S. medical equipment manufacturers face strong competition from European companies. EU suppliers increased market share due to their competitive prices as well as availability of EU assistance packages for Poland. Poland imports medical equipment primarily from Western Europe, the United States, and Asia.

### **Current Demand**

Some forms of independent private health coverage are currently offered in Poland, although they are designed more for companies than for private individuals. In addition, major local and foreign companies offer private health care packages as fringe benefits for their employees. The majority of these cover only outpatient care including screenings, check-ups, and pre-arranged consultations with specialists, etc. Nevertheless, these alternatives are paving the way for a very real expansion of private institutions offering attractive packages with various options for a significant portion of the Polish population. This system is expected to create a solid foundation for the development of private health care services and insurance in Poland.

Private medical firms operate along the lines of Health Maintenance Organizations but are still too small to provide national coverage for all their members. The majority of these medical clinics provide basic medical services internally. They usually contract some or all of the specialized services to third parties and cooperate with specific hospitals to provide their members with hospitalization services. Each year, these companies open new medical centers and offer services not only in large cities, but also at the regional level.

It is estimated that in 2009 Polish citizens paid 12.7 billion PLN\* (out of pocket and through fringe benefits package) on private healthcare/medical services including 7.9 billion PLN\* on outpatient care (ambulatory service), 4.2 billion PLN\* on dental visits, and only 0.6 billion PLN\* on hospital care.

\*2009 exchange rate: 1 USD = 2.9 PLN;

Beneath the hum of criticism and discontent, private companies working with National Health Fund have begun to see changes in health care. Faced with being left out of funding if they were not competitive, public hospitals and clinics are slowly beginning to reorganize. The reform has also forced improvements in service quality among competitors.

### **Barriers**

As Poland is a member of the European Union, import regulations for medical equipment are harmonized with the European Union's Medical Device Directives, which cover essential safety, health and environmental requirements. Products manufactured to standards adopted by European standards organizations, and published in the Official Journal as harmonized standards, are presumed to conform to

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the requirements of EU Directives. The manufacturer then applies the CE Mark and issues a declaration of conformity. With these, the product will be allowed to circulate freely within the European Union.

There are no restrictions on sales or importing of used medical equipment by either state-owned or private medical facilities. Medical equipment and supplies for the public hospitals are purchased through a competitive bidding process. Private clinics can purchase medical equipment and supplies from any sources they wish or through any trading organization they choose.

### Trade Events

**Name of event:** SALMED

**Location:** Poznan

**Website:** <http://www.salmed.pl/en/>

**Description:** It is the largest event for the healthcare/medical industry sector in Poland held biannually. The organizer is MTP Międzynarodowe Targi Poznańskie. The next show, the XXIV edition of SALMED, will take place March 14-16, 2012.

### Available Market Research

Additional information on the healthcare sector in Poland as well as more general information on the Polish market, including the country commercial guide, can be requested from the US Commercial Service Warsaw at [http://export.gov/poland/marketresearchonpoland/eg\\_pl\\_026434.asp](http://export.gov/poland/marketresearchonpoland/eg_pl_026434.asp).

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## Romania

*Capital:* Bucharest  
*Population:* 21.9 Million  
*GDP:* US \$161.63 Billion  
*Currency:* Romanian Leu (RON)  
*Language:* Romanian



### Summary

Romania has one of the largest populations in the EU, with approximately 22 million. However, the fate of the medical device market will largely depend on the state's willingness to shift its attention and funding to the healthcare sector.

Healthcare in Romania is dominated by the public sector, which owns most of the hospitals and provides national health insurance to all Romanian citizens. Despite this access, the standard of healthcare in Romania is well below that found in other EU countries, due to a combination of systemic failures and chronic under-funding.

Healthcare funding in Romania is through the National Health Insurance Fund. The public healthcare system includes national health insurance, covering all Romanian citizens, as well as a growing and parallel network of private healthcare. The National Health Insurance Fund (NHIF) is funded by a combination of employer (5.2% of gross wages) and employee (5.5%) contributions, and allocations from the national budget.

The provision of healthcare is predominantly managed by the state and currently in a state of reform from a general taxation model to a social insurance system for further compliance with EU regulations and towards privatization. Government health expenditure is very low, even by Eastern European standards, on both an absolute and a per capita basis. Romania spent around 4% of GDP on healthcare in 2009. This percentage may increase to 5.4% in 2012; this would stimulate demand for medical equipment. Today, much of the growth in demand is coming from a growing network of private hospitals and clinics.

Competition in the market comes from third country suppliers as Romania produces very little in the field of medical equipment, and only basic consumables. Around 90% of the medical device market is supplied by imports, including 100% of the more complex devices. The Romanian medical equipment market is predicted to grow by up to 10% yearly until 2013, based on Romanian Association of Medical Products Suppliers (AFPM) calculations.

### Market Entry

A local presence in Romania is necessary to be successful. Most U.S. exporters in this industry enter and operate in the Romanian market by hiring a distributor, establishing an office or licensing joint venture, or – in some cases – by franchising.

U.S. exporters must comply with EU and national legislation. Further information can be found in the Romania Country Commercial Guide - 2010 accessing:

[http://www.buyusa.gov/romania/en/doing\\_business\\_in\\_romania.html](http://www.buyusa.gov/romania/en/doing_business_in_romania.html)

### Current Market Trends

In 2010, the Romanian market for medical equipment and supplies was valued at \$394 million or \$18 per capita. By 2013, the market for orthopedic equipment is likely to see the biggest growth rate, with an annual average of 14.2%. Despite the fact that local made producers are cheaper than imports, they are

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not attractive as the imported ones. Medical equipment imports have risen sharply in recent years, as the general level of private health spending increases and new diagnostic equipment has been purchased for hospital refurbishments. Diagnosis and imaging equipment accounted for 18.8% of the sales in 2008, while dental equipment accounted for 8.1%. However, imports in these areas have fallen back in 2009.

The segment of medical equipment in 2010 reached 3.8% from the total budget allocated for the health system in Romania, respectively 0.2% from the GDP.

The Romanian market for private medical services was valued at approximately 420 million Euros in 2010, a 13% increase over the previous year. The Bucharest Metropolitan Market represented about 45% of the national market.

The private medical services market is varied, including small clinics with 2 - 3 consultation rooms and large clinics with 10 - 20 consultation rooms. Specialized ambulatory healthcare is currently delivered through hospital outpatient departments, centers for diagnosis and treatment and medical specialized offices. A number of private medical services providers have been able to increase their business by providing corporate health plans through growing networks of outpatient clinics.

Public health care covers ambulatory health care, hospital care, dentistry services, medical, emergency services, complementary medical rehabilitation services, pre-, intra and post birth medical assistance, home-care nursing, drugs, health care materials, and orthopedic devices.

### **Main Competitors**

Right now, over 100 medical equipment companies are active on the Romanian market, with the most important suppliers coming from the US, Germany, Italy, France, Japan, China, and Switzerland. Among them are big names such as Roche, Johnson&Johnson, Olympus, Nihon Kohden, Philips, Siemens, Draeger, Greiner, Becton Dickinson, Beckman Coulter, Bioomerieux, Trinity Biotech and Oxoid. Annual exports of Romanian medical equipment are worth around 50 million dollars, with orthopedic equipment taking up the lion's share. U.S. suppliers generally will have to compete with European suppliers. Major European competitors are Germany, Italy and the Netherlands supplying medical devices, and together account for around 47% of imports. China is also one of the leading suppliers overall, especially active on the consumables market.

### **Current Demand**

The best prospects for U.S. suppliers are in diagnostic equipment, monitoring solutions, ventilation, high-tech surgical devices, oncology and nuclear medicine, and cardiovascular surgical devices. Romanian Health Authorities announced as priority the development and modernization of Intensive Care Units and Oncology. Also, there is still the need to improve maternity and newborn care.

Some of the best opportunities for American firms lie with the private medical clinics and services. These facilities have experienced steady growth despite the recession and are investing aggressively in new equipment.

### **Barriers**

For information on existing trade barriers, please see the National Trade Estimate Report on Foreign Trade Barriers, published by USTR and available through the following website: [http://www.ustr.gov/Document\\_Library/Reports\\_Publications/2007/2007\\_NTE\\_Report/Section\\_Index.html](http://www.ustr.gov/Document_Library/Reports_Publications/2007/2007_NTE_Report/Section_Index.html)

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## Trade Events

**Name of event:** ROMMEDICA - UFI approved event

**Date:** 25 April 2010 - 28 April 2012

**Website:** [www.rommedica.ro](http://www.rommedica.ro)

**Description:** An International exhibition of medical equipment and instruments - 20th edition  
ROMPHARMA - international exhibition of medicines for human and veterinary applications - 20th edition  
ROMOPTIK - international exhibition for optical equipment and apparatus - 16th edition

**Name of event:** DENTA - SPRING EDITION

**Date:** 14 April 2012 - 17 April 2012

**Website:** [www.denta.ro](http://www.denta.ro)

**Description:** An International exhibition of equipment, instruments, accessories, materials, chemical-pharmaceutical products for dentistry, and oral care products -23rd edition.

**Name of event:** DENTA - AUTUMN EDITION

**Date:** 16 November 2011 - 19 November 2011

**Website:** [www.denta.ro](http://www.denta.ro)

**Description:** An International exhibition of equipment, instruments, accessories, materials, chemical-pharmaceutical products for dentistry; oral care products - 24th edition.

## Available Market Research

- Ministry of Health, Government of Romania, <http://www.ms.ro>
- Espicom Business Intelligence, [https://www.espicom.com/prodcat.nsf/Product\\_ID\\_Lookup/00000576?OpenDocument](https://www.espicom.com/prodcat.nsf/Product_ID_Lookup/00000576?OpenDocument)
- CBI Market Survey, <http://www.cbi.eu/marketinfo/cbi/?action=showDetails&id=4427>
- Medlife, <http://www.medlife.ro/>
- Euroclinic, <http://www.spitaluleuroclinic.ro/>
- Centrul Medical Unirea, <http://cmu.ro/en/>

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## Slovak Republic

<i>Capital:</i>	Bratislava
<i>Population:</i>	5.4 Million
<i>GDP:</i>	US \$86 Million
<i>Currency:</i>	Euro
<i>Language:</i>	Slovak



### Summary

The healthcare system in Slovakia is currently undergoing a profound transformation under the leadership of a new coalition government. In terms of the business environment for the pharmaceutical industry, Slovakia ranks very favorably when compared to other Central and Eastern European countries. The strong position in pharmaceuticals is boosted by relatively strong “risk scores,” which take into account the regulatory environment and the economic and political climate. Slovakia is seen as generally complying with international requirements for approvals as well as intellectual property (IP) protection. The country has a tradition of medical device manufacturing, but it is increasingly difficult for domestic production to compete with Western imports. The alignment of older domestic regulations with broader E.U. legislation is a positive step towards a higher degree of transparency in the pharmaceutical and medical device industries. Such developments make the Slovak market increasingly attractive for U.S. suppliers.

### Market Entry

Slovakia is one of the more developed health device and pharmaceutical markets in the Central and Eastern European region. Slovakia remains one of the most attractive of the 18 markets surveyed in Central and Eastern Europe, with per capita drug expenditures estimated at \$74.2 in 2008.

Looking at Slovakia’s wider economic and business environment, one of the key recent changes was the adoption of the euro as Slovakia’s currency as of January 1, 2009. For Slovakia, Euro zone membership has made trade with Slovakia easier by providing more transparent pricing and greater currency stability. Slovakia has also been successful in keeping inflation low and boosting domestic productivity and competitiveness, benefiting not only domestic producers but also foreign companies, which can take advantage of more transparent trading regulations. A foreign producer that would like to import medical devices into Slovakia must first establish a contract with a local importer, who can help the company fulfill regulations such as the CE mark, Declaration of Conformity, translation of directions and manuals into Slovak, and a guarantee that the product has been approved by the Ministry of Health. Medical devices and pharmaceuticals are also subject to a customs duty and value added tax (VAT) of 20%. Some products carry a 10% VAT.

### Current Market Trends

In 2008, the Slovak market for medical equipment and supplies was estimated at \$402 million, or \$74.2 per capita. In per capita terms, Slovakia’s market size is similar to Slovenia and Hungary.

Slovakia continues to implement a new e-Health system, which is part of a project aimed at introducing information technology into healthcare, including e-records and e-prescriptions. In general, e-Health services are still developing in Slovakia and thus there is a significant potential for growth in both supply and demand.

Slovakia has also been one of the more proactive European Union members in addressing the complexities associated with patients receiving treatment outside their home countries. Slovakia is now participating in the launch of Smart Open Services for European Patients (epSOS), a large-scale pilot

project aimed to improve interoperability between e-Health systems across Europe. The key objectives behind the system will be to allow a doctor to make an informed decision when choosing a pharmacological intervention based on both the patient's history and the relevant availability of pharmaceuticals. In addition, the system should be able to feed the information back to a patient's home country for updating their records and electronic reimbursement.

The healthcare sector's current debt is \$399 million, out of which 74% has been generated by state-owned hospitals. Hospitals are undergoing an extensive right-sizing program under which departments and bed numbers are being cut. Even so, Slovak hospitals are relatively under-equipped and there is a great demand for new medical technologies. Within the next four years, the private health care sector is expected to grow at a higher pace due to the government's revised legislation on restricting competition among private hospitals and health insurers. Private health insurers are again entitled to use generated profit independently if two conditions are met: (1) health insurance companies will create a reserve fund of up to 20% of the paid-up share capital and (2) technical reserves for paying for planned procedures of policy holders on waiting lists must be created. Privatization of healthcare facilities through public and international tenders could occur in the long-term future.

## Main Competitors

Slovakia's medical device manufacturing sector is skilled, yet it still remains small. Local producers focus a large part of their resources on export markets such as the Czech Republic. Thus, most of the Slovak medical device market is dominated by imports mainly from the U.S. and European Union countries. Germany and the U.S. are statistically the leading suppliers, accounting for almost 50% of all imports.

Since Zentiva Group was formed from the merger of the biggest Slovak pharmaceutical company Slovakofarma Hlohovec and other pharmaceutical companies in Europe in 2003, it has been the leading pharmaceutical company in the Slovak market. In general, the Slovak over-the-counter (OTC) pharmaceutical market is shared among well-known multinational players such as Zentiva, Walmark, GlaxoSmithKline and many others.

## Current Demand

Slovakia has excellent market opportunities in the fields of sophisticated health technologies and equipment, dental care equipment and many other devices that increase efficiency and reduce occupancy rates in hospitals. The following specific items were the leading exports from the U.S. to Slovakia covered by this "leading sector," ranked by U.S. dollars from January – September 2010:

ITEM	YTD(SEP) 2009	YTD(SEP) 2010
9018--medical; surgical; dental or veterinary instruments	2,540,719	5,221,902
9031--machines in chapter 90; profile project	2,389,116	4,401,914
9013--liquid crystal devices, lasers	176,630	2,410,779
9027—instruments for physical and anal microtome	1,384,421	2,348,982
9021--orthopedic appliances; artificial body parts; hear aid	2,355,749	2,108,468
9022--x-ray apparatus; tubes; panels; screen	697,382	1,956,779
9030--oscilloscopes; spectrum analyzers	870,602	1,350,621
9026—instruments for measure or check flow or level	634,589	1,038,805
9019—mechanical thermo massage, ozone apparatus	114,447	340,730
9023—instruments & apparatus for demonstrational use & parts	375,415	264,733
9032--automatic regulating or control instruments and parts	77,803	227,237

9001--optical fibers & bund sheets	171,021	194,213
9024--machines for testing of mechanical prop of material	100,899	181,266
9029--revolution & production count taximeters	106,799	168,280

## Barriers

Debt remains a key concern in the Slovak health system. State-run hospitals registered a debt of million Euros (US \$299 million) at the end of 2010. The cabinet has approved a debt settlement plan of about 200 million Euros. Debts were paid with refundable financial aid and a 15 year repayment plan.

Medical device or pharmaceuticals importers may sometimes have problems in obtaining approval to be placed on insurance reimbursement lists – something that is also a challenge in other Central and Eastern European countries. If a product is not included on the reimbursement scheme paid by insurance companies, the market for the product is limited.

## Trade Events

**Name of event:** SLOVMEDICA

**Date:** September 22-24, 2011

**Location:** Incheba Expo Bratislava

**Website:** [http://www.incheba.sk/exhibitions/Slovmedica\\_2011/3022?lang=en](http://www.incheba.sk/exhibitions/Slovmedica_2011/3022?lang=en)

**Description:** SLOVMEDICA presents an opportunity for experts active in the field of medicine, working in hospitals, nursing homes, as well as expert health education and science to meet with representatives of companies providing products and services in a wide range of healthcare fields. The exhibition resents the latest medical techniques, technologies and equipment. SLOVMEDICA is the most important event of its kind in Slovakia and will be taking place alongside two other prominent health care exhibitions: NON HANDICAP and SLOVAK DENTAL DAYS.

**Name of event:** NON HANDICAP

**Location:** Incheba Expo Bratislava

**Date:** September 22-24, 2011

**Website:** [http://www.incheba.sk/exhibitions/Slovmedica\\_2011/3022](http://www.incheba.sk/exhibitions/Slovmedica_2011/3022)

**Description:** The 9<sup>th</sup> annual specialized exhibition for handicapped people, NON HANDICAP, will host exhibitors promoting equipment and medical aids for the disabled.

**Name of event:** SLOVAK DENTAL DAYS

**Location:** Incheba Expo Bratislava

**Date:** September 22<sup>nd</sup>-24<sup>th</sup>, 2011

**Website:** [http://www.incheba.sk/exhibitions/Exhibition\\_SDD\\_2011/3021?lang=en](http://www.incheba.sk/exhibitions/Exhibition_SDD_2011/3021?lang=en)

**Description:** Incheba Expo Bratislava will host an annual specialized exhibition of dental instruments, tools and materials under the banner of the SLOVAK DENTAL DAYS. The exhibition is supported by the Slovak Chamber of Dentists and Association of Dental Producers and Sellers. Throughout its existence, Slovak Dental Days exhibition has established a significant position in the calendar of dental exhibitions in Slovakia and given its size, side events and number of exhibitors, it remains a very attractive event for dental suppliers.

## Available Market Research

Dental Equipment and Services (2009)

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## Spain

*Capital:* Madrid  
*Population:* 46.9 Million  
*GDP:* US \$1.5 Trillion  
*Currency:* Euro  
*Language:* Spanish



### Summary

According to the latest OECD statistics, Spanish healthcare spending in 2009 was 9.5% of GDP, in comparison with 10.9% in Belgium, 11.5% Denmark, 11.8% in France, 11.6% in Germany, 9.5% in Italy and 9.8% in the U.K.

The total healthcare technology equipment market for 2010 is estimated at over USD 10 billion. Diagnostics, orthopedics and disposable items account for 70% of the market. Spain has a comprehensive public health system. The public sector accounts for approximately 85-90 percent of the sector's activity, while the private sector accounts for the remainder.

The sector depends heavily on imports. Imports for 2010 are reported at USD 5.7 billion, According to the Spanish Ministry of Trade, the U.S. import share is estimated at \$1 billion. The United States and Germany are two of the main suppliers.

Healthcare technology and equipment exports are estimated to be in the \$2 billion range, with exports to the U.S. estimated at approximately \$266 million. The European Union accounts for almost 70 percent of all exports.

Given the current economic situation, greater emphasis is being placed on cost-effective products and equipment to help reduce healthcare costs.

### Market Entry

All medical products/equipment imported into Spain need to have the CE Mark. The exporter also needs to notify the Ministry of Health. Importers of medical products require an authorization issued by the Ministry of Health. As a consequence of the requirement that medical products need the CE Mark, many U.S. companies have been centralizing their import operations into one single country from which they register and distribute their products to the rest of the EU.

The official approach to vitamins and health supplements in Spain is quite different to that of the United States. Many vitamins and supplements commonly found in the U.S. health food stores are still considered by the Spanish Ministry of Health as prescription medicine and may need to be approved as such. U.S. companies interested in the Spanish market need to provide the Spanish Ministry of Health with technical data on the product's composition and need to meet the labeling requirements. The approval of products considered drugs can be lengthy.

Most purchases (85-90 percent) are made through hospital public tenders from companies that are pre-selected for the public tender's opening bids. That is the main reason why having a qualified importer/distributor with access to the purchase's decision makers is so important for U.S. SME's. All importers/distributors of medical equipment and products into Spain need to be resident in the EU and registered with the Spanish Ministry of Health.

The import of refurbished medical equipment into Spain is technically permitted, but both public and private medical providers in Spain have traditionally preferred new equipment. Refurbished equipment also requires a current CE mark.

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U.S. products that are competitive in price or innovative in the U.S. market have a better chance of success in Spain. There is zero duty on medical devices.

### Current Market Trends

U.S. medical equipment is highly regarded by Spanish doctors, domestic importers, and distributors. However, current budgetary concerns and the ongoing need to cutback public spending are severely limiting current procurement and growth. The last few years have seen a significant shift in sourcing. More and more items are being imported from Asia. The explanation given by sector contacts is that the Public Health System, as the principal end-user of imports, goes for the cheaper products, particularly disposables, in an effort to restrain expenditures. The current economic situation is having a strong impact on decision-makers in the private sector also. However, when it comes to more complex and sophisticated items, quality continues to be a decisive factor in the purchasing decision.

Patients are also becoming more demanding. There is room for more modern and sophisticated equipment. Furthermore, life expectancy continues to improve. A growing ageing population will generate greater demand for products directly connected with geriatric ailments and illnesses.

### Main Competitors

The United States and Germany are the two main suppliers, with France, the U.K., Italy and Switzerland following. However, France, the U.K. and Holland are also used as storage and redistribution centers for U.S. companies. Imports from Asia are on the rise.

Many suppliers in the Spanish industry are subsidiaries of overseas corporations, including leading U.S. firms. These well-established firms often represent serious competition for companies trying to break into the market.

### Current Demand

Both the public and private sectors provide healthcare in Spain. The public system accounts for 85 - 90 percent of total healthcare expenditure. The private sector covers the rest.

Because of the current economic situation, demand for products has decreased and cost-efficiency has become a determining factor in many cases. The problem of late payments has also been aggravated. The volume and pricing of healthcare /pharmaceutical products is influenced by official healthcare policies.

### Trade Events

**Name of event:** ORPROTEC

**Dates:** October 20 – 22, 2011

**Location:** Valencia

**Description:** Rehabilitation and Personal Autonomy

**Website:** <http://feria.feriavalencia.com/ferias/index?&&&>

**Name of event:** Feria Tecnológica

**Dates:** October 26, 2011

**Location:** Málaga

**Description:** Multi-sector technological fair focused on connecting R&D centers with market players. Coincides with MIT's Technology Review magazine's emerging technologies conference, EmTech.

**Website:** [www.enfedit.com](http://www.enfedit.com)

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**Name of event:** EmTech SPAIN

**Dates:** October 26-27, 2011

**Location:** Málaga

**Description:** MIT's Technology Review magazine hosts its Emerging Technologies conference in Europe for the first time. EmTech Spain is a multi-sector event that aims to bring together business leaders, senior technologists, investors, and innovative entrepreneurs. Sectors include nanotech, biotech, and robotics.

**Website:** <http://www.emtechspain.com/en/>

**Name of event:** EXPOOPTICA

**Dates:** February 17-19, 2012

**Location:** Madrid

**Description:** Ophthalmology

**Website:** <http://www.ifema.es/web/ferias/expooptica/default.html>

**Name of event:** EXPODENTAL

**Dates:** February 23-25, 2012

**Location:** Madrid

**Description:** DentasI

**Website:** <http://www.ifema.es/web/ferias/expodental/default.html>

**Name of event:** BIOSPAIN

**Dates:** 2012

**Location:** Palma de Mallorca

**Description:** Biotechnology

**Website:** [www.asebio.com](http://www.asebio.com)

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## Sweden

*Capital:* Stockholm  
*Population:* 9.4 Million  
*GDP:* US \$406 Billion  
*Currency:* Swedish Krona  
*Language:* Swedish



### Summary

Sweden's health system is one of the best and most well developed in the world. The population of just over 9 million enjoys very good health. Sweden invests about 9 per cent of its GDP in health and medical services, a figure that has been fairly stable since the early 1980s. The infant mortality rate is less than 2.8 deaths per 1,000 in the first year of life and the average life expectancy is 78 years for men and 83 years for women. As Sweden has a population that is one of the oldest in the world, more than 5 percent are 80 years or older, there will be increasing demand for medical equipment and supplies, and longer medical treatments, to meet the health needs of an ageing population.

There are about 33,000 doctors in Sweden, one for every 277 inhabitant. Outpatient care is organized into primary care districts, each with 5,000 to 50,000 inhabitants.

### Market Entry

Sweden's customs laws and regulations follow those of the EU. This means that Sweden applies external EU tariffs to imports from the U.S. and other non-EU countries. Goods imported to Sweden are also subject to a value-added-tax (VAT) of 25%. Marking and labeling requirement must follow EU standards, and all instruction manuals must be translated into Swedish. Sweden uses the metric system. Products sold in Sweden should be adapted for use with the metric system whenever possible. Electric current in Sweden is 50 Hz, AC 230V single-phase and 230/240V three-phase.

In Sweden three political and administrative bodies control health care for the country: the central government, the county councils and the municipalities. The 21 county councils have the responsibility to provide health and medical services and to work for a good standard of health among the population. The county councils decide on the allocation of the resources to the health services and are responsible for the overall planning of the services offered. It is also the county councils that own and run the hospitals, health centers and other institutions. The 290 municipalities are responsible for the nursing homes, care of the elderly and the disabled. Private health care, accounting for some ten percent of total health care costs, mainly offers primary care like running health care centers or homes for the elderly. There are a few hospitals that are managed by private entrepreneurs.

U.S. firms interested in entering the Swedish market will find that the market is highly competitive and are therefore recommended to establish a local presence, either through local agents and distributors or sales subsidiaries.

### Current Market Trends

The two main factors that are expected to have strong effects on the future Swedish health care system are:

- An aging population, which is likely to lead to increased demand for health care products as well as health care related services such as equipment and supplies for the home health care sector.
- Life style related diseases (diabetes, overweight, etc).

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Of the predominant diseases the main causes of death are cancer and cardiovascular conditions including strokes.

## Main Competitors

There are an estimated 480 medical device companies active in Sweden – out of this number some 180 companies are manufacturing in Sweden. .

U.S. suppliers dominate the import market and enjoy a good reputation. Major third-country competitors include Germany, Netherlands and Denmark. Domestic production is strong and the medical device sector is one of the leading export sectors in Sweden. Some of the internationally known Swedish medtech companies include Gambro (dialysis equipment, blood component products), Getinge (Medical Systems, Extended Care and Infection Control), Molnlycke Healthcare (single- use surgical and wound care) and Elekta (the Leksell Gamma Knife), Major Swedish dental equipment manufacturers include AstraTech (implants), Nobel Biocare (dental implants), and TePe (oral health products).

## Current Demand

Although the health care market operates under cost-containment regulations, there is an eagerness to be at the forefront of technological developments. The market looks to the U.S. for developments in research and application of the newest medical technology. U.S. firms will find that the market is quite receptive to high-quality equipment that offers both ease of use and cost efficiency. Future demand are expected in the following areas: Telemedicine, Medical informatics, Non-invasive surgical equipment, Orthopedic and prosthetic equipment and Home health care - equipment and supplies

## Barriers

Companies exporting to Sweden will not encounter any trade barriers or quotas. Further, there are no restrictions or barriers on the movement of capital, foreign exchange earnings or dividends.

## Trade Events

**Name of event:** Apoteksmassan (pharmacy)

**Location:** Stockholm, September 7-8, 2011

**Website:** [www.apoteksmassan.se](http://www.apoteksmassan.se)

**Name of event:** Health, Wellness & Fitness

**Location:** Stockholm, November 10-13, 2011

**Website:** [www.alltforhalsan.se](http://www.alltforhalsan.se)

**Name of event:** Swedental

**Location:** Stockholm, November 17-19, 2011

**Website:** [www.swedental.org](http://www.swedental.org)

**Name of event:** Riksstamman

**Location:** Stockholm, November 30 – December 2, 2011

**Website:** [www.sls.se/riksstamman](http://www.sls.se/riksstamman)

**Description:** Annual General Meeting of the Swedish Society of Medicine

**Name of event:** Vitalis (telemed, e-health)

**Location:** Goteborg, April 17-19, 2012

**Website:** [www.vitalis.nu](http://www.vitalis.nu)

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## Available Market Research

Telemedicine  
Medical Equipment

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## Switzerland

*Capital:* Bern  
*Population:* 7.9 Million  
*GDP:* US \$327 Billion  
*Currency:* Swiss Franc  
*Language:* German, French, Italian, Rhaeto-Romanic



### Summary

The Swiss market for medical equipment and devices is strong and dynamic. Based on the growth in Switzerland's aging population combined with new technologies and surgical procedures offering faster recovery for patients, the projected annual growth is estimated between 3%-6% over the next few years. In 2009 total import of medical equipment and devices, valued at USD 2.6 billion accounted for about 80% of the total market.

### Market Entry

Hospitals, clinics, cantonal health departments, and MD's buy directly. There is no central procurement agency. U.S. firms can best sell in Switzerland through a qualified importer and distributor who can also offer after-sales service. Swiss medical importers and distributors are experienced and know how to reach out to the numerous market segments and the end-user trade.

### Current Market Trends

With cost-savings pressure on the Swiss healthcare system, a growing trend is a decrease in the length of hospital stays. Monitoring of outpatients will therefore become more important, and there will be an increased demand for technologies that decrease hospitalization times and for new innovative products that help quicken recovery and rehabilitation. IT also plays a leading role in medical technology and is one of the sectors with highest growth rates. The infrastructure and expertise required for telemedicine are correspondingly well distributed, creating ideal conditions for the future expansion of telemedicine.

### Main Competitors

With an import market share of 34.6% in 2009, the U.S. is the largest foreign supplier followed by Germany with 30.7%, Netherlands with 12.3%, Italy 4.2% and France with 3.4%.

The Swiss medtech sector comprises of around 700 firms that are wholly or partly focused on medical technology. Of these, 300 manufacture their own products – either under their own brand or as an OEM. Many US-based and other international corporations have chosen Switzerland for their European headquarters. While coordinating international activities from their Swiss base, many notable firms also produce complex instruments and devices in Switzerland in knowledge-intensive processes.

### Current Demand

According to experts therapy systems, implants and prosthetics are the fastest growing subsectors. Further market trends are miniaturizing and digital techniques. The average Swiss expects that hospitals will have the latest technology; therefore, U.S.-made products that are on the cutting-edge of technology will have great market potential. Furthermore, there is a growing recognition in the medical community that new innovative technologies often contribute to more economical patient care by helping to reduce the length of hospital stays.

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## Barriers

The Swiss import climate is favorable to imports of medical equipment and devices with no major roadblocks. Switzerland has aligned its regulatory requirements, over a period of years, to those of the European Union. The 1972 Free Trade Agreement between Switzerland and the European Community eliminated customs duties and other trade restrictions for industrial and agricultural products. Free trade is, therefore, possible for about 90% of the goods of Swiss and EU origin. This free trade is also applicable to the European Free Trade Association (EFTA), of which Switzerland is a member.

Products from the U.S. falling under HS Codes 9018.20, 9018.50, 9019.10, 9019.20, 9021.10, 9021.40, 9021.50, and 9021.90 are duty free. There is levied a customs duty on U.S. exported products not benefitting from the European Free trade Agreement under HS Codes 9020.00, 9022.3010, 9022.3090, 9022.9010, 9022.9020, 9022.9030, 9022.9090, which varies between USD 13-369 per 100 kg gross weight. Moreover, a Value-Added Tax (VAT) of 7.6% is assessed.

## Trade Events

**Name of event:** Dental 2012 (June 14-16, 2012)

**Location:** Bern, Switzerland

**Website:** <http://www.dental2012.ch>

**Description:** Biannual trade fair for dental equipment and supplies

**Name of event:** eHealthCare.ch (September 21-22, 2011)

**Location:** Nottwil, Switzerland

**Website:** <http://www.ehealthcare.ch>

**Description:** Annual congress and trade fair covering e-healthcare

**Name of event:** IFAS (October 23-26, 2012)

**Location:** Zurich, Switzerland

**Website:** <http://www.ifas-messe.ch>

**Description:** Biannual trade fair for medical and hospital equipment and supplies

**Name of event:** ILMAC (September 24-27, 2013)

**Location:** Basel, Switzerland

**Website:** <http://www.ilmac.ch>

**Description:** Triennial U.S. Department of Commerce certified industrial exhibition and conference for research and development, environmental and process technology in pharmaceuticals, chemicals and biotechnology

**Name of event:** MipTec (September 20-22, 2011)

**Location:** Basel, Switzerland

**Website:** <http://www.miptec.com>

**Description:** Annual U.S. Department of Commerce certified leading European convention and trade fair for drug discovery

**Name of event:** Swiss NanoConvention (May 23-24, 2012)

**Location:** Lausanne, Switzerland

**Website:** <http://www.swiss-nanoconvention.ch>

**Description:** Annual trade show and conference covering nanosciences and relevant equipment and services

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## Available Market Research

Dental Market (March 2007)

Laboratory Equipment & Scientific Instruments (November 2007)

Medical Equipment and Devices (October 2008)

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## Ukraine

*Capital:* Kyiv  
*Population:* 45.76 Million  
*GDP:* US \$136.84 Billion  
*Currency:* Hryvnya  
*Language:* Ukrainian



### Summary

There is no accurate statistics for Ukrainian medical equipment market. In 2010, the Ukrainian market for medical equipment and supplies is estimated at \$ 509 million. This is around 35% lower than in 2008, reflecting the country's significant reduce in ability to import equipment. Growth from this low point is expected to be about 7% per year. Imported equipment dominates with leading suppliers including Germany, Japan, China and USA. Medical equipment traders are prime contacts for U.S. businesses entering the Ukrainian market, due to their extensive networks and ability to identify buyers.

The Ukrainian market is receptive to advanced medical equipment offering ease of use and cost savings. Receptivity to used medical equipment is average – on the one hand, there is a demand from end-users, but on the other hand, used equipment cannot be purchased through government tenders. However, a potential market for used medical equipment exists, with a preferred approach to allocating buyers (private hospitals and clinics), rather than distributors.

### Market Entry

U.S. companies entering the Ukrainian market should approach with a long-term perspective. Business in Ukraine is often based on relationships, so selecting a good local partner and/or establishing a local office are crucial to long-term success. To find a potential partner, we recommend the U.S. Embassy's Commercial Service's International Partner Search and Gold Key programs to conduct initial screening. (For more details please refer to <http://www.buyusa.gov/ukraine/en/8.html>) U.S. companies should use appropriate due diligence in selection of partners and should be mindful of the parameters of the Foreign Corrupt Practices Act.

Kyiv is not the only hub of trade in Ukraine. Look for distributors that have nationwide capabilities, including those located in the cities of Dnipropetrovsk, Donetsk, Lviv, Odessa, Zaporizhzhya, and Kharkiv. These regions are considered important industrial centers of Ukraine and are densely populated. Covering the Ukrainian market from regional offices in Poland or Russia is not effective. On-the-ground presence is crucial to business development here.

Joining the American Chamber of Commerce and obtaining experienced legal and accounting support are other basic steps.

While many U.S. firms have experienced marked success here, Ukraine is not a market for the first-time exporter. Companies doing business here must develop a tolerance for uncertainty, and the persistence to overcome obstacles to doing business.

### Current Market Trends

Healthcare funding in Ukraine is largely through taxation and healthcare services (ambulatory and hospital) are provided predominately by the public sector. Equipment used in public hospitals is typically obsolete and worn-out. Given the financial condition of many health institutions, replacement will be slow. The number of private clinics and practitioners is reporting steady growth.

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A system of public healthcare insurance has been under discussion since at least 1996, but there has been no real action, nor a long-term policy implemented. Government health expenditure is very low, even by Eastern European standards: Ukraine spends around 7.0% of GDP on healthcare (one of the lowest levels in Europe). Due to a lack of funding, patients are usually forced to make under-the-table payments.

The Ukrainian market is open to advanced medical equipment, offering ease of use and cost savings. Receptivity to used medical equipment is average – on the one hand, there is a demand from end-users, but on the other hand, used equipment cannot be purchased through government tenders. However, a potential market for used medical equipment exists, with a preferred approach to allocating buyers (private hospitals and clinics), rather than distributors.

### **Main Competitors**

Looking at the dynamics of foreign medical manufacturers' penetration of the Ukrainian market, it can be seen that European and Japanese firms are more aggressive than their American competitors. They were the first to establish representative offices and focus on Ukraine as a separate market.

Domestic medical equipment production is not competitive on a global scale. Ukraine has some production capacity, but firms are generally under-capitalized and unable to compete with imports.

### **Current Demand**

- Emergency medical equipment (ambulances, mobile hospitals)
- Diagnostic equipment (ultrasound, computer tomographs, magnetic-resonance tomographs)
- Operating rooms
- Telecommunication equipment for telemedicine
- Dental equipment and materials
- Laser surgery devices
- Sterilization equipment

The Ukrainian market is receptive to high-quality, advanced diagnostic and therapeutic equipment. Innovative technologies such as laser-optics in vascular surgery, urology, gastroenterology, dermatology and neurosurgery, and new diagnostic devices are becoming more popular. Modern equipment offering ease of use and cost savings is required in the fields of micro-surgery, radiology and bio-medicine.

### **Barriers**

Medical equipment and devices (both locally manufactured and imported) can be used for medical practice on the territory of Ukraine only after being recorded in the State Register of Medical Equipment and Devices of Ukraine and upon issuance of a registration certificate. Registration is performed by the State Service for Drugs and Medicinal Use Products.

According to current regulations, government tenders are to be non-discriminatory against foreign bidders, with some exceptions granted on a tender-by-tender basis. These exceptions give priority to domestic suppliers.

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## Trade Events

**Name of event:** Public Health

**Location:** Kyiv

**Website:** <http://www.publichealth.com.ua/en/>

**Description:** Public Health is the largest medical equipment (including dental, clinical laboratory and optical) and pharmaceuticals trade show in Ukraine with about 400 exhibitors. Public Health 2011 will be held in Kyiv on October 11-14, 2011, at the International Exhibition Center. The show organizer for Public Health is Premier Expo, a part of the International Trade Exhibitions Group, UK.

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## United Kingdom (UK)

<i>Capital:</i>	London
<i>Population:</i>	62.2 Million
<i>GDP:</i>	US \$2.3 Trillion
<i>Currency:</i>	Pound
<i>Language:</i>	British



### Summary

The UK healthcare sector was worth \$279 billion in 2010. The sector is split between the public healthcare system (National Health Service (NHS)), which was valued at \$234 billion in 2009, and private healthcare (\$45 billion). The NHS provides, essentially, free treatment at the point of delivery, while the private segment is mainly funded through private medical insurance. Despite cuts to the public sector, healthcare spending is expected to remain steady.

The country's medical equipment market was valued at \$9.58 billion in 2010. It is the world's sixth largest and Europe's fourth largest. The market is expected to grow by around 4.5% in 2011. The U.S. is the most important overseas source of medical equipment in the UK, accounting for 22% of the market.

The UK's pharmaceutical sector was worth an estimated \$28 billion in 2010. The Pharmaceutical Price Regulation Scheme (PPRS) limits the profits companies are allowed to make on their sales to the NHS. There are plans to introduce more value-based pricing and grant access to all cancer drugs regardless of cost. The country's aging population will continue to create demand for drugs used to treat conditions such as Alzheimer's and cancer.

### Market Entry

The NHS is comprised of around 485 regional trusts that have the choice of purchasing through NHS Supply Chain ([www.supplychain.nhs.uk](http://www.supplychain.nhs.uk)), which maintains a product catalog of "approved" medical products and services. Trusts may also procure individually, or pool resources with each other for procurement decisions. There is very little opportunity to sell directly to the NHS from overseas. It is therefore advisable for U.S. exporters to form distribution partnerships with well-established UK companies. This enables new entrants to take advantage of their partner's market expertise as well as their access to buyers and other decision makers within the NHS.

### Current Market Trends

In common with many developed countries, the UK's population is aging. This is causing an increase in age-related health problems and demand for social care. One way the NHS is seeking to address this is through the use of assistive technology, such as telecare and telehealth products, which enables patients to self monitor their health and maintain independence. The growing use of home technology is part of a general trend towards a shift in healthcare from hospitals to community services. There continues to be a focus on preventative care, in areas such as oral health and diet/lifestyle, to address conditions such as diabetes and obesity, especially in regions where members of the population are more susceptible to specific dental or health problems. Opportunities exist in the following segments:

- The dental market where the private sector should continue to benefit from the shift of patients from the public sector to private providers. This is because the NHS limits the treatments it offers, while the private sector is able to offer more aesthetic and innovative treatment that patients are willing to pay for. Evidence shows that UK dentists are receptive to new dental technology and equipment.

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- The rehabilitation and orthopedic area due to government efforts to promote disabled and elderly independence.

## Main Competitors

Many of the leading U.S. medical device and pharmaceutical manufacturers have subsidiaries in the UK. They include companies such as Abbott Laboratories Ltd, Johnson & Johnson Medical Ltd, Medtronic, GE Healthcare Ltd., GlaxoSmithKline PLC, and Pfizer Ltd. The UK medical device industry is still fragmented with many small companies selling specialist equipment and devices.

## Current Demand

The Department of Health is currently committing substantial resources in treating the following diseases:

- Cancer; Alzheimer's; Parkinson's; Diabetes; Rheumatoid Arthritis; Digestive disorders; Sexually Transmitted Diseases; and Obesity.

## Barriers

U.S. companies should not encounter any political or trade barriers to market entry. The UK adheres to EU procurement rules and conducts most buying through commercial negotiation. That said, the NHS faces considerable financial pressure and so will often make purchasing decisions based on price alone, rather than factoring in quality or patient outcomes. The Medicines and Healthcare Products Regulatory Agency (MHRA), an agency of the Department of Health, governs the regulation of medicines and devices. Medical devices and medicines require an appropriate CE mark or marketing license, respectively, to be sold and marketed in the UK. U.S. suppliers must ensure that they familiarize themselves with the relevant regulations and comply with them. For additional information please refer to: [www.mhra.gov.uk](http://www.mhra.gov.uk)

Another hurdle that companies can face is the UK National Institute of Health and Clinical Excellence (NICE), which judges the clinical and cost-effectiveness of new and existing drugs, treatments, and medical devices. It provides the NHS with guidance on treatment strategy and influences procurement decisions by stating which products are reimbursable on the NHS.

## Trade Events

**Name of event:** Primary Care Live & Naidex October 19-20, 2011

**Location:** London, UK

**Website:** [www.primarycarelive.com](http://www.primarycarelive.com) & [www.naidex.co.uk](http://www.naidex.co.uk)

**Name of event:** Medical Device Technology Exhibition (MEDTEC): May 23-24, 2012

**Website:** [www.medtecshowuk.co.uk](http://www.medtecshowuk.co.uk)

**Location:** Birmingham, UK

**Name of event:** Healthcare Innovation Expo: 2012

**Location:** TBD

**Website:** <http://www.healthcareinnovationexpo.com>

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## Argentina

*Capital:* Buenos Aires  
*Population:* 41 Million  
*GDP:* US \$306.7 Billion  
*Currency:* Peso (ARS)  
*Language:* Spanish



### Summary

Overall healthcare expenditures in Argentina has traditionally accounted for approximately 7-10 percent of GDP, one of the largest in the region. Imports in the overall medical product sector have been traditionally estimated to account for around 70-75 percent of the total market. The United States continues to lead the Argentine import market of medical products and equipment, and currently holds 28 percent market share, particularly in higher-end technology products. Imports from the U.S. have grown almost 14 percent in 2010 versus 2009 figures. The rising trend of imports from the United States that started with peak growth in 2005 is expected to continue at a moderate rate during 2011 and beyond.

### Market Entry

Imports of medical products must be performed by an importer registered with the ANMAT (the Argentine equivalent to the FDA) as a frequent importer of medical equipment. Imported products appear under the name of the local registered importer who will be responsible for the products and the registration process as a representative of the U.S. company. Requirements vary according to product classification.

The Mercosur common external tariff (CET) applies to imports from countries outside the MERCOSUR area, (Argentina, Brazil, Uruguay and Paraguay). The CET currently ranges from zero to 16 percent for medical products plus 0.5% in statistics fee. However, legislation in force until end of 2011 exempts imports from non-Mercosur countries from tax and duties on some critical new medical and lab equipment, instruments, disposables, implants, diagnostic reagents and pharmaceuticals, that cannot be supplied by Argentine manufacturers. In addition, under the Capital Goods Law, a zero percent import duty for capital goods produced in non-Mercosur countries will remain in effect until December 31, 2012.

### Current Market Trends

The market has been growing in the past five years, with a slight decrease in 2010. Imports of medical equipment, devices and instruments are projected to account for approximately \$600 million in 2011, with the United States comprising \$172 million of this segment. Imports dominate the high complexity technology market. Given their high unit cost, they have a more concentrated demand.

Measures such as import duty exemptions to alleviate cost burdens on importers and ultimately the end-users, are resulting in a continuous flow of critical imported products. While the healthcare market has not completely recovered from the economic crisis of 2001/2002, medical products that cannot be produced locally continue to be a best prospect sector for U.S. exporters.

### Main Competitors

More than two thousand companies sell medical products and equipment in Argentina, of which 25 percent are manufacturers and 75 percent are importers. Brazil poses strong competition since imports enjoy a 0 percent import duty under Mercosur. U.S., Japanese and European-made equipment is known for its high technology and precision, whereas Argentine equipment, although durable, is generally low-tech. Domestic production has been growing, although in general, it is more limited to lower-middle range

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equipment and supplies, such as x-ray devices; and peripheral equipment, illumination systems, furniture, operating tables, ecographs and ECGs; monitors; oximeters; cobalt pumps; anesthesia equipment; sterilization equipment; basic lab equipment; instruments for arthroscopy, fixation instruments for videoendoscopy surgery wheelchairs; scales; etc

## Current Demand

Medical products that cannot be produced locally continue to be a best prospect sector for U.S. exporters. Niche opportunities for U.S. exports include middle and higher-end equipment such as imaging diagnostics echographs, CAT scans, NMR apparatus, molecular biology products, diagnostic reagents. Components and electro medical equipment parts offer a strong sales-potential, in large part because the market conditions require the reconditioning of equipment already in use, particularly in the interior provinces of Argentina.

Given that most international brand names are already in the market, local companies are eager to obtain quality products at a more competitive price.

Simpler technology is more easily financed and thus considered mass-market goods. In this competitive market the demand for these products is for the most part met, although there is still room for new players to enter into niche markets. In any case, product potential should be determined on a case-by-case basis.

## Barriers

Restrictions apply to imports of used medical equipment. Scarce financing available at the local market is an issue. However, two U.S. banks operate in Argentina to offer loans to importers of U.S. equipment using Exim Bank guarantees, which increases opportunities for sales of U.S. technology.

Some measures taken by the local government to protect local manufacturers, may present obstacles to imports of products for which there is a local competitor.

## Trade Events

**Name of event:** Expomedical 2011

**Location:** Centro Costa Salguero, Buenos Aires

**Website:** [www.expomedical.com.ar](http://www.expomedical.com.ar)

**Description:** International exhibition of medical equipment, products, and supplies. Parallel seminars.

## Available Market Research

Electro Medical Equipment (2010); Imaging Diagnostics Equipment (2010); Orthopedical Equipment and Devices (2010); Medical Equipment (2009); Clinical Laboratory Instruments and Reagents (2009)

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## Brazil

<i>Capital:</i>	Brasília
<i>Population:</i>	192 Million
<i>GDP:</i>	US \$2.013 Trillion
<i>Currency:</i>	Real
<i>Language:</i>	Portuguese



### Summary

Brazil is the largest medical equipment market in South America. It accounts for approximately U\$ 5 billion in sales. The total market for medical equipment in Brazil should continue to expand approximately 10% through 2011. Brazil is both a major medical equipment producer and importer. Imports of medical products increased 19% in the first months of 2010.

Brazilian medical equipment revenues in 2008 reached an estimated US\$ 3.96 billion, which represents an increase of 12% from the previous year. The United States accounts for approximately 30% of the import market, with U.S. sales mainly going through local agents, distributors and importers who sell to hospitals and clinics. The market for electro medicine equipment is around US\$200 million, which represents approximately 50% of total sales in Latin America.

### Market Entry

For medical products, it is necessary to have a local agent or distributor to import products from manufacturers. Because of regional economic disparities, varying states of infrastructure, and a host of other issues, it is often difficult to find one distributor that has complete national coverage. Main cities are São Paulo, Rio de Janeiro, Belo Horizonte, Brasília, Porto Alegre, Salvador, Recife and Curitiba.

Either setting up a company in Brazil or acquiring an existing entity is an investment option for Brazil. Setting up new companies is relatively complex, although the Ministry of Development has signaled a desire to simplify the process.

Companies are also joint venturing with Brazilian industries for final assembling and packaging of products. This process reduces import duties and documentations that are required for finished goods.

### Current Market Trends

Brazil's recently strengthened currency has meant that private and public hospitals have greater purchasing power, and with continued expansion of Brazil's private health care sector, the market should grow. New opportunities for US exporters abound, particularly for:

- *Clinical Chemistry, Biomedical and advanced medical devices* – high demand for new technologies;
- *Laboratory equipment* – investments in R&D, including some duties and registration exemptions;
- *Disposables and surgical* – high consume from private and public hospitals;
- *Diagnostic devices and monitoring equipment* – high demand for innovative products to replace bigger and more expensive equipment;
- *Orthopedics and Implants* – high demand of imported products, despite higher sanitary requirements;
- *Health IT* – demand in hospitals, including education and second opinion programs;
- *Dental* – Brazil has one of the highest number of dentists in the world;
- *Drugs, Pharmaceuticals and Nutrition Supplements* – high dependency on imported products. New rules to facilitate imports of supplements. High demand for modern life products.

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## Main Competitors

There are few high-quality Brazilian manufacturers of advanced medical products so Brazil's reliance on imports should continue for some time. Local buyers view US and other foreign products (mainly Canadian and European) as having comparable quality and reliability. Thus, financing terms often become the differentiating criteria in making a sale.

## Current Demand

An interesting trend in Brazil is the growing market for home health care products, which has increased dramatically in recent years. Brazil has approximately 150 home health care companies compared to approximately 1,440 in the US. In Brazil, these companies are increasingly viewed as good ways to cut hospitalization costs while offering better services for patients. Brazilian health insurance companies are responsible for paying 99% of the costs related to home care treatment, and as such, the U.S. Commercial Service sees the market for home health care products growing dramatically during the coming years. Brazil's Regional Nursing Council is currently developing procedures on how to regulate this market, including standards for health professionals.

In addition to the attractive size of the Brazilian medical market, US exporters should consider the opportunities offered by Mercosur, and use Brazil as a "spring board" for export into Argentina, Uruguay and Paraguay. Since compulsory product registration before sale is required for all of Mercosur countries, US exporters should consult a local lawyer/consultant before signing a contract with any agent/distributor.

## Barriers

Medical products in Brazil are highly regulated by Anvisa, the Brazilian counterpart of FDA. All products must be registered or be notified in order to be commercialized. For products with higher grade risk, it may be necessary to have additional local certifications, international market data and even inspections in manufacturing plants.

Import system is very complex and can add up to 100% fees over products. For a more detailed explanation of this system, weblink: [http://www.focusbrazil.org.br/ccg/PDFs/chapter5\\_traderegulations.pdf](http://www.focusbrazil.org.br/ccg/PDFs/chapter5_traderegulations.pdf)

## Trade Events

Name of event: Hospitalar – May 22-25, 2012.

Location: São Paulo

English language website: [www.hospitalar.com](http://www.hospitalar.com)

Description: This is the largest medical event in Latin America and one of the best opportunities to U.S. firms that are looking for business partnership in Brazil. Hospitalar is focused on Medical Equipment, Orthopedic Rehab, Clinical Chemistry, Dental, Pharmacy and Hospital Services.

## Available Market Research

For industry highlights, visit the weblink: <http://www.focusbrazil.org.br/siteUSA/index.htm>

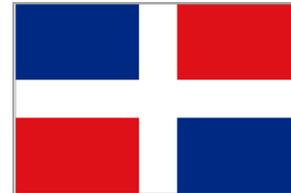
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## Dominican Republic

*Capital:* Santo Domingo  
*Population:* 10 Million  
*GDP:* US \$87.25 Billion  
*Currency:* Dominican Peso  
*Language:* Spanish



### Summary

In the Dominican Republic, the demand for medical equipment and supplies will continue to grow over the next years driven by the changes in the Dominican Social Security law, the continuous growth of the number of private-owned hospitals, and the constant need for medical products for a growing population. The Dominican market prefers U.S. sources if the prices are competitive. Among the factors that maintain and support U.S. exports of medical equipment and supplies to the Dominican Republic are: the positive reputation as manufacturers of good quality, quick delivery time, proximity with the U.S. that reduces shipping charges, and small order accommodations. Also, many Dominican physicians are trained in the U.S., thus they are comfortable with U.S. products.

### Market Entry

The market access situation is extremely favorable for U.S. products. The Central American Free Trade Agreement-Dominican Republic (CAFTA-DR) provides for duty-free entrance of medical equipment and pharmaceutical products. To succeed in the Dominican market in the healthcare sector, it is advisable to have a local distributor that can provide after-sales and leasing services, support guarantees, and maintain inventories for parts and supplies. Exporting directly to the private hospitals is extremely difficult and procurement practices in public hospitals dictate that all purchases must be done by a local company. Local importers and distributors usually have sales agents who distribute the products to small retailers throughout the country. Local distributors also conduct promotional activities to encourage doctors and nurses to use and recommend their products.

### Current Market Trends

The Dominican market for medical equipment and supplies depends on imports, which is largely dominated by the U.S. The medical equipment market has maintained a consistent demand for equipment and is expected to continue increasing due to a very competitive situation between healthcare facilities in the private sector and the Social Security healthcare facilities for the acquisition of modern technologies in machinery and equipments. The principal purchasing factors in the Dominican Republic, in order of importance are price and quality. The importance of these factors varies. When purchasing disposables such as gauze, surgical drapes, surgical catgut, and the like, price is a very important factor. But when purchasing surgical sterilizers, ophthalmic surgery instruments, breathing appliances and gas mask, etc., quality is the deciding criteria. The public sector bases most purchasing decisions on price and is very often more receptive to less expensive products even if the quality is questionable.

### Main Competitors

The Dominican market for medical equipment and supplies depends on imports, which is largely dominated by the U.S, which has 85 percent of the import market. In the Dominican Republic there is extensive production of surgical instruments and supplies. However, 95 percent of this production is exported through the Free Trade Zone (FTZ) Program. Some of the products that are manufactured at the FTZ are: wound management products (wadding, gauze, and bandages), general surgery and minimally invasive surgery Instruments, ophthalmic surgery instruments, disposables (syringes, needles,

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catheters, surgical gloves, clothing for operating rooms, and surgery sponges). There is limited manufacture of surgical supplies beyond the FTZs and this production is not sophisticated, mainly involving textile products (gauzes, bandages, and surgical drapes).

## Current Demand

### Best Prospects:

#### 1) Surgical Instruments and Disposable Supplies

Public hospitals and private clinics are by far the largest potential users of surgical instruments and supplies. For disposable surgical products such as gauze, adhesive dressings, sterile surgical catgut, sterile suture materials and sterile tissue adhesives for surgical wound closure, the primary purchaser and user is the Dominican government. For more technologically advanced surgical products, such as sterilizers, the most important purchasers are the private clinics.

#### 2) Homecare Medical

The incidence of respiratory difficulties and diabetes, the aging of the Dominican population, and the CAFTA-DR free trade agreement are the primary factors behind the industry 15 percent growth over the next three years. The market for these products is entirely supplied by imports and U.S. products enjoy a positive receptivity (65 percent of the market).

#### 3) Used/Refurbished Medical Equipment

The Dominican market offers opportunities to exporters of used and refurbished medical equipment. This market prefers used equipment that has been refurbished by the manufacturer, who can use original replacement parts and provide a limited guarantee. In addition, buyers of used equipment usually require assurances that parts and maintenance can be obtained locally. Therefore, American firms interested in this market should appoint a local distributor. The market for used devices (not refurbished) is limited to hospital furniture such as operating tables and hospital beds. There are good opportunities for these products, which do not always need to be refurbished and will generally be accepted with minor defects such as scratches and tears. The Dominican government does not impose restrictions on the importation of used/refurbished medical equipment and all imports of used equipment are treated the same as new.

#### 4) Diagnostic Equipment

Tomography equipment represents a very large percentage (approximately 69.1%) of the imports for diagnosis and imagery medical equipment, along with the corresponding supplies and spare parts.

## Barriers

There are no trade barriers. Registration of healthcare products is only required for Drugs and Medical Devices and is a straightforward process. The Dominican government institution responsible for issuing the Sanitary Registration certificates is the Department of Drugs and Pharmacies (Departamento de Drogas y Farmacias). For more information on the Sanitary Registrations American firms should visit: [www.drogasyfarmacias.gov.do](http://www.drogasyfarmacias.gov.do)

## Available Market Research

Regulations on Registration of Pharmaceutical Products  
Dominican Market for Used/Refurbished Medical Equipment

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## Ecuador

*Capital:* Quito  
*Population:* 13.9 Million  
*GDP:* US \$62.04 Billion  
*Currency:* U.S. Dollar  
*Language:* Spanish



### Summary

One of the primary goals of the Government of Ecuador is to strengthen healthcare services. In this context, the Government has increased the budget for public health and has once again declared the sector in emergency to expedite the purchase of medical equipment, instruments, and supplies. The market for medical equipment, instruments, and supplies is mainly served by imports. Domestic production is limited to basic metal furniture and basic disposable supplies. U.S. products are well regarded due to their high performance which has contributed to the U.S. being the main supplier. There are no trade restrictions; however, there are certain health certification and entry requirements.

### Market Entry

It is strongly recommended to utilize a local representative or distributor to assist with local requirements and relations. Business in Ecuador is mostly conducted through agents and distributors who will assist in promoting/retaining the product in the market. When appointing a local distributor, U.S. firms should seek counsel from an Ecuadorian law firm to ensure that their distribution agreements give them appropriate protection. It is advisable to appoint non-exclusive representatives for a limited period of time and to include an arbitration clause as a means to resolve any disputes that may arise.

The U.S. dollar is Ecuador's official currency. At the present time, typical terms of sale are either a down payment or advance cash payments. In the case of a long-standing relationship, individual payment plans and schedules are more flexible. Most distributors cover the whole country and use their own sales forces.

Imports into Ecuador require an import permit. Importers must register at the National Customs Service of Ecuador (SENAE). Medical equipment, instruments, and supplies are subject to an import duty ranging between 0 to 20 percent depending on the type. In addition, a 0.5 percent tax for the Children's Development Fund, and 12 percent value-added (IVA) tax are also required. These charges are based on the CIF value of the merchandise. Ecuador has negotiated exceptions under the Andean common tariff that allow for lower duties. U.S. firms may wish to take advantage of this circumstance to distribute their products from Ecuador to Peru, Colombia, and Venezuela.

Depending on the type of products, either price and/or quality are the key factors when making the final purchase decisions. Quality, being a synonym for safety, is the key factor in purchasing electromedical equipment. Price is a factor when purchasing by volume and when the quality of the items being purchased is the same for all brands quoted. Certain disposable items, such as surgical head caps and boots, where quality is not indispensable, are purchased by price. Surgical gloves, however, are purchased by quality. Given the financial constraints, public hospitals generally focus on price.

### Current Market Trends

Since the Government declared the medical sector in emergency, public investment has increased thereby providing opportunities for suppliers of medical equipment. The Ministry of Health is responsible for the establishment of health plans, national health strategies, and the provision of integral health services.

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Approximately 85 percent of the population has access to health care services. The public sector serves 42 percent of the population, while the private sector covers 43 percent of Ecuadorians. The budget for the public health sector is \$1.27 billion for 2010. The current administration fosters the development of social programs. Therefore, it has provided more funds to the health sector than any other government, with a goal of providing free healthcare services to the population.

### **Main Competitors**

The U.S. is the major supplier with an estimated 41 percent overall share of the market. The estimated U.S. market share for medical equipment is 47 percent, for instruments 25 percent, and for disposables 30 percent.

The main competitors are Germany (image segment and instruments), Japan (video endoscopy), Pakistan (instruments), South Korea, France, Holland, Italy (echography), Brazil, Malaysia, China, and Colombia (disposable supplies).

### **Current Demand**

Best prospects for equipment include laser apparatus for non-invasive surgery, MRIs, laser electro-surgical units, lasers for ophthalmology and urology, multi-parameter patient monitors, dental lasers, ultrasound machines, and adult and pediatric incubators and ventilators.

Best prospects for disposable medical supplies include syringes, IVs, needles, gloves, gauze, bandages, sheath contraceptives, adhesives, and catheters for heart surgery.

Best prospects for instruments include diagnostic kits, scales, and ophthalmoscopes.

### **Barriers**

There are no trade barriers as such. However, there are several import requirements, as follows:

Import of disposable medical products and certain types of equipment are subject to authorization from the Ministry of Health and require a Sanitary Registration Certificate. Current legislation allows for the mutual recognition (homologation) of sanitary registration certificates and the presentation of certificates of free sale from countries approved by the Ministry of Health, including the U.S.

Anesthetics require prior authorization from the Ministry of Health and the National Drug Council (CONSEP), while X-ray equipment and supplies require authorization from the Ministry of Electricity Undersecretary's Office for Nuclear Control, Investigation, and Application prior to importing.

INEN, the Ecuadorian Standards Institute, requires that medical supplies in packages (including sample products) bear a label in Spanish.

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## El Salvador

*Capital:* San Salvador  
*Population:* 5.7 Million  
*GDP:* US \$21.7 Billion  
*Currency:* US Dollar  
*Language:* Spanish



### Summary

The Salvadoran health sector is composed of the public sector that consists of the Ministry of Public Health and Social Assistance (MSPAS), the Salvadoran Social Security Institute (ISSS), the Salvadoran Integral Rehabilitation Institute (ISRI), Teachers Welfare, and the Military Health Service; and the private sector, that includes hospitals, clinics, and non-profit organizations.

The Solidarity Fund for Health (FOSALUD) was created by the Salvadoran Government to increase healthcare services coverage, and support urban and rural clinics and units. The Fund entered into effect in January 1, 2005, and is funded by sin taxes to alcoholic beverages, tobacco products, firearms, ammunitions, and similar products.

The Salvadoran Social Security has 11 hospitals, 32 health units, 33 community clinics, 197 corporate clinics, and 1 physician health unit. The ISSS provides coverage to workers in the private enterprises and government employees, along with their respective beneficiaries.

In the private system, hospitals and clinics are concentrated in the country's three main departments: San Salvador, Santa Ana and San Miguel.

### Market Entry

The local hospitals and clinics prefer products with high quality, competitive price, durability, maintenance, and availability of spare parts and accessories. Post-sale service is very important. Additionally, to allow operators to easily handle the equipment, operating instructions and manuals are preferable in Spanish, as well as product brochures and literature.

To enter the market, a U.S. company needs a legally appointed distributor or representative in the country. It is recommended that the U.S. company work closely with a local partner to have effective promotion strategies, and continuous presence in the market. Selling to public institutions implies participation in public bidding processes.

Ionizing radiation devices or equipment need import permit from the Ionizing Radiation Advisor and Regulatory Unit (UNRA) at the Ministry of Health.

Government tenders are posted in the procurement official website [www.comprasal.gob.sv](http://www.comprasal.gob.sv).

### Current Market Trends

The Salvadoran medical equipment market relies on imports, as local production is limited to hospital furniture. The public sector is the key primary purchaser of medical equipment and supplies through the Ministry of Health and the Salvadoran Social Security Institute. Public institutions differ from private entities as they only buy new equipment. Some private hospitals can occasionally acquire used or refurbished equipment; however, this type of equipment is preferred by small clinics and hospitals. The market is approximately 80% for new equipment and 20% for used and refurbished.

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## Main Competitors

The U.S. is the main exporter of medical products to El Salvador; competitors are products coming from Germany, Mexico, and China.

U.S. products are preferred for quality, training programs, competitive price, and geographic proximity, which facilitate the rapid shipment of spare parts.

## Current Demand

Best prospects for U.S. companies are for the following products:

- Diagnostic imaging equipment
- Cardiac monitors
- X-ray equipment
- Oxygen therapy and artificial respiratory ventilators
- Ultrasonic scanning equipment
- Magnetic resonance imaging apparatus
- Computerized Axial Tomography Scanners (CT apparatus)
- Beds, lamps
- Disposable products in general

## Barriers

The importation of medical equipment is not restricted, and no tariffs are applied except for the 13% value added tax.

## Trade Events

No local shows.

## Available Market Research

[www.export.gov](http://www.export.gov)

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## Mexico

*Capital:* Mexico, D.F.  
*Population:* 118 Million  
*GDP:* US \$1.04 Trillion  
*Currency:* Mexican peso  
*Language:* Spanish



### Summary

Mexico is a big market for all types of medical devices. Imports of medical equipment, instruments, disposable and dental products reached US \$3.5 billion in 2010.

Imports of U.S. products are duty free if they comply with the NAFTA certificate of origin. U.S. products are appreciated because of their high quality and good prices. U.S. companies should take advantage of geographical proximity to start or increase their presence in Mexico.

### Market Entry

All medical equipment and devices can be imported duty free with a NAFTA certificate of origin. Imports are subject to a 16% VAT tax over the invoice value.

About 90% of medical equipment and instruments and about 20% of medical disposable products are imported. Medical products of U.S. origin are very appreciated in Mexico because of their high quality, after sales service, and good price compared to other similar quality products. U.S. exporters of medical equipment and instruments thus have good sales opportunities in Mexico.

### Current Market Trends

Most large public and private hospitals try to have modern and very specialized medical devices. Some medium and small private hospitals with limited budgets buy used or refurbished equipment. Public hospitals by law, cannot buy used or refurbished products. In order to save resources, recently many public and private hospitals are hiring companies that offer “integral surgery services” and provide service “per event”, offering all the necessary products required to perform a surgery. In this way, hospitals avoid making large investments in materials, pharmaceuticals, and instruments, and also reduce the costs involved in keeping and controlling inventories, and maintaining instruments for specialized surgeries.

All public institutions ask suppliers to register with their organization. These institutions may award purchases under US\$3,100 directly to a selected provider. Purchases over that amount must be done through public tenders.

All private health care facilities select suppliers by requesting price quotations. Their decisions are based on the best equipment at the best price.

### Main Competitors

Most large international corporations offering medical devices have a presence in Mexico. Medium and small foreign suppliers usually sell through legally appointed distributors.

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## Current Demand

Imports supply 90% of the Mexican market for medical equipment and instruments, and 20-30% of demand for medical disposables and dental products.

In 2009, total imports in these four groups of products reached \$3.5 billion. Of these imports 57 %, or 2.0 billion dollars, were of U.S. origin. Main competitors are from Belgium, Brazil, Canada, China, France, Germany, Israel, Italy, Japan, Netherlands, South Korea and UK.

## Barriers

All medical and health care products that touch or affect the human body need to be registered with the Mexican Secretariat of Health (SSA) prior to sale or use in Mexico.

Foreign manufactures of medical devices need to have a legally appointed distributor/representative in Mexico responsible for the registration process and for the product(s) in Mexico.

To be imported into Mexico, some medical products need to comply with technical standards or NOMs (Norma Oficial Mexicana). All standards are classified based on the Harmonized System Code (HS). There are few Mexican standards for medical devices, but various agencies are preparing more standards to be issued in the near future. Updated information on NOMs and other sanitary processes can be found on the web page of the COFEPRIS, the Mexican Agency in charge of registering and approving medical devices: [www.cofepris.gob.mx](http://www.cofepris.gob.mx).

## Trade Events

There are some small medical events in Mexico open to the public. However, the most important events for companies offering technology medical devices are the academic events organized by medical academies and associations. These are focused on very specialized niche sub-sector.

## Available Market Research

Standards for Medical Equipment, May 2008.  
Import Market for Medical Instruments, May 2008.  
Mexican Health Care System, June 2008.  
Events in the Medical Sector 2009, March 2009.  
Sanitary Registration for Medical Devices 2009, August 2009.  
Labeling for Medical Devices. February 2010

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## Panama

*Capital:* Panama City  
*Population:* 3.9 Million  
*GDP:* \$20.1 Billion  
*Currency:* U.S. Dollar  
*Language:* Spanish



### Summary

Panama continues to be an excellent market for both Health Service companies and medical equipment and supplies exporters. It enjoys the highest per capita income in Central America, one of the highest economic growth rates in Latin America, and has a relatively well developed health care sector. Its hospitals are modern and most leading doctors have been trained in the U.S.

An increasing number of wealthier Panamanians travel to the United States for medical treatment. This trend will continue because the U.S. offers state of the art treatment for a wide range of diseases. Best sales prospects in Panama are hospital administration and design, health services management, medical treatment in the U.S., and consulting services in the public health area.

Foreign companies will find a friendly business environment in Panama, with no restrictions or barriers to doing business. Companies with a serious interest in maintaining a long-term presence in the Panamanian market should consider appointing a representative who understands the market, the culture, the government procurement system, and other local conditions.

### Market Entry

There are no import restrictions for health care services in Panama. No barriers exist for foreign companies providing such services. Leading doctors in Panama normally belong to professional associations in the U.S., and to local associations in their respective specialties.

Regarding medical equipment, the public sector requires certification of equipment which is issued by the Ministry of Health and the Social Security organization. The private sector has no restrictions to buy medical equipment.

### Current Market Trends

The U.S. is the prime supplier of medical equipment, supplies, and related products to Panama. It is also the main supplier of health care services. Services provided by U.S. suppliers include medical treatment in U.S. hospitals, training for Panamanian doctors in the U.S., technical training for use of U.S. equipment, and consulting services for the public sector. Estimates indicate that Panamanians spend about \$8-10 million annually on medical services in the U.S.

Panama is in an early stage to become a “medical tourism destination”. The Government has plans to implement programs to promote Panama as a medical destination for foreigners, but so far there have not been concrete actions.

### Main Competitors

Spain has recently been active in the medical services sector. In the past a number of Spanish companies have participated in bids for hospital construction and administration, and procurement of medical equipment. Due to availability of export credits from the Spanish Government, these companies

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have been able to secure a number of projects for hospital construction and to sell substantial amounts of equipment, both in Panama City and the interior.

Colombia is another competitor, especially for ophthalmologic treatment. Colombia has the potential to become a major competitor in other medical areas because it offers excellent medical facilities at reasonable prices.

French companies were involved in the past in hospital design and equipment but have not been active in the recent past.

### Current Demand

The Ministry of Health and the Caja del Seguro Social have been traditional users of imported health care services, medical equipment, and consulting services. Most of these services have been financed by multilateral development organizations.

The Caja del Seguro Social is always modernizing its services to make them more efficient and cost-effective. Affiliation with the social security system is mandatory for all Panamanian workers.

The Ministry of Health and the Caja del Seguro Social have significant investment plans to expand and modernize their services to the Panamanian population. This includes new hospitals and clinics constructions all over the country. In many cases the projects are awarded under “turn key” schemes.

### Barriers

Panama has no significant trade barriers for health products or services. Panama is considered to have one of the most open economies in the region.

### Trade Events

**Name of event:** Expocomer 2012, March 2012.

**Location:** Panama City

**Website:** [www.expocomer.com](http://www.expocomer.com)

**Description:** This is Panama’s largest trade show that covers a number of sectors, including health services and equipment.

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## Israel

<i>Capital:</i>	Jerusalem
<i>Population:</i>	7.7 million
<i>GDP</i>	US \$219 billion
<i>Currency:</i>	Shekel
<i>Language:</i>	Hebrew



### Summary

Israel's public healthcare system provides a universal healthcare coverage via 4 health management organizations and a network of hospitals and doctors. Easy market entry conditions, a favorable Shekel-Dollar exchange rate and receptiveness to buy U.S. technologies and services make Israel an ideal destination for U.S. medical exports. Key import sectors include imaging, diagnostics, hospital disposables and surgical tools/technologies.

Israel has a population of 7.7 million and a technologically advanced market economy. Israeli hospitals are modern and quickly adopt new, cost effective, technologies and medicines. According to the OECD Health Data, Israel's total health spending accounted for 7.9% of GDP in 2009. Between 2000 and 2009, health spending per capita in Israel increased, in real terms, by 1.5% per year on average. Despite the relatively low level of public health expenditure in Israel, there are more physicians per capita than in many OECD countries. In 2009, Israel had 3.4 practicing physicians per 1,000 population, above the OECD average of 3.1.

The number of acute care hospital beds in Israel is 2 per 1,000 population, lower than the OECD average of 3.5 beds per 1,000 population. As was the case for most OECD countries, the number of hospital beds per capita in Israel has fallen over time. This decline has coincided with a reduction of average length of stays in hospitals and an increase in the number of surgical procedures performed on a same-day (or ambulatory) basis.

In 2010 Israel's healthcare policy makers shifted their focus to preventive medicine. This includes public campaigns for early detection of breast and colon cancer and inclusion of standard, age-based diagnostic procedures in the universal healthcare "basket".

### Market Entry

The Israel Ministry of Health (MoH) recognizes the U.S. FDA and CE mark for local registration purposes. The licensing procedure for American-made, FDA-certified medical devices is fairly easily facilitated. U.S. companies that are interested in exporting medical devices into Israel should appoint a local representative to apply for a device registration from the MoH. The MoH recognizes FDA's standards and ECRI nomenclature for licensing purposes, as well as the FDA 510(k), Pre-Market Approval (PMA) or Investigational Device Exemption (IDE). For additional market entry guidelines please write to: [yael.torres@trade.gov](mailto:yael.torres@trade.gov)

### Current Market Trends

- Israel's healthcare market is among the most advanced in the world.
- New, cost effective, technologies and medicines are quickly adopted.
- The U.S. medical device market share is 25% and steady.
- Israel spends around 8% of total GDP on healthcare services and equipment.
- Israel is a global player in the medical field, with one of the world's most highly educated workforce and dynamic economy.

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- Israelis have strong connections to the U.S. and are very receptive to American products.
  - By exporting to Israel you will gain a stake in one of the region's most important markets.

### Main Competitors

Israel is a sophisticated and mature market. U.S. suppliers face intense European competition. U.S. companies should be ready to compete and support their local distributors through educational presentations and material. Major multinationals and large companies have established direct sales and marketing offices in Israel. Other exporters operate through local distributors. There are hundreds of medical distributors that are well established throughout the country.

### Current Demand

Israel's elderly population is growing and its life expectancy is high among OECD countries. Therefore, demand for hospital beds, nursing aids and homecare products is up. The market for medical and surgical dressings grew from \$13.6 million in 2006 to \$20 million in 2008, registering an almost 50% increase. Wound care continues to be a high priority in preventive care. In addition, a well-developed private sector health care in the areas of dental, eye laser surgery and plastic/aesthetic surgery keep up the demand for advanced medical instruments and appliances. Medical tourism is a growing niche service that helps generate additional income for the healthcare sector and supports market growth. Both private healthcare and medical tourism prompt the need and provide the funds for upgrading existing systems and purchasing new medical equipment.

Best sales prospects include minimally invasive surgical instruments and technology that are integrated with imaging capabilities, cardiology equipment, equipment and supplies for plastic surgery, dental instruments, equipment and technologies for pain management, physiotherapy, ozone & oxygen therapy, OR equipment & single use products, point of care diagnostic kits and wound management technologies. According to the OECD Health Data 2011 during the past decade, there has been rapid growth in the availability of diagnostic technologies such as computed tomography (CT) scanners and magnetic resonance imaging (MRI) units in most OECD countries.

In Israel, the number of MRIs has increased but less rapidly than in many other countries, to reach 1.9 per million population in 2009. This was well below the OECD average of 12.0. The number of CT scanners in Israel has also increased to 9.4 per million population in 2009, which is also below the OECD average of 22.1. The Israel Ministry of Industry Trade and Labor estimated that the electronic medical and cosmetic device market accounted for over \$1 billion in 2010, including from imports.

### Barriers

All tariffs on trade between the U.S. and Israel have been eliminated since 1995. Because the Israel Ministry of Health uses the FDA's standards for the purpose of issuing licenses, the licensing procedures for American-made, USFDA approved medical equipment are fairly easily facilitated.

Israel is a sophisticated and mature market. U.S. suppliers face intense European competition. U.S. companies should be ready to compete.

### Trade Events

**Name of event:** Medical Device Design & Manufacturing, October 10, 2011

**Location:** Haifa Convention Center

**Website:** <http://www.imagnet.co.il/customers/mddmi/>

**Description:** A conference and tradeshow focused on medical devices design & manufacturing.

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**Name of event:** Medax, February 2012

**Location:** Tel Aviv Fairgrounds

**Website:** [http://www.stier.co.il/english/fair\\_medax.htm](http://www.stier.co.il/english/fair_medax.htm)

**Description:** A trade show and conference, exhibiting the entire spectrum of medical devices and services, offered by local distributors and sales reps to the professional healthcare market.

**Name of event:** BioMed Israel, May 21-23, 2012

**Location:** Tel Aviv

**Website:** <http://www2.kenes.com/biomed>

**Description:** Exhibition and conference of Israel's latest biotechnology and medical innovations.

### Available Market Research

The Commercial Service at the U.S. Embassy in Israel provides customized market research and company financial reports. To request a quote please contact: [yael.torres@trade.gov](mailto:yael.torres@trade.gov)

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## Saudi Arabia

*Capital:* Riyadh  
*Population:* 28.7 Million  
*GDP:* US \$434.7 Billion  
*Currency:* Saudi Riyals  
*Language:* Arabic



### Summary

The health care sector is the largest in the Gulf region in terms of expenditures, size, activity, and potential. The aging population, and greater material wealth along with an upsurge in lifestyle diseases and favorable government policies all combine to boost the demand for healthcare services, and thus create the environment for purchases of new medical equipment and increased investments in that sector. Annual spending on health care is estimated at \$21 billion in 2011, 75 percent by the Saudi government. The government has allocated \$18.3 billion for the health and social development sectors in the 2011 budget, 12 percent more than in 2010. The funds will be used to finance the construction of 12 new hospitals and to renovate and refurbish four existing hospitals.

With an annual population growth rate of 2.5% to 3%, Saudi Arabia will require an additional average annual investment of \$587 million in hospital bed capacity to keep pace with the demand. Hospital beds are likely to grow from 60,200 in 2010 to 62,000 by the end of 2011.

The high budgetary allocation valued at \$18.3 billion will cover new health projects, expansion and growth of existing hospitals and clinics, privatization, and compulsory healthcare insurance.

### Market Entry

It is highly advisable to designate a local agent/representative to conduct business in Saudi Arabia, as well as local legal counsel when drawing up a contractual agreement in Saudi Arabia. The Shari'a courts are the courts of general jurisdiction in the Saudi judicial system. While foreign companies are allowed to have 100% equity investments in various sectors and industries, including the healthcare sector, practically speaking such firms may be at a disadvantage when competing with joint ventures that include Saudi equity, or firms that use a local representative.

Medical equipment is charged 5% customs duty; in some instances, however, imported equipment is exempted.

A new government agency, the Saudi Food & Drug Authority (SFDA), monitors and controls the import and distribution of medical devices, pharmaceuticals, and food items. For medical devices, the SFDA will usually accept, register, and authorize the marketing and sale of any device that complies with applicable provisions of the SFDA's Interim Regulations and relevant regulatory requirements applicable in one or more of the countries of the Global Harmonization Task Force (GHTF), which includes Australia, Canada, Japan, USA, and EU/EFTA.

### Current Market Trends

The public sector dominates the provision of health care services and expenditures, representing more than 75 percent of total spending and around 77 percent of bed capacity. With the implementation of a compulsory health insurance system, the private sector's contribution to the Saudi health care system has been growing faster than the government's rate of growth, especially in terms of additional bed capacity and expenditures. In 2010, the private sector accounted for 23 percent of bed capacity, with about 13,846 hospital beds, which is expected to grow to 14,191 beds in 2011.

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The Saudi pharmaceutical market is highly dependent on imported drugs: 85 percent of the market is accounted for by imports. Pharmaceutical sales are estimated to have reached \$3.2 billion in 2010, growing 10 percent annually, mainly fueled by a growing population with a growing disease burden and the introduction of compulsory health insurance.

Major diseases in Saudi Arabia include diabetes, respiratory infections, cardiovascular, and recently an increasing number of cancer patients, especially breast cancer:

- Over 50% of the population is classified as overweight
- Asthma affects 10-15% of children
- More than 22% of the population are regular smokers
- High incidence of respiratory tract hepatitis C and B
- Heart disease increasing an average 5.3% annually
- An estimated 30% of the population is diabetic

### **Main Competitors**

The Saudi market is completely dependent on imports for medical devices; while U.S. suppliers enjoy some advantages, including competitive prices, language, and exchange rate, European suppliers are aggressively gaining market share with their close proximity to the market and perceived better customer support.

On the other hand, the pharmaceuticals sector is characterized by a growing domestic manufacturing base, mainly for generic and OTC drugs, as well as licensing arrangements with branded research-based foreign principals. However, domestic industry lacks R&D capabilities and it remains focused on producing basic formulations. The lack of R&D is compounded by an unpredictable IPR regulatory system and, recently a vague pricing structure, which is affecting the introduction of many new research-based products into the market.

Nonetheless, government policies are biased in favor of domestic producers, providing them with exemptions, including interest-free funding, subsidized utility charges, and no import duties on raw materials and intermediate products. Domestic production represents 16 percent of the total pharmaceutical market, about \$522 million.

### **Current Demand**

Total health care expenditures are estimated at \$23.5 billion in 2011, 22 percent by the private sector. The demand for health care services has already surpassed supply and both the public and private sectors are struggling to accommodate the growing demand. A growing population, compulsory health insurance coverage, and the prevalence of diseases that strike the affluent are serving to boost the demand for services and hospital bed occupancy. Likewise, the Ministry of Health plans to:

- Privatize 200 hospitals (28,000 beds), and a number of Primary Health Care Centers
- Open 20 clinics for HIV/AIDS counseling and testing, and establish eight specialist treatment centers
- Establish 400 first-aid centers
- Finalize the \$1.7 billion King Abdullah Center for Tumors and Liver Diseases
- Build 12 new hospitals in 2011

Similarly, the Ministry of Higher Education also plans to build three teaching hospitals (500-700 beds) in Assir, Ahsa, and Hail; while the Saudi Arabian National Guard is expected to invest into two specialized hospitals, a 400-bed Neurology hospital and a 600-bed Maternity hospital. Other government agencies also envisage investments in the health care field, including two new medical cities for the Ministry of Interior in Riyadh and Mecca and another medical city for the Ministry of Defense and Aviation in Riyadh.

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The major players in the Saudi health care sector include (by expenditures):

- Ministry of Health
- Saudi Arabian National Guard
- Ministry of Defense & Aviation
- Ministry of Higher Education
- Ministry of Interior
- General Organization for Social Insurance
- Royal Clinics
- Saudi Aramco
- Private Sector
- Executive Board of the Health of the Health Ministers' Council for the GCC States

## Barriers

**Commercial Dispute Settlement:** The enforcement of foreign arbitration awards for private sector disputes has yet to be upheld in practice. Each arbitration award or legal decision must be “reviewed” – in effect, retried – in a local court, a process that can take years. Furthermore, government agencies are not allowed to agree to international arbitration without approval from the Council of Ministers, which is rarely granted.

**Business Visas:** All visitors to Saudi Arabia must have a Saudi sponsor in order to obtain a business visa to enter Saudi Arabia. On the positive side, in May 2008, the United States and Saudi Arabia signed an agreement to grant reciprocal 5-year, multiple-entry visas for business travelers. This agreement represents a significant step forward in the visa process.

**Intellectual Property Protection:** Intellectual property protection has steadily increased in the Kingdom. Over the last seven years, Saudi Arabia has comprehensively revised its laws covering intellectual property rights to bring them in line with the WTO agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs). The Saudi Government undertook the revisions as part of Saudi Arabia's accession to the WTO, and promulgated them in coordination with the World Intellectual Property Organization (WIPO). The Saudi Government updated its Trademark Law (2002), Copyright Law (2003), and Patent Law (2004), with the dual goals of TRIPs-compliance and effective deterrence against violators. In 2008 the Violations Review Committee created a website and has populated it with information on current cases. The patent office continues to build its capacity through training, and has streamlined its procedures, hired more staff, and reduced its backlog.

In September 2009, the King approved a mechanism to protect Exclusive Marketing Rights (EMR) for certain pharmaceutical products which lost patent protection when Saudi Arabia transitioned to a new TRIPs-compliant patent law in 2004. The Saudi Ministerial Council in December 2009 approved the Kingdom's accession to both the Intellectual Property Owners Association Patent Cooperation Treaty (PCT) and its Implementing Regulations and the Patent Law Treaty (PLT) adopted by the Diplomatic Conference in Geneva on June 1, 2000. The Council of Ministers issued a resolution on 23/11/1428H (December 3, 2007) approving the Law of Trademarks for GCC countries.

**Counterfeiting:** Although anti-counterfeiting laws exist, manufacturers of consumer products and automobile spare parts are particularly concerned about the widespread availability of counterfeit products in Saudi Arabia. The Saudi Government remains committed to stopping counterfeit products from entering into the country.

**Arab League Boycott:** The Gulf Cooperation Council (GCC: Saudi Arabia, Kuwait, Bahrain, Oman, Qatar, and the United Arab Emirates) announced in the fall of 1994 that its members would no longer enforce the secondary and tertiary aspects of the Arab League Boycott. The primary boycott against Israeli companies and products still applies.

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**Government Procurement:** Government contracts on project implementation and procurement strongly favor Saudi and GCC nationals. However, most Saudi defense contracts are negotiated outside these regulations on a case-by-case basis. Saudi Arabia published its revised government procurement procedures in August 2006. Foreign suppliers participating in government procurement are required to establish a training program for Saudi nationals.

**Shipping:** Saudi Arabia gives preference to national carriers for up to 40% of government-related cargos. Two local companies take full advantage of this situation.

**Standards and labeling:** As part of the GCC Customs Union, the six Member States are working toward unifying their standards and conformity assessment systems. However, each Member State continues to apply its own standard or a GCC standard. A new ICCP mandates that a Certificate of Conformity must accompany all consumer goods exported to Saudi Arabia. Labeling and marking requirements are compulsory for any products exported to Saudi Arabia.

## Trade Events

**Name of event:** Saudi Healthcare Forum, September 25 – 27, 2011

**Location:** Jeddah Hilton Hotel, Jeddah, Saudi Arabia

**Website:** [www.saudi-healthcare.com](http://www.saudi-healthcare.com)

**Description:** The Saudi Healthcare Forum is a three day exhibition and conference, showcasing the latest products, technology and services that the sector has to offer. This is the only event with the full support of the Ministry of Health and will cover the full spectrum of healthcare, as well as all aspects of infrastructure and construction.

**Name of event:** MENA Healthcare Infrastructure Finance & Investment Summit, October 10 – 11, 2011

**Location:** Riyadh Marriott Hotel, Riyadh, Saudi Arabia

**Website:** [www.euroconvention.com](http://www.euroconvention.com)

**Name of event:** Saudi Medicare 2012, May 6 – 9, 2012

**Location:** Riyadh International Exhibition Center, Riyadh, Saudi Arabia

**Website:** [www.receexpo.com](http://www.receexpo.com)

**Description:** The 15th International exhibition and conference for health care services, medical equipment and hospital supplies

## Available Market Research

[http://buyusainfo.net/docs/x\\_2599464.pdf](http://buyusainfo.net/docs/x_2599464.pdf) (Medical Equipment Market 2010)

[http://buyusainfo.net/docs/x\\_2454706.pdf](http://buyusainfo.net/docs/x_2454706.pdf) (Medical Equipment Market 2009)

[http://buyusainfo.net/docs/x\\_1357949.pdf](http://buyusainfo.net/docs/x_1357949.pdf) (Country Commercial Guide 2011)

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## Turkey

*Capital:* Ankara  
*Population:* 78.8 Million  
*GDP:* \$960.5 Billion  
*Currency:* Turkish Lira (TL)  
*Language:* Turkish



### Summary

Turkey has a population of 78 million people and is a growing market for the medical products and services sectors. The Ministry of Health (MOH) is the largest provider of healthcare and the only public provider of preventive services in Turkey, to which approximately \$11 billion was allocated in FY 2011 by the Government of Turkey. A key driver behind Turkey's continued growth in healthcare budget is the country's enhanced health insurance coverage and need to build new health facilities all around the country. The implementation of state-funded health insurance for the lowest earners is expected to make a significant contribution to continued healthcare budget growth over the next five years. Besides investments by the state, private sector is very involved in building private health facilities which contributes to purchasing of state of the art medical equipment and devices.

### Market Entry

U.S. medical equipment manufacturers can either open their own offices in Turkey and equip it with their own sales and marketing force or appoint national and, most of the time, exclusive distributors in Turkey. The distributor/importer should have strong reseller base to market and service the products all around the country, follow the tenders and also be knowledgeable about shipping products into Turkey. In the latter case, as the distributor/importer will almost be the sole representative of the U.S. manufacturer on ground, its performance is a very critical factor in the U.S. company's success in Turkey.

### Current Market Trends

As Ministry of Health is the largest supplier of healthcare solutions to general public, they are pursuing a number of Public Private Partnership (PPP) projects with Turkish and foreign companies to establish healthcare campuses, large medical complexes with several hospitals, labs and recreational areas, in large cities. Besides these PPP projects, the Ministry is also renovating the hospitals already operating by upgrading their facilities and technology used. On the other hand, there is a strong trend in the Turkish private sector for investing and building state of the art private health facilities. Especially, in the last 10 years, about ten major hospital investors and operators have emerged in the market that are building hospitals all around the country and lately in neighboring countries, too. Construction of many private hospitals offers increased sales opportunities and less complicated procurement requirements compared to the confusing tender requirements used by government agencies. These projects are business opportunities for U.S. medical companies and healthcare service providers.

Medical tourism is a new sector developing in Turkey, which is a triggering factor in the investments made by the private sector in healthcare. Increasingly, patients from Europe and the Middle East go to Turkey for medical treatment, as costs are more affordable. Size of the medical tourism market in Turkey is around \$ 500 million. Increased emphasis on medical tourism will also have a positive impact on U.S. manufacturers as it will bring create avenues for medical equipment exports.

Ministry of Health has recently introduced a structured primary healthcare system nationwide which assigns a family practitioner per 3,000 people. Health situation of each person registered under this system is followed through a comprehensive e-health system. U.S. companies with e-health solutions may find good opportunities for business development in Turkey.

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## Main Competitors

Imports of U.S. origin is about 15% of the total imports market in Turkey. The rest are mainly from the European Union, predominantly from Germany, Italy, United Kingdom, France and the Netherlands, and China and India. There is also an emerging group of medical device and equipment manufacturers in Turkey, which are active in the manufacturing of disposables, orthopedic devices and tools, surgical and cardiological tools; like stents.

## Current Demand

According to figures collected from World Trade Atlas and industry feedback, these are the estimates about the size of the market in millions of US\$:

	2010	2011	2012
Total Market Size	2,000	2,100	2,260
Total Local Production	200	210	226
Total Exports	200	220	240
Total Imports	1,800	1880	2,034
Imports from the U.S.	270	280	305

As the healthcare market is in a growing trend and is expected to stay so in the coming years and medical facilities are being built both by state and the private sector, there will be market for high-end medical technologies and equipment in all areas of medicine, but especially in diagnostics, laboratory systems, and robotic surgery equipment. As there is price-based competition in commodity medical devices and disposables, opportunities could only exist for U.S. companies who can meet these prices.

## Barriers

As Turkey is an accession country to the European Union (EU) and has been part of Customs Union with the EU since early '90s, medical rules and regulations applicable in the EU are mostly applicable in Turkey, too. This cannot be considered a barrier but U.S. companies have to be abiding with the requirements set by EU when selling to Turkey. This implies that FDA certification is not, by itself enough, for exporting to Turkey but where CE Mark is asked, devices and equipment have to have it. Due to Customs Union, products manufactured in the EU are exempt from customs tax; however, customs tax is levied on some medical equipment and devices imported from non-EU countries, which includes the U.S.

## Trade Events

**Name of event:** MEDIST 2011

**Location:** Istanbul, Turkey

**Date:** October 13-16, 2011

**Description:** MEDIST 2011 is a 4-days exhibition hosting medical equipment and device, laboratory equipment, disposables, hospital furniture manufacturers and healthcare information technology companies as exhibitors.

**Name of event:** EXPOMED 2012 & LAB-TECH 2012

**Location:** Istanbul, Turkey

**Date:** April 12-15, 2012

**Website:** <http://www.tuyap.com.tr/webpages/expomed/index.php> <https://labtechistanbul.com>

**Description:** Largest medical and laboratory technology expos in Turkey. They are held simultaneously in the same venue. Please see the following link to see the types of companies that exhibit: <http://www.tuyap.com.tr/webpages/expomed/index.php?main=kapsam>

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## Available Market Research

You may download a 2011 market research on the medical market at [www.buyUSA.gov/turkey/en](http://www.buyUSA.gov/turkey/en)

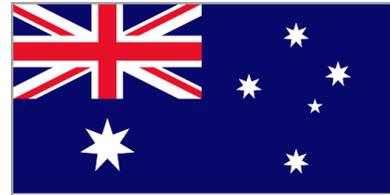
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## Australia

*Capital:* Canberra  
*Population:* 22.6 Million  
*GDP:* \$1.24 Trillion  
*Currency:* Australian Dollar  
*Language:* English



### Summary

The Australian medical equipment industry sector has consistently provided good prospects for U.S. exporters. Australia is the ninth largest market for U.S. exporters of medical products. Approximately 80 percent of medical devices and diagnostics used in the market are imports. The three major suppliers are the United States, the European Union, and Japan. U.S. medical equipment is traditionally well received due to its perceived high quality. The market is sophisticated, mature, and quick to adopt new healthcare technologies. Importers seek to obtain cost-effective and innovative products that will improve patient outcomes and reduce healthcare costs.

### Market Entry

The Therapeutic Goods Administration (TGA) regulates Australia's medical equipment industry. Australia's regulatory framework is based on Global Harmonization Task Force (GHTF) and European Community guidelines. U.S. exporters must appoint an Australian representative/sponsor to obtain regulatory approval from the TGA. U.S.-manufactured medical devices require an EC Certificate from a European Union Notified Body. Alternatively, U.S. manufactures can apply to the TGA for a Conformity Assessment Certificate.

Information on Australia's regulatory requirements is available on the TGA's website: [www.tga.gov.au](http://www.tga.gov.au)

### Current Market Trends

Australia has a high per capita income and there is demand for a full range of medical equipment. The \$5 billion market is price sensitive and competitive. Australia spends approximately 8.7 percent of its GDP on healthcare, which is similar to the United Kingdom (8.4 percent), but less than the Italy (9.1 percent) and less than the United States (16 percent). Australia's ageing population will significantly influence the demand for products and products that serve the ageing population are likely to experience growth.

The growth of chronic disease in Australia is similar to that in other developed nations. Australians increasingly suffer from asthma; cancer; diabetes; obesity; heart, stroke, and vascular disease; osteoarthritis, rheumatoid arthritis; and osteoporosis. Opportunities exist for technologies that avert or reduce disability because of these diseases.

### Main Competitors

Imports supply approximately 80 percent of Australia's demand for medical equipment. Key suppliers include the United States, the European Union, Switzerland, and Japan. Many suppliers in the Australian industry are subsidiaries of overseas corporations. The major American medical companies represented in Australia (either through local representatives or subsidiary offices) include: Bard, Baxter Healthcare, Boston Scientific, Cook Medical, Johnson & Johnson Medical, Medtronic, St. Jude Medical, Stryker, and Zimmer. U.S. companies may experience strong competition from American firms or multinationals already in the market.

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## Current Demand

Australia's high standard of medical practice and aging population underpin a continued demand for a range of sophisticated, high quality, and innovative medical equipment. Importers seek to source cost-effective and innovative products that will improve patient outcomes and reduce healthcare costs. Opportunities exist for products that provide a significant improvement in clinical outcomes, and product with clearly differentiated capabilities. There is also a growing demand for products that lead to faster patient recovery, reduce hospital and rehabilitation costs, and alleviate or manage disability and chronic pain.

Government healthcare policies and public health influence the volume and pricing of healthcare products and services. Both the public and private sectors provide healthcare in Australia. Federal and State government spending accounts for 70 percent of total healthcare expenditure. The non-governmental sector (individuals and private health insurance) funds are the remaining 30 percent. Approximately 45 percent of Australians have private health insurance.

## Trade Events

**Name of event:** AusBiotech 2011  
**Location:** Adelaide Convention & Exhibition Centre  
**Website:** [www.ausbiotech2011.com.au/](http://www.ausbiotech2011.com.au/)  
**Description:** October 16-19, 2011

## Available Market Research

Australia: Aged Care Sector (March 2009)  
Australia: Analytical and Clinical Chemistry (April 2008)  
Australia: Australia Allied Health (August 2009)  
Australia: Chronic Disease (March 2010)  
Australia: Hospitals (February 2008)  
Australia: Medical Equipment (April 2008)  
Australia: Musculoskeletal Conditions (August 2010)

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## China

*Capital:* Beijing  
*Population:* 1.34 Billion  
*GDP:* US \$4 Trillion  
*Currency:* Reminbi (RMB)  
*Language:* Mandarin Chinese



### Summary

China is now the world's 2<sup>nd</sup> largest market for medical equipment. China's healthcare market is severely underdeveloped and offers significant potential for US companies interested in expanding into the Chinese market. The Chinese government has mandated US\$124 billion to develop basic healthcare infrastructure in hopes of providing every Chinese national the basic healthcare coverage they deserve. Chinese medical device companies provide low to mid-range technology and generally lack the expertise and experience deemed appropriate by Western standards. The Chinese also view foreign medical device companies as more credible than their Chinese counterparts. The Chinese healthcare market is poised to be explored by those foreign enterprises interested.

### Market Entry

According to statistics from the China Chamber of Commerce for Import and Export of Medicines and Health Products (CCCMHPIE), by the end of 2010, China's import and export value reached US\$22.7 billion, an increase of 23.47% over 2009. Please see the top three countries in the import and export of medical equipment to China in 2010.

By Country	Import	Share	Export	Share
World	7.3	100%	14	100%
US	2.3	31%	3.9	27%
Germany	1.3	17%	7.8	6%
Japan	1.1	15%	1.4	10%

### Current Market Trends

According to information from the China Association for Medical Devices Industry (CAMDI), China's medical equipment market grows at 15% annually, and reached a total size of RMB100 billion in 2010 (about US\$156 million), ranking 2<sup>nd</sup> in the world behind the US. An annual sales growth of large, high-end, medical equipment was reported to be between 20%-30%. The production volume in China of low-mid range medical equipment and products ranked top in the world at 75%; high-end products only accounted for 25%, showing that the majority of medical equipment and products produced by domestic Chinese manufacturers are low-tech. Several foreign companies such as General Electric (GE), Philips, and Hitachi supply 80% of China's medical equipment.

Clinical laboratory equipment and reagent sales are growing at about 15%-20% per annum. According to incomplete figures from the World Trade Atlas, China's imports of medical equipment accounted for about US\$5.7 billion in 2007, and US\$7.2 billion in 2008, showing an increase of over 27%.

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## **Current status of Healthcare in China**

1.27 billion people in China, about 95% of the population, have basic medical insurance. One of China's goals is to ensure that 1.32 billion in China have basic medical insurance within the next five years.

China has over 20,000 hospitals, 85% of which are publicly-owned; the remaining 15%, or around 2,000 hospitals, are private. Most public hospitals are in urgent need of new medical equipment, and over 30,000 hospitals in rural areas need to do the same.

Public hospitals fall into one of three categories: a Ministry of Health (MoH) hospital, a People's Liberation Army (PLA) hospital, or a hospital attached to a state-owned enterprise (SOE); most hospitals, including medical colleges, clinics, and research institutions are under the Ministry of Health. Additionally, depending on the facilities available in a hospital, the hospital is classified as Class I, II or III, Class III being the best, but only about a quarter of hospitals are Class II or III.

The PLA runs around 400-500 hospitals and 4 medical colleges, primarily providing care to servicemen and their families; these hospitals are always well-equipped with up-to-date equipment.

SOE hospitals cater to the employees of state-owned enterprises, and are run by either the SOE itself or by the ministry under which that SOE falls. They are not always well-equipped, and a lot of the equipment will be older than that of the larger MoH or PLA hospitals.

Traditionally, each hospital determines its own budget and expenditure. Each department of a hospital will bid for funds at the start of the year. Recently there have been moves to change this system in an attempt to reduce the cost of healthcare for the patient. Many hospitals are now joining together to purchase collectively. Large-sized MoH hospitals, those affiliated with education and research institutes, Sino-Foreign joint venture hospitals, and privately-owned hospitals are all permitted to import medical equipment for their own use.

The annual growth rate of high-end medical equipment is about 10%, whilst that of low-mid range medical equipment is around 30%. Therefore foreign companies such as GE and Siemens are adjusting their strategy to make more affordably priced products and equipment for China's more rural areas.

### **Main Competitors**

Depending on the specific type of products, foreign competitors are those from EU or Japan as their respective markets for healthcare are structured and well developed.

### **Current Demand and Opportunities**

Chinese end users consider U.S. products to be of superior quality and the most technologically advanced. China's hospitals particularly welcome medical equipment and products with high-technology content. At the same time, domestic medical device companies are consolidating, upgrading quality, and beginning to compete in medium-level technology niches.

Released in late 2008, China's healthcare system reform scheme is expected to have a significant impact on the market outlook in China. It is intending to provide basic healthcare access and coverage for the entire population of China. The government has guaranteed to designate US\$124 billion from 2009-2011, US\$24 million in 2009 alone. This scheme is directed to development of basic healthcare infrastructure.

Building, equipping and managing super specialty hospitals is another area for future growth.

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## Best Products/Services

The Best selling prospects in the healthcare sector include:

- In vitro diagnostic equipment and reagents: Clinical and diagnostic analysis equipment, diagnostic reagents, medical test and basic equipment instruments
- Implantable and intervention materials and artificial organs: Interventional materials, implantable artificial organs, contact artificial organs, stent, implantable materials, and artificial organ assisting equipment.
- Therapeutic products: Tri-dimensional Ultrasonic focused therapeutic system, body rotary Gamma knife, simulator, linear accelerator, laser diagnostic and surgery equipment, nuclide treatment equipment, physical and rehabilitation equipment.
- Medical diagnostic and imaging equipment: Black & white and colored supersonic diagnostic unit, sleeping monitor, digital X-ray system, MRI, CT, DR, and ultrasound equipment.
- Surgery and emergency appliances: Anesthesia ventilation systems and components: high frequency surgery equipment, high frequency and voltage generators.
- Healthcare Information Technology related equipment and products: Medical software, computer-aided diagnostic equipment, and hospital information systems (HIS, CIS, and HLT).
- Medical equipment parts and accessories.

## Barriers

Barriers exist with an uncertain regulatory environment and extensive delays in registration and re-registration of products, although efforts are reportedly being made to reduce the large backlog. Besides, pricing, tender, and bar code system also play a role of delaying the company's entry into the Chinese medical device market.

## Healthcare Reform

China's new healthcare reform plan was approved by the State Council in January, 2009. Some goals with the reform plans include:

- Expanding basic healthcare insurance to cover all Chinese nationals.
- Decrease and eventually eliminate the hospitals' reliance on the income from pharmaceutical sales.
- Convert some public hospitals into privately-owned hospitals
- Establish a nation-wide drug system, whereby the government formulates and issues a catalogue of all pharmaceuticals, and monitors their manufacture and distribution.
- Improve the service in local medical institutions of rural, township, and other remote areas.
- Ensure the service levels of urban and rural hospitals are more equal.

China's Central Government recently reallocated RMB18.4 billion to subsidize medical reform in 2011 in order to support the local medical reform in the five key aspects. By end of 2011, healthcare reform subsidies from the Central Government are expected to reach RMB171.7 billion.

## Trade Events

**Name of event:** CMEF Autumn 2011, Oct 31<sup>st</sup> – Nov 3<sup>rd</sup>, 2011

**Location:** Fuzhou (Fujian Strait International Conference and Exhibition Center)

**Website:** <http://en.cmf.com.cn/>

**Description:** 2012.

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**Name of event:** Care & Rehabilitation Expo China 2011, November 4<sup>th</sup>-6<sup>th</sup>, 2011

**Location:** Beijing (China International Exhibition Center)

**Website:** <http://www.crexpo.com/cn/enzhgy.aspx>

**Description:** Over 150,000 visitors are expected to attend mainly from the Central People's Government and local government officials. Doctors, nurses, volunteers, rehabilitation employees, manufacturers, distributors, and the general public will be in attendance. C&R Expo China is the largest exhibition in China focused exclusively on the care and rehabilitation industry. In keeping with rapid growth across the industry, C&R Expo China has grown substantially over the past three years. The fair attracts companies from more than 15 countries to exhibit, and in 2008 there were more than 100 000 visitors. C&R Expo China offers you a platform to look for suitable partners, establish distributing channels and understand the needs of end-users from the care and rehabilitation industry in China.

**Name of event:** China Med 2012 (The 24<sup>th</sup> International Medical Instruments and Equipment Exhibition, March 23-25, 2012)

**Location:** Beijing (China National Convention Center)

**Website:** <http://www.Chinamed.net.cn/en/Vistor.asp>

**Description:** in Mumbai.

**Name of event:** CMEF Spring 2012, April 16-19, 2012

**Location:**

**Website:** <http://en.cmf.com.cn/>

**Description:** 2012.

**Name of event:** Sino- Dental 2012, June 9-12, 2012

**Location:** Beijing (China National Convention Center)

**Website:** <http://www.chinamed.net.cn/en/default.asp>

**Description:** Started in 1995, SINO-Dental is the largest dental exhibition in China. Its popularity continues to grow as the 28,000 sq meter facility drew 540 exhibitors from 18 countries for 62,800+ visitors from 75 countries in 2008 alone.

**Name of event:** MEDTEC China, September 26-27, 2012

**Location:** Shanghai - Intex

**Website:** <http://www.devicelink.com>

**Description:** The annual MEDTEC China Exhibition and Conference will allow manufacturers to have access to the latest technologies, techniques, and equipment. Experts now attend MEDTEC China on an annual basis to view, learn, and meet suppliers as well as attend seminars.

## Available Market Research

### China: Clinical Laboratory Market

[http://www.buyusainfo.net/docs/x\\_5325735.pdf](http://www.buyusainfo.net/docs/x_5325735.pdf)

### China Ophthalmic Equipment and Products Market

<http://www.buyusainfo.net/info.cfm?id=14265329&keyx=A2290215CB1509A59081A430A99C8D84&dbf=mrsearch1&loadnav=&archived=no&addid=>

### China: Gynecological Devices and Products

[http://www.buyusainfo.net/docs/x\\_3244830.pdf](http://www.buyusainfo.net/docs/x_3244830.pdf)

### Pre-hospital Emergency Medical Service and Equipment in China

[http://www.buyusainfo.net/docs/x\\_918621.pdf](http://www.buyusainfo.net/docs/x_918621.pdf)

### Measures for the Administration of Medical Device Registration (English Translation)

[http://www.buyusainfo.net/docs/x\\_525872.pdf](http://www.buyusainfo.net/docs/x_525872.pdf)

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## India

*Capital:* New Delhi  
*Population:* 1.21 Billion  
*GDP:* US \$3.339 Trillion  
*Currency:* Indian National Rupee (INR)  
*Language:* Hindi, English



### Summary

The Indian healthcare industry is experiencing a rapid transformation. According to a World Health Report, India spends about 5.2 percent of its GDP on the healthcare sector which is expected to rise to 6.1 percent of GDP by 2012. The World Health Organization forecasts that India needs at least 80,000 hospital beds per year for the next five years to meet the expanding local demand. The Indian Healthcare industry is estimated at \$35 billion and is expected to reach over \$75 billion by 2012. The medical equipment market is growing at an impressive rate of 15 percent. The hospital facilities depend on the import of high-end medical equipment.

### Market Entry

In India, healthcare is delivered through both the public sector and private sector. The private sector's contribution to healthcare has been growing at a faster pace than government. There are no restrictions on foreign direct investment in healthcare services. Import of medical equipment is allowed under the "Open General" category of the Import regulations, except for nuclear medicine. Customs duty levied on imported products depends on the product classification, for some devices the duty has been brought down from 25 to 7 percent. Products classified as "life saving equipment" have reduced duty applicable on them.

Price, quality and after-sales service support are major factors in medical equipment purchase decisions. Letter of credit is usual the mode of payment for imports. Purchase decision in government follow a tendering process and is time consuming, while it is faster in the private hospitals.

### Current Market Trends

Indian population of 1 billion people is growing at a rate of 1.6 percent per year. The growth in affluence of over 400 million strong middle-income consumers is creating demand for higher standard of healthcare. Many in the growing "middle income" segment look for international quality medical services in private super-specialty hospitals, and this trend is expected to continue for the next five years and beyond. According to a World Bank report, 79 percent of all outpatient care among the poor is provided by the private sector.

The number of lives covered by health plans is estimated at 20 million presently, leaving a large Indian population that needs to be insured. Healthcare insurance premium collections are growing steadily to reach \$3.8 billion by 2012. With the private sector continuing to aggressively market healthcare insurance the healthcare industry is witnessing a change.

The type of healthcare service requirement has changed due to the change in demographic profile and rise of lifestyle-related diseases such as diabetes, cardiovascular diseases, and diseases of the central nervous system.

Both the government and private sector are planning new hospitals as well as up-gradation of existing hospitals. Corporate are sensing the huge untapped opportunity in delivery of quality healthcare to the Indian masses and focusing on tertiary-level preventive and diagnostic healthcare. The public sector is

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engaged in prevention and elimination of infectious diseases and accessibility of basic healthcare facilities to the rural masses. The National Rural Health Mission 2005-2020 aims to provide medical care to the all rural Indians. Not only provider but also the global PE and Venture funds are vying to explore opportunities.

The demand for medical equipments is expected to reach \$5 billion by 2012 from current figure of \$2.7 billion. Imports account for over 65 percent of the entire medical equipment market and of which 85% is from US. The medical device market is becoming too big to ignore.

Medical Tourism is also fueling additional growth in the Indian healthcare sector. The cost of major surgeries in India is much less than the cost for the same surgery in a developed economy. Government and private sector estimates the value of this segment of the industry to reach \$1.48 billion by 2012. The healthcare industry is now proactively creating standards for the medical tourism industry with the help of credit rating agencies, insurance companies and others involved in the self regulation of the sector.

### **Main Competitors**

The large private healthcare services providers are actively seeking growth by enhancing their reach across the country through the building new hospitals and acquiring and upgrading existing hospitals. There are several groups operating hospital chains including Apollo Group, Fortis Healthcare, Manipal Group, Max Healthcare, and Wockhardt Hospitals. In the medical equipment segment competition is from the imports from European companies and Japan. India being a price sensitive market there is competition from low priced Chinese products.

### **Current Demand and Opportunities**

The growing demand for quality healthcare and the absence of matching delivery mechanisms pose a challenge and certainly a great opportunity. In infrastructure – building, equipping, managing and financing of hospitals are areas for growth. Some best sales prospects in the medical equipment market include medical and surgical instruments, medical imaging, electro medical equipment, orthopedic and prosthetic appliances, cancer diagnostic, ophthalmic instruments and appliances.

A proper supply of equipment and medical consumables will also be an area with significant for American companies. Several leading U.S. purveyors of hospital equipment and supplies have opened Indian operations to cater to this growing market.

Health insurance and hospital administration is another area in which U.S. companies can make a difference. This opportunity includes introducing and maintaining industry standards, and also classifying and certifying healthcare centers.

Building, equipping and managing super specialty hospitals is another area for future growth.

### **Barriers**

To ensure quality healthcare in October 2005, the Government of India (GOI) increased the list of medical devices covered under the Drugs and Cosmetics Act of 1940, bringing ten categories of implantable devices under regulatory control. These include stints, heart valves, catheters, intra-ocular lenses, hip and knee implants and bone cements. An improved central licensing authority must license these devices for manufacture, sale or distribution. Hospitals are also seeking quality accreditations like JCI, NABH and ISO. The authority regulating medical devices is Central Drug Standard Control Organization has listed devices for regulation (<http://www.cdsc.nic.in>). The Indian government has identified healthcare as a priority sector.

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## Trade Events

**Name of event:** World Dental Show, September 16-18, 2011

**Location:** Mumbai

**Website:** <http://www.wds.org.in/>

**Description:** In September 2011, the show and workshops will highlight dental technology and dentistry. Companies will also have an option to participate in the U.S. pavilion at the World Dental Show 2011 in Mumbai.

**Name of event:** Medical Fair India, March 2-4, 2012

**Location:** New Delhi

**Website:** <http://www.medicalfair-india.com/>

**Description:** This event will advance the goals of India Commercial Engagement Strategy (ICES) in the medical/healthcare sector. Companies will also have an option to participate in the U.S. pavilion at the Medical Fair India 2012.

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## Indonesia

*Capital:* Jakarta  
*Population:* 240 Million  
*GDP:* \$707 Billion  
*Currency:* Rupiah  
*Language:* Indonesian



### Summary

With over 240 million people and steady economic growth, Indonesia presents excellent opportunities for U.S. companies. Increases in public awareness in healthcare and social conditions and the expansion of public and private hospitals have led to increased demand for more sophisticated and modern medical equipment and supplies. Total imports of medical equipment grew from \$508 million in 2009 to \$543 million in 2010, with U.S. imports accounting for 20 percent of this market. Continued strong growth for this market is predicted over the next two years. U.S. manufacturers of medical devices should take advantage of this growing market.

### Market Entry

U.S. companies must appoint Indonesian agents/distributors to market medical equipment and supplies in Indonesia. Local agents/distributors play an important role in developing the market and providing after-sales services.

### Current Market Trends

Indonesians spend over \$1 billion annually for quality healthcare overseas, mostly in Singapore, Malaysia, Thailand, and a few other countries. In a bid to stem the flow of patients seeking medical treatment abroad, the Indonesian government continues to urge hospitals to improve their services to compete with world-class hospitals abroad. Indonesia has 1,520 hospitals and 8,737 health centers. These hospitals and health centers provide health services to more than 240 million people spread over the 33 provinces of Indonesia. Central and regional governments continue to upgrade their facilities in order to provide basic healthcare services.

### Main Competitors

The market for medical equipment and supplies is highly competitive. The U.S. is the largest exporter of medical equipment to Indonesia accounting for 20 percent. Currently third country producers of medical equipment competing with the U.S. include Japan, Germany, China, and France. Chinese products are geared more towards low-end supplies and price sensitive buyers.

### Current Demand

#### Best Prospects

- Diagnostics and laboratory reagents
- Electro-diagnostic equipment and x-ray units
- Rapid tests for HIV, TB, and other infectious diseases
- Life support equipment such as ventilators, anesthesia and patient monitoring equipment

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## Barriers

There are no restrictions on imports of medical equipment; however, imports of used equipment are prohibited. Medical equipment is subject to 0-5 percent import tax and value added tax of 10 percent. The Ministry of Health controls the registration of medical equipment in Indonesia. In general, products that are FDA-approved and sold in the U.S. will be approved to enter the market in Indonesia.

## Trade Events

**Name of Event:** Hospital Expo 2011

**Location:** Jakarta

**Website:** <http://www.hospital-expo.com/>

## Available Market Research

Dental Equipment and Supplies (April 2010)

Medical Equipment and Supplies (May 2011)

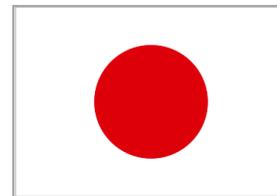
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## Japan

*Capital:* Tokyo  
*Population:* 126.5 Million  
*GDP:* US \$5.459 Trillion  
*Currency:* Yen  
*Language:* Japanese



### Summary

Japan's market for medical devices and materials continues to be one of the world's largest. According to the latest official figures from Ministry of Health, Labour and Welfare's (MHLW) Annual Pharmaceutical Production Statistics, the Japanese market for medical devices and materials in 2009 was approximately \$23.2 billion (USD1=JPY 93.68). U.S. products represented an approximately 54 percent import share and accounted for 26 percent of Japan's total device market.

While the market remains heavily dependent on imports, especially sophisticated medical technologies, many globally available advanced medical technologies have not yet been introduced into the Japanese market. The Government of Japan (GOJ) has recognized that Japan suffers from a medical device "lag" and medical device "gap" which prevents timely patient access to innovative and life-saving products. The GOJ intends to make the pharmaceutical and medical device industries key drivers of Japan's future industrial growth and to attract foreign direct investment in these sectors. The June 2010 GOJ New Growth Strategy identified the drug and device lags as urgent issues and stressed the need to improve the clinical trials environment and to accelerate review times in Japan. Although the New Growth Strategy and other policy programs aim to enhance the international competitiveness of Japanese industries, these programs will also benefit U.S. medical equipment companies that can offer innovative products to Japanese patients.

### Market Entry

Japan does not levy customs duties on medical devices. Medical devices are heavily regulated under the Pharmaceutical Affairs Law (PAL). A Japanese company that intends to market a U.S. medical device needs to receive a "license for manufacturing/marketing business" (seizo hanbai gyo kyoka). The company holding this license is called a "Marketing Authorization Holder (MAH)." An MAH must be physically located in Japan. The MAH must obtain a marketing approval (hanbai shonin) for each product. A U.S. manufacturer intending to manufacture medical devices in the United States and export them to Japan, is required to be accredited by the Ministry of Health, Labor and Welfare (MHLW) as an "Accredited Foreign Manufacturer" in the same way that a Japanese manufacturer is licensed. Typically, an MAH can make an accreditation application on behalf of a U.S. manufacturer. Please see [www.pmda.go.jp/english/operations/pdf/application.pdf](http://www.pmda.go.jp/english/operations/pdf/application.pdf) for further details. A U.S. manufacturer that lacks a Japanese subsidiary can continue to receive and maintain the shonin approval under its own name. However, the U.S. firm will need to designate an MAH when applying for a product approval. This Designated MAH (D-MAH) will have to assume the same responsibilities as an MAH. Review processes for medical devices differ depending on the classification. Medical devices are classified by risk level into four classes (Class 1, Class 2, Class 3 and Class 4). Class 1 (lowest risk) is defined as general medical devices; Class 2 (relatively low risk) is defined as controlled medical devices; Class 3 (relatively high risk) and Class 4 (highest risk) are defined as specifically controlled devices. General medical devices can be marketed by submitting a notification to the Pharmaceutical and Medical Device Agency (PMDA). Controlled medical devices, with established certification standards, can be reviewed by third-party certification bodies. Controlled medical devices without certification standards and specifically controlled devices must be reviewed by PMDA and approved by MHLW. Please see [www.pmda.go.jp/english/about/pdf/profile\\_of\\_services.pdf](http://www.pmda.go.jp/english/about/pdf/profile_of_services.pdf) for further details about Japan's review system and services provided by PMDA. For new-to-market U.S. companies, the best way to enter the Japanese market is to work with a Japan based agent, distributor or licensee. It is very difficult for a U.S. company

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to establish its own sales channels in Japan since the market is full of both local and foreign affiliated companies with existing sales channels. After establishing a market position, the U.S. company can choose to continue working with their existing importer/distributor or establish their own Japanese office. A U.S. company without an office in Japan cannot directly apply for marketing approval. Therefore, unless a U.S. company plans to open an office in Japan, it is extremely important that the company work with an importer/distributor in Japan who is interested in a long-term relationship. If a U.S. company would like to obtain a marketing approval under its own name, the U.S. firm can designate an MAH when applying for a marketing approval. This Designated MAH (D-MAH) can be an importer/distributor and/or a neutral third party (such as a healthcare consulting company).

### **Current Market Trends**

While the market remains heavily dependent on imports, especially sophisticated medical technologies, many globally available advanced medical technologies have not yet been introduced into the Japanese market. The Government of Japan (GOJ) has recognized that Japan suffers from a medical device "lag" and medical device "gap" which prevents timely patient access to innovative and life-saving products. The GOJ intends to make the pharmaceutical and medical device industries key drivers of Japan's future industrial growth and to attract foreign direct investment in these sectors. As a result, the demand for advanced medical technologies is expected to increase.

### **Main Competitors**

The major product categories comprising Japan's domestic medical device production include: diagnostic imaging equipment; therapeutic and surgical equipment; biophenomena measuring and monitoring systems, home therapeutic equipment, dialyzers, and endoscopes. Japanese medical device companies maintain high market share in those product segments. Top Japanese medical device companies, in terms of sales, include Terumo, NIPRO, Olympus Medical Systems, Toshiba Medical Systems, Hitachi Medico, Nihon Koden, Fukuda Denshi, etc. U.S. medical device companies produce a wide variety of medical devices, but they are especially strong in sophisticated segments of the medical market such as pacemakers, advanced interventional cardiology products, orthopedic implants, laser surgical equipment, and advanced diagnostic imaging equipment. Most major U.S. medical device firms have either a Japan office or a Japanese partner.

### **Current Demand**

Given Japan's aging population and with an increasing number of patients with chronic and life-style diseases, medical devices that alleviate pain, complement lost functions, and improve the quality of life (QOL) should show steady growth in demand. Also, the market for in-home care devices, technologies, and health IT related products is expected to grow as the number of people in out-patient care increases. Due to stronger consumer health concerns, other promising growth areas include self care and preventive care medical devices and products. The "New Vision for Medical Device and Medical Technology Industry" issued by the Ministry of Health, Labor and Welfare (MHLW) in August 2008, cited the following fields and technologies as focus areas: navigation medical devices (operation robotics); implantable devices (e.g., customized artificial joints, artificial hearts, artificial heart valves, intraocular lenses, and artificial dental roots); regenerative medicine (e.g., tissue sheets, iPS (induced pluripotent stem cells), and periodontal membrane sheets); tailor made medical diagnostics (DNA chips and protein chips); etc.

### **Barriers**

While the market for U.S. medical equipment in Japan remains strong, U.S. firms have been facing challenges with pricing and reimbursement due to the GOJ's efforts to contain overall healthcare costs. In 2009, national health expenditures reached a record \$376.8 billion (USD1=JPY93.68), up 3.5 percent over the previous year. This marks the seventh consecutive annual increase driven by Japan's aging

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population. Nearly 44 percent of all medical expenditures were for elderly patients over the age of 70. With a declining population, currently at 127.6 million, Japan faces serious economic consequences as a quarter of its citizens are projected to be over the age of 65 by 2015. As a result, national health expenditures are expected to further increase in the coming years.

## Trade Events

**Name of event:** International Technical Exhibition of Medical Imaging (ITEM)

**Location:** Yokohama

**Website:** <http://www.jira-net.or.jp/e/index.htm>

**Description:** ITEM is a comprehensive academic exhibition in Japan for the latest medical imaging systems and peripheral devices.

**Name of event:** International Modern Hospital Show (IMHS)

**Location:** Tokyo

**Website:** <http://www.noma.or.jp/english/index.html>

**Description:** IMHS is one of the major Japanese trade shows in Japan for healthcare products with 380 companies and 78,000 visitors.

**Name of event:** INTERPHEX Japan

**Location:** Tokyo

**Website:** <http://www.interphex.jp/ipj/english/index.phtml>

**Description:** INTERPHEX JAPAN is the ASIA'S LARGEST pharmaceutical industry event with 1,400 exhibitors and 63,000 visitors.

**Name of event:** HOSPEX Japan (International Hospital Engineering

**Location:** Tokyo

**Website:** <http://www.jma.or.jp/indexeng.html>

**Description:** HOSPEX Japan is one of the major trade shows for hospital facility products; health and medical treatment information systems; etc. with 200 companies and 35,000 visitors.

**Name of event:** MEDTECH Japan

**Location:** Tokyo

**Website:** <http://www.canontradeshows.com/expo/mdmshows/>

**Description:** MEDTEC Japan is the only trade show in Japan that is designed for technical and engineering professionals from medical device manufacturing companies seeking new technologies and suppliers.

## Available Market Research

Japan External Trade Organization (JETRO) – Market Information

<http://www.jetro.go.jp/en/market/>

Japan Pharmaceutical Manufacturers Association (JPMA) – “Pharmaceutical Administration and Regulations in Japan”

<http://www.jpma.or.jp/english/>

U.S. International Trade Commission – “Medical Devices and Equipment: Conditions Affecting U.S. Trade in Japan and Other Principal Foreign Markets”

<http://hotdocs.usitc.gov/docs/pubs/332/pub3909.pdf>

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## Philippines

*Capital:* Manila  
*Population:* 95 Million  
*GDP:* US \$373.6 Billion  
*Currency:* Philippine Peso  
*Language:* Pilipino



### Summary

The Philippine market for medical equipment is small with a strong U.S. presence. In the medium to long term, the sector presents good opportunities for U.S. firms.

The medical equipment market is almost 100% imported since the Philippines do not manufacture medical equipment. The total importation in 2009 was US\$229 million, a quarter of which was imported from the U.S. The next big supplier was China, with a 14% market share, followed by Singapore with 12%, and Germany with 11%. Local production consists of parts for medical equipment (presumably microchip parts manufactured in the export processing zones).

The market is price-sensitive, which explains the growth of importation from China. Over the last two years, few private sector companies or individuals invested in hospital development. Hospitals with limited budget source medical equipment from China or Taiwan, and distributors that supply equipment and replacement parts now also carry disposables and consumables.

Although imports from the U.S. dipped 5% in 2009, market shares reflect a strong preference for U.S. products. The U.S. performs well with high value, low volume medical equipment such as ultrasound equipment, magnetic resonance imaging (MRI) equipment, breathing equipment, and other radiology and electronic medical equipment. U.S. manufacturers, however, face increasing competition from third country suppliers.

There are approximately 1,700 licensed hospitals in the country, of which more than 60% are privately owned. Total bed capacity is more than 90,000. There is no official data on the number of smaller community clinics.

### Market Entry

U.S. suppliers interested in selling in the Philippines should appoint a local distributor. A distributor handles all aspects of importation including registration, obtaining a license, and getting customs clearance for the products. He not only helps facilitate the product's entry into the market, but also assumes responsibility for advertising and promotion through sales and dealer networks. A distributor registers with the Food & Drug Authority (FDA), formerly the Bureau of Food and Drugs, before operating and receives a License to Import and a License to Operate (LTO) from the FDA.

The average tariff rate for Medical equipment is 3% plus a 12% value-added tax (VAT). The VAT is based on the valuation determined by the Bureau of Customs for the application of customs duties, plus those duties themselves, excise taxes, and other charges (i.e., charges on imports prior to release from customs custody, including insurance and commissions). The Bureau of Customs (BOC) is responsible for all customs valuation, classification, and clearance functions.

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## Current Market Trends

Public hospitals tend to place a greater emphasis on preventive healthcare, while private hospitals concentrate on curative services. Private hospitals have traditionally been equipped with more sophisticated medical equipment due to their larger revenues and budgets.

Incidence rates for hypertension and heart diseases, lung and kidney diseases, and other respiratory diseases are rising. In response, most hospital improvements concentrate on specialized services for radiology, cardiac, lung and kidney examinations, and pathology. As such, demand for ECGs, CT Scans, X-ray and Dialysis machines, and other laboratory instruments continue to grow.

Another growing medical specialty is dermatology because of the increased number of clients who visit derma clinics for mostly anti-ageing and skin whitening services.

## Main Competitors

U.S. market share in 2009 was 25%, but American brands face increasing third-country competition, notably from China, which had a 14% market share, followed by Singapore with 12%, and Germany with 11%. Industry believed that much of Singapore's share could actually be U.S. equipment that is transshipped through its ports.

## Current Demand

The most promising subsectors are ultrasound equipment, magnetic resonance imaging (MRI) equipment, breathing equipment, and other radiology and electronic medical equipment.

## Barriers

Except for radiation emitting equipment, US FDA-approved medical equipment does not require registration, according to the Center for Device Regulation, Radiation Health, and Research (CDRRHR), formerly the Bureau of Health Devices and Technology (BHDT).

While waiting for new guidelines to be developed and approved, the CDRRHR issues Certificates of Exemption for all medical devices including IVDs (in vitro diagnostic products) that are NOT yet required for mandatory registration. The requirements for issuance of a Certificate of Exemption are:

1. Letter of intent
2. Brochure of the product with product profile (intended use, etc)
3. Product Sample (only when necessary)

## Trade Events

There are no Philippine-based trade events in the Healthcare Industry. Instead, CS Manila supports the events under the U.S. Department of Commerce's International Buyer Program and those promoted by the Global Healthcare Team.

## Available Market Research

An updated report on Clinical Laboratory Market was uploaded in June 2011.

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## Republic of Korea

*Capital:* Seoul  
*Population:* 48.9 Million  
*GDP:* US \$1,467 Billion  
*Currency:* South Korean Won  
*Language:* Korean



### Summary

(Unit: USD million)

	2008	2009	2010 (E)
<b>Total Market Size</b>	3,286.7	3157.4	3608.4
<b>Total Local Production</b>	2,295.6	2468.1	2838.3
<b>Total Exports</b>	1,132.0	1190.1	1297.2
<b>Total Imports</b>	2,123.1	1879.4	2067.3
<b>Imports from the U.S.</b>	739.0	763.0	839.3

Exchange Rate: USD1= KW 1,100 (2008), 1,120 (2009), 1,120 (2010)

Source: Korea Medical Devices Industry Association)

NOTE: Given the sharp decline in Korean Won/ US \$ exchange rates in 2009, the above table distorts the positive real growth we anticipate in this sector.

The Korean medical device market was expected to reach USD 3.6 billion in 2010. Imports account for about 60% of the total market demand. In 2010, total imports of medical devices were estimated at USD 2.1 billion, with U.S. imports, estimated to be USD 839.3 million. The U.S. market share represents a 40 percent of the import market share.

The importation of medical devices requires the assignment of an importer or representative based in Korea to manage medical device approval and to ensure regulatory compliance. As part of the pre-market approval requirements, the Government of Korea requires testing reports of imported devices for safety and efficacy. In addition to the medical device approvals, companies would also negotiate pricing terms with the Korean Health Insurance Review & Assessment Service (HIRA). Current issues for medical device industry in Korea include reimbursement pricing, re-evaluation of medical devices, and healthcare technology assessment system for medical devices.

### Market Entry

Medical devices are distributed through local distributors mostly. A local distributor may directly cover the whole country on an exclusive basis. Or, the master distributor may contract with other regional sub-dealers for sales nationwide.

Major international suppliers work directly on advertising, make direct contact with doctors, and provide them with technical assistance. However, actual sales are made through Korean distributors. Most Korean distributors working with the major international firms maintain close relationships with senior doctors and department chairpersons at major hospitals.

Sales leads for medical devices in Korea are normally created through steady communication with local subsidiaries or distributors/commission agents and physicians on an individual basis. Local representatives call on physicians frequently and provide information on products to maintain good relationships.

One reliable distributor to cover the country on an exclusive basis is highly recommended for the Korean market since Korea is a geographically small country, and major users for high end medical devices are

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limited to general hospitals and university hospitals. More than one distributor often confuses clients in terms of representation and prices and diminishes the reliability of the foreign supplier.

### **Current Market Trends**

Following are top 10 medical devices imported to Korea in 2010:

- Stent
- Orthopedic implants (Knee)
- Soft contact lens
- CT systems
- Dialyzer
- MRI
- Accelerator system collimator electron applicator
- Ophthalmic lens
- Staple
- Surgical instruments

### **Main Competitors**

Korea depends on high end medical devices from the U.S., EU, and Japan to supply about 60 percent of total market demand. Currently, the United States has largest import market share in Korea followed by EU and Japan. Korean manufacturers supply primarily low and to medium technology products and equipment.

### **Current Demand**

Market demand for foreign advanced and innovative medical devices in 2010 was estimated to grow slowly since the Korean economy has not recovered, and exchange rate of the Korean Won vis-à-vis the U.S. dollar is still not stable. Factor favoring the use of imported advanced medical equipment and devices is the growing number of elderly population and Korean doctors educated in the U.S. and Europe who are accustomed in using advanced medical devices.

### **Barriers**

#### *Pre-market License*

All medical devices are required to obtain marketing clearance from the Korea Food & Drug Administration (KFDA) before they are manufactured in or imported into Korea. Currently, medical devices are classified into four categories in Korea depending upon technical attributes and product use. KFDA requires pre-market notification for class I devices and pre-market approval for class II, III, and IV devices. Class III and IV devices must pass the most stringent technical review by a KFDA with authorized labs to prove their safety and effectiveness. Therefore, most cardiovascular devices fall under class IV devices. Since KFDA issues product licenses only to locally based firms, all foreign suppliers must submit required documentation and receive necessary approvals through their Korean importers, or U.S. supplier's corporation located in Korea.

For reference, Class I devices are subject to pre-market notification which requires KFDA's document review of product information. No product testing is required in Korea. To apply, your Korean importer will complete a "Medical Device Act Implementing Rules Attachment Form 5" and will submit this form with your supporting documents to the KFDA District Office responsible for the region where your importer's main office is located.

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Class II, III, and IV devices are subject to pre-market approval for which KFDA or KFDA-authorized local labs perform more rigorous document review, with product tests at KFDA-authorized local laboratories. To obtain approvals for Class II or III or devices, in general, the following procedure is required: documentary review of technical file, type test in the Korean laboratories, approval of Korean importer's product management system and final approval.

The lead-time for approval is typically 6 to 12 months, including company-working time for preparing applications. Although KFDA has requirements for the approval in regulations, specific requirements could be different according to each product item. Thus, it is difficult to predict KFDA's requirements for approval on many products, and U.S. firms should closely work with their Korean importers to determine KFDA's requirements on a case-by-case basis and to obtain approvals.

#### *National Health Insurance Program & Reimbursement pricing*

Korea has compulsory National Health Insurance (NHI) system for 48.9 million citizens. The NHI system was introduced in 1977 and covered entire population in 1989. Korean government administers funds, coverage, coding, payment and pricing.

#### *Tariffs*

Tariffs of medical devices in Korea currently average 5.4%, ranging from zero to as high as 8%. Tariff rates for overall medical devices are expected to lower step by step after the Korea-US Free Trade Agreement is ratified. In 2008, U.S. and Korea have completed the FTA negotiations and are still awaiting ratifications of the two governments. Approximately 85-90% of imported medical devices in Korea will receive duty-free treatment within one year upon implementation of the FTA, and tariffs on the rest will be eliminated over the next 7 years.

### **Trade Events**

**Name:** 27<sup>th</sup> Korea International Medical & Hospital Equipment Show (KIMES) 2011

**Date:** March 17 (Thurs) – 20 (Sun), 2011 (Dates for KIMES 2012 has not been decided yet)

**Location:** Convention & Exhibition Center (COEX)

**Website:** <http://www.kimes.kr>

**Description:** KIMES is a total healthcare related show. The range of exhibits at KIMES include consultation, diagnosis central supply, clinical examination, hospital accommodation, emergency equipment, radiology, medical information system, surgical apparatus, oriental medicine, cure apparatus, pharmaceutical, physiotherapy apparatus, obesity cure, healthcare, ophthalmic apparatus, medical device component, medical service, dental apparatus, disposable apparatus and others.

### **Available Market Research**

Clinical Laboratory Industry – IVD (October 2009)

Cardiovascular Industry (December 2008)

Dental Equipment Industry (July 2008)

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## Singapore



*Capital:* Singapore  
*Population:* 5 Million  
*GDP:* US \$222.7 Billion  
*Currency:* Singapore Dollar (SGD)  
*Language:* English (Business), Mandarin, Malay, Tamil (Other)

### Summary

Demand for healthcare in Singapore is set to grow as the population increases and ages. The island state's population is likely to increase to 5.5 million by 2020. Demand for state of the art medical technologies is also expected to grow as Singapore strengthens its reputation as the region's healthcare hub and center for healthcare excellence offering first class healthcare delivery systems and facilities to both its resident population and the international patient market.

Singapore serves as a showcase for healthcare delivery and medical technology and is considered the gateway to the regional economies of South East Asia. The three key healthcare strategies Singapore is pursuing are clinical research, improving long-term care and moving towards more sophisticated care.

The national healthcare plan covers almost 100% of the population. This augurs well for the healthcare industry as Singaporeans all have access to medical care.

### Market Entry

U.S. companies who are new to the market and interested in exporting to Singapore may consider appointing a local distributor to represent their company's product and services. Given the small market size of the island state, most potential distributors would request for exclusive rights to sell the product. They will also likely to ask for distribution rights for the regional South East Asia countries as Singapore serves as a gateway into the region. U.S. exporters of medical equipment should evaluate the suitability of the distributor based on the company's contacts in the market, their product range and whether their products complement that of the U.S. firm. As the sales in the local market increases, the U.S. firm can look into setting up an on-going presence in Singapore much like how some large MNCs have set up regional offices in Singapore. This brings the U.S. firm closer to their customers, demonstrates their commitment to the region and allows for prompt and enhanced customer service.

### Current Market Trends

Singapore's public hospitals and specialty centers engage in clinical research with the many pharmaceutical, biotechnology and medical technology companies based in Singapore. Singapore's goal is to become Asia's premier healthcare hub via the attraction of foreign patients. The target is to treat one million patients by 2012. There is also an emphasis towards a healthy lifestyle and a focus on preventive care.

Doctors here are also pushing ethical and professional standards, and it is expected that every major hospital in Singapore will have attained the widely recognized American mark of quality health care. Already, several private and public sector hospitals have been accredited by the Joint Commission International (JCI), the overseas arm of the United States' main hospital accreditation agency.

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## Main Competitors

Major competitors of the U.S. are medical devices from Germany, other European economies, Japan and Australia. Local production by multinational corporations and indigenous Singapore companies is primarily for export or contract manufacturing.

## Current Demand

Singapore's healthcare services are comparable to those of other industrialized nations. The plan is to raise health spending to reach US\$1.37billion / S \$2 billion a year in the next five years. The Singapore government is focused on moving up the value chain by building up services that assist research and healthcare delivery in Singapore and the region. A total of 23 hospitals and six specialty centers, provide a complete spectrum of clinical services from basic health screening to complex quaternary care.

## Barriers

There are no barriers to entry as Singapore is an open economy and a firm believer in keeping trade open. There are no custom duties on medical devices. A 7.0% goods and services tax (GST) is imposed on all goods sold and services provided, locally. Imports are subject to GST, but payments are refundable on re-exports.

## Trade Events

**Name of event:** Hospital Build Asia 2012

**Dates:** May 9 – 11, 2012

**Location:** Singapore

**Website:** <http://www.hospitalbuildasia.com/>

**Description:** Hospital Build Asia 2012 provides an ideal platform for the healthcare industry across the Asia Pacific region. Exhibitors will showcase products, solutions and services across all areas of hospital investment, planning, designing, building, operating, managing and refurbishing. This event has a strong conference component.

## Available Market Research

1. Singapore: Dental Industry 2010 – report dated 07/10
2. Singapore: Healthcare for the Elderly 2009 – report dated 06/09
3. Singapore: Healthcare Overview 2008 – report dated 11/08
4. Singapore: Biomedical Sector Overview 2007 – report dated 09/07

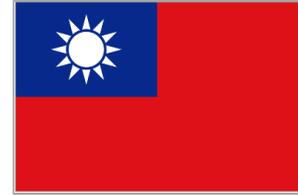
## U.S. Commercial Service Contact Information

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## Taiwan

*Capital:* Taipei  
*Population:* 23 Million  
*GDP:* US \$430 Billion  
*Currency:* New Taiwan Dollar  
*Language:* Chinese, Mandarin



### Summary

Taiwan offers U.S. suppliers a healthy market for healthcare products. Imports account for the bulk of Taiwan's market due to consumer perceptions of international brands being of superior quality. The Taiwan healthcare products market is expected to maintain continued growth as a result of market trends: the desire to pursue healthier lifestyles, a growing awareness of the health benefits of natural products, increasing purchasing power, and an aging population.

### Market Entry

Taiwan offers excellent opportunities for companies with the right product line, an aggressive local partner, and a proactive market entry strategy. Foreign-made products are normally imported to Taiwan through branch offices, agents/distributors, or trading companies. For the majority of small and medium-sized enterprises, the most cost effective way to enter the market is to find a local distributor or agent. Most local agents/distributors or trading companies request for exclusivity as Taiwan market is very small, geographically. However, foreign suppliers, which export bulk ingredients, could sell directly to various local buyers.

### Current Market Trends

Quality of life issues, particularly related to healthcare, are a growing concern for the people of Taiwan. With increased wealth and prolonged life expectancy, Taiwanese are seeking ways to maintain overall good health. As a result, an increasing number of people are spending more money to maintain a healthy life and prolonged life expectancy. The healthcare spending in Taiwan is expected to increase from 7.1% of its GDP in 2010 to 9% in 2015. More than 10% of the 23 million population in 2010 were people aged 65 and above and the percentage is forecasted to reach by 15% in 2020. The aging population is expected to create numerous business opportunities for healthcare product suppliers that provide special needs for the elderly. Local consumers are also increasingly knowledgeable about organic certification and natural standards. They generally more trust on foreign-made products than local brands as they perceive that international certification processes, especially those withheld by North American and European manufacturers, ensure product standards and quality.

### Main Competitors

Foreign suppliers have played an important role in the Taiwan market for healthcare products for years. U.S. firms dominate the market for the high-end sector. U.S. products have been recognized by local end-users as technologically superior, of high quality, and more durable than other competing products. Firms from Japan and European countries, such as Germany and the Netherlands, are also active in the Taiwan market. They have invested increased amount of money on promotional activities, such as massive advertising campaigns, free samples, and seminars, to increase their competitiveness. Local firms are the main sources of

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low-medium priced items and expected to remain less competition to foreign suppliers due to lacks of R&D efforts and technological know-how.

### Current Demand

Many high-quality imported products are accepted by local end-users and have enjoyed rapid market growth. Imported demand for elderly care and treatment for cancer, cardiovascular diseases, and diabetes remain strong. Procedures, such as plastic surgery/aesthetic and dental implantations, have been gaining popularity in Taiwan. This is driving the market demand for relevant equipment and supplies. Increased consumer interest in chemical free products is also leading to continued growth for the market sectors for natural and organic health and personal care products. Overall, the outlook for sales of imported products will continue to be bright as they are perceived to be superior to domestically-made items which are limited to low-medium market sector.

### Barriers

The Department of Health (DOH) is the local healthcare authority that regulates the importation of healthcare products. Under the Pharmaceutical Affairs Law, all products are required to obtain premarket registration approval from the DOH and import license from the Board of Foreign Trade before they can be imported to Taiwan. Since the DOH issues licenses only to locally registered companies, all foreign suppliers must submit required documentations and receive necessary approvals through their Taiwan importers or their Taiwan-registered subsidiaries.

### Trade Events

**Name of event:** MEDIPHAR Taipei – Taipei International Medical Equipment & Pharmaceuticals

**Date of event:** November 10-13, 2011

**Location:** Taipei World Trade Center Exhibition Hall, Taipei, Taiwan

**Website:** [www.taipeiTradeShows.com.tw/Mediphar](http://www.taipeiTradeShows.com.tw/Mediphar)

**Description:** This event provides U.S. firm with an effective promotional vehicle in the Taiwan market. It includes medical equipment & instruments, hospital supplies, medical materials, bio-tech products, pharmaceuticals, and rehabilitative products.

### Available Market Research

Taiwan: Personal Care Products (2010)

Taiwan: Natural Products Market Update (2011)

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## Internet Guide to Federal Export Resources

Website	Description	Address
U.S. Department of Commerce's Global Healthcare Team	Information on trade events, trade leads, HTS codes, newsletters and much more.	<a href="http://www.export.gov/industry/health/index.asp">http://www.export.gov/industry/health/index.asp</a>
U.S. Department of Commerce's U.S. and Foreign Commercial Service (USFCS) and the U.S. Government's Export Portal	Locate your local U.S. Commercial Service office in 102 U.S. cities and 145 U.S. Embassies and Consulates for more information about our international business services. Learn about export basics: Identifying your market, developing export plan, conducting market research, etc.	<a href="http://www.export.gov">www.export.gov</a>
International Trade Administration (ITA) of the Department of Commerce	Provides you access to ITA's valuable information and services regarding U.S. international trade policy.	<a href="http://www.trade.gov">www.trade.gov</a>
Trade Finance Guide: A Quick Reference for U.S. Exporters, 2008 edition	Offers the basics of numerous financing techniques, from open accounts, to forfeiting, to government	<a href="http://www.trade.gov/media/publications/pdf/tfg2008.pdf">www.trade.gov/media/publications/pdf/tfg2008.pdf</a>
Export Programs Guide; A Business Guide to Federal Export Assistance, 2009 edition	This publication is a comprehensive guide to federal programs that assist U.S. exporters, containing detailed descriptions of more than 100 programs offered by 20 different federal agencies, along with full contact information for each. It also includes a complete list of the nationwide network of more than 100 U.S. Export Assistance Centers that provide one-on-one counseling and information programs at the local level.	<a href="http://www.trade.gov/media/publications/abstract/epg2009desc.html">http://www.trade.gov/media/publications/abstract/epg2009desc.html</a>
U.S. Free Trade Agreements	Information on on-going and pending U.S. Free Trade Agreements	<a href="http://www.export.gov/fta">www.export.gov/fta</a>
Basic Guide to Exporting	This venerable textbook, first published in 1938, has been completely revised to better help U.S. businesses, especially small and medium-sized enterprises, face the challenges of today's global economy.	<a href="http://www.export.gov/basicguide/">www.export.gov/basicguide/</a>
Bureau of Industry and Security.	Learn about export control basics and how to apply for an export license	<a href="http://www.bis.doc.gov">www.bis.doc.gov</a>

## Sub Sector Matrix

	Medical Devices	Medical Devices - Monitoring Equip.	Medical Devices - Orthopedic	Medical Devices - Surgical	Medical Capital Equip.	Bio Medical	Clinical Chemistry and Diagnostics	Dental	Dietary Supplements	Drugs & Pharma	Health IT	Lab Equip.	Used Equip.	Veterinary	Consulting Services
<b>Europe</b>															
Austria	4	4	2	4	3	4	4	3	2	4	3	4	1	3	2
Belgium	3	3	3	3	3	3	3	3	2	2	2	3	1	2	1
Bulgaria	3	3	2	3	2	3	3	3	2	3	3	2	2	3	3
Czech Republic	3	3	3	3	2	3	3	3	2	3	3	3	2	3	2
Denmark	3	3	3	3	3	3	3	3	1	3	3	3	1	3	2
Finland	2	3	3	3	2	2	2	1	2	2	3	3	1	2	2
France	3	2	2	3	2	3	3	3	2	3	4	2	2	2	4
Germany	3	2	3	3	2	3	3	3	2	2	3	3	2	3	3
Greece	3	2	3	3	2	2	3	3	3	3	3	2	1	2	2
Hungary	3	3	2	2	3	2	2	3	2	3	4	2	2	2	3
Ireland	3	2	2	2	2	3	2	2	3	3	3	2	2	3	3
Italy	3	4	2	3	2	3	4	3	2	2	3	3	2	2	2
Netherlands	3	3	3	3	2	3	3	2	2	2	4	3	1	3	2
Norway	3	2	2	3	2	3	3	3	2	3	3	2	1	3	3
Poland	2	2	2	3	1	2	2	2	1	1	2	2	2	2	2
Romania	3	4	3	3	3	2	3	3	2	3	4	3	2	3	3
Slovak Republic	3	3	2	3	2	3	3	3	2	3	4	3	2	2	2
Spain	2	2	2	3	2	3	2	2	1	2	2	2	1	2	2
Sweden	3	3	3	3	2	3	3	3	2	3	4	3	1	2	3
Switzerland	3	3	3	3	2	3	3	3	2	3	3	3	1	3	2
Ukraine	2	3	2	3	3	2	3	3	2	3	2	3	2	2	1
United Kingdom	3	3	3	3	2	2	3	3	2	2	2	2	2	3	3
<b>Western Hemisphere</b>															
Argentina	3	3	3	3	3	3	3	3	2	2	3	3	2	2	2
Brazil	4	3	3	3	2	3	3	3	3	3	3	3	1	2	2
Dominican Republic	3	3	4	3	3	2	3	3	3	2	3	3	4	3	2
Ecuador	3	4	1	4	3	3	4	4	2	3	3	4	2	3	1
El Salvador	3	3	3	3	3	3	3	3	3	3	2	3	2	3	1
Mexico	3	3	4	3	3	3	2	3	1	3	4	3	4	3	2
Panama	4	4	4	4	4	3	4	4	2	3	4	4	2	2	3

	Medical Devices	Medical Devices - Monitoring Equip.	Medical Devices - Orthopedic	Medical Devices - Surgical	Medical Capital Equip.	Bio Medical	Clinical Chemistry and Diagnostics	Dental	Dietary Supplements	Drugs & Pharma	Health IT	Laboratory Equipment	Used Equip.	Veterinary	Consulting Services
<b>Middle East/ Africa</b>															
Israel	3	3	4	4	3	3	3	3	3	3	3	3	1	3	2
Turkey	3	2	3	3	2	3	4	4	3	3	4	4	1	3	3
<b>Asia/ South East Asia</b>															
Australia	4	4	4	4	4	4	4	4	2	3	3	4	1	4	3
China	3	3	3	3	3	2	3	3	3	2	3	4	1	<b>2</b>	<b>1</b>
India	4	3	4	4	4	3	3	3	3	3	3	3	3	3	2
Indonesia	3	3	3	2	3	3	3	3	3	2	2	3	1	2	1
Japan	3	3	3	3	3	3	3	2	2	2	2	3	1	2	2
Philippines	4	3	3	4	4	2	3	3	3	3	3	3	4	3	1
Republic of Korea	3	2	3	3	2	2	3	3	3	2	3	2	1	2	1
Singapore	3	3	3	2	3	3	3	3	3	2	3	3	1	2	2
Taiwan	1	2	2	2	3	3	3	1	2	1	2	3	1	2	1

**Rating Definitions**

- 1 Little to No Probability of success for U.S. exporters
- 2 There are more challenges than opportunities for U.S. exporters
- 3 There are more opportunities than challenges for U.S. exporters
- 4 Very high probability of success for U.S. exporters

## Certification Matrix

Country	Requires FDA Certification	Accepts FDA Certification	Requires CE Mark Certification	Accepts CE Certification	Other Certifications Required	Other Certifications Accepted	Certifying Body	Preferred Certified
<b>Europe</b>								
Austria	No	No	Yes	Yes	No	No	TueV Oesterreich - <a href="http://www.tuev.at">www.tuev.at</a>	
Belgium	Yes	No	Yes	Yes	No	No	Federal Agency for Medicines and Health <a href="http://www.fagg-afmps.be/en/human_use/health_products/medical_devices_accessories/">http://www.fagg-afmps.be/en/human_use/health_products/medical_devices_accessories/</a>	Yes
Bulgaria	No	Yes	Yes	Yes	WEEE/RoHS and GM	ISO	Bulgarian Drug Agency, Bulgarian Food Control Agency	Yes
Czech Republic	No	No	Yes	Yes	No	No	CE certification companies	CE
Denmark	No	No	Yes	Yes	No	No	The National Board of Health ( <a href="http://www.sst.dk">www.sst.dk</a> ); Danish Standard ( <a href="http://www.ds.dk">www.ds.dk</a> )	
Finland	No	No	Yes	Yes	No	No	VTT Expert Services Ltd.	
France	No	No	Yes	Yes	No	No	Yes Agency for Health Products Safety - AFSSAPS <a href="http://www.afssaps.fr">http://www.afssaps.fr</a>	Yes
Germany	No	No, but FDA certification will assist with CE marking	Yes	Yes	Depending on product, X-ray ordinance; recycling ordinance, WEEE and RoHs	N/A	EU Notified Bodies	N/A
Greece	No	No	Yes	Yes	Yes (for the high-risk products, from the relevant authorities)	No	EOF, ELOT, EKEVYL	Yes
Hungary	No	No	Yes	Yes	No	No	Institute for Medical Quality Improvement and Hospital Engineering <a href="http://www.emki-korhaztechnika.hu/site/index.php?lang=en">http://www.emki-korhaztechnika.hu/site/index.php?lang=en</a>	
Ireland	No	Yes - but not as final certification	Yes	Yes	EU Directives: *90/385/EEC, *93/42/EEC, 98/79/EC	N/A	Irish Medicines Board <a href="http://www.imb.ie">www.imb.ie</a>	N/A
Italy	Yes	Yes	Mandatory	Yes	Compliance EU Directives		Yes	CE Certification
Netherlands	No	No	Yes	Yes	No	No		
Norway	No	No	Yes	Yes	No	No	Nemko, Justervesenet, Nordic Dental, DnV	
Poland	No	No	Yes	Yes	Yes		CEN, CENELEC, URPL, and ETSI	CE mark is accepted in Poland for Class I and Class IIa (low risk) medical products
Romania	No	No	Yes	Yes	N/A	N/A	COMPETENT AUTHORITY: Ministry of Health Notified Body: OTDM Certificare	N/A
Slovak Republic	No	Yes, but it's insufficient	Yes	Yes	Product Specific	Yes	State Institute For Drug Control ( <a href="http://www.sukl.sk">www.sukl.sk</a> )	CE

Country	Requires FDA Certification	Accepts FDA Certification	Requires CE Mark Certification	Accepts CE Certification	Other Certifications Required	Other Certifications Accepted	Certifying Body	Preferred Certified
Spain			Y	Y	All products need to be registered with the Ministry of Health and have the CE Mark..	While other certifications may lend weight to registration process, there is no substitute for CE Mark.	Directorate General of Pharmacy and Medical Devices. Notified Body No. 0318 Agencia Española de Medicamentos y Productos Sanitarios Parque Empresarial " Las Mercedes", Edificio 8 Calle Campezo 1 28220 Madrid Contact: Sra. Carmen Abad Tel: + (34) 91 822 5261 /(34) 902 510 000 Fax: + (34) 91 822 5148 E-mail: sdaem@agemed.es/	
Sweden	No	No	Yes	Yes	No	No	Medical Products Agency (www.lakemedelsverket.se)	
Switzerland	No	No	Yes	No	No	No	Yes	No
Turkey	No	Yes; even though not a requirement, products with FDA certification are preferred in the market.	Yes	Yes	-	-	- Turkish Standards Institution (http://www.tse.org.tr/english/tsedefault1.asp) '- certifying bodies approved by the EU are accepted in Turkey	
Ukraine	No	No	No	No	Registration within the Ministry of Health	N/A	State Service for Medicinal Products and Medical Devices under the Ministry of Health of Ukraine	
United Kingdom	No	No	Yes	Yes	Medicines require marketing authorization from the MHRA*	N/A	*MHRA: Medicines and Healthcare products Regulatory Agency (www.mhra.gov.uk)	
<b>Western Hemisphere</b>								
Argentina	Yes				ANMAT		ANMAT	FDA
Brazil	Yes	Yes	Yes	Yes	Yes	Local Certifications	Anvisa	FDA, CE
Dominican Republic	No	Yes	No	Yes	No	Yes	N/A	N/A
Ecuador	No	Yes *	No	Yes	Sanitary Registration	Yes	Ministry of Health	No
El Salvador		Yes			Depends on products: Certificate of Free Sale; Certificate of Good Manufacturing Practices		National Health Council (Consejo Superior de Salud Publica - www.cssp.gob.sv); Ministry of Health (Ministerio de Salud Publica y Asistencia Social- www.salud.gob.sv)	
Mexico	Yes	Not Automatically	No	No	N/A	N/A	Cofepris	
Panama	No	Yes	No	Yes		Major countries	Panama Ministry of Health	

Country	Requires FDA Certification	Accepts FDA Certification	Requires CE Mark Certification	Accepts CE Certification	Other Certifications Required	Other Certifications Accepted	Certifying Body	Preferred Certified
<b>Middle East/ Africa</b>								
Israel	No	Yes	No	Yes	No	No	Ministry of Health	
<b>Asia/ South East Asia</b>								
Australia	No	No	No	Yes	TGA Certification in some circumstances depending upon product classification	No	TGA	
China	yes	no	yes	no			SFDA-China State Food and Drug Administration	
India	Yes	Yes	Yes	Yes	None	N/A	Central Drug Standard Control Organization (CDSCO) <a href="http://www.cdscsco.nic.in">http://www.cdscsco.nic.in</a>	N/A
Indonesia	Yes	Yes	Yes	Yes	Certificate of Analysis, Certificate of Free Sales			
Japan	No	No	No	No	No	No	Ministry of Health, Labour and Welfare (MHLW), Third Party Certification Bodies for devices with certification standards.	
Korea (South)	No	No	No	No				
Philippines	No	Yes	Yes	Acceptable international standards for equipment are recognized by local FDA and the CDRRHR	Legislation is pending.		Philippine Food & Drugs Authority (formerly Bureau of Food and Drugs) and the Center for Device Regulation, Radiation Health and Research (CDRRHR)	
Singapore	No	Yes	No	Yes	Needs some form of approved certification	MLHW (Japan), TGA (Australia), MDB (Canada)	Health Sciences Authority, Singapore	Yes
Taiwan	Yes	No	Yes	No	Yes	N/A	Yes	