

Medical Device Regulatory Requirements for the Czech Republic

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The Czech Republic is a member of the World Trade Organization. In 2004, the country also became a member of European Union (EU) and follows EU laws and regulations.

The Czech republic is a country of 10 million people. Life expectancy has grown in recent years to 72 years for men and 78.5 years for women. The most common cause of death is circulatory system problems followed by neoplasm. (The Czechs are heavy smokers, and the air in many industrial cities is somewhat polluted.)

To import medical devices to 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). This is mainly the responsibility of manufacturer. By the use of the CE mark the manufacturer proves that the product is in compliant with the requirements of EU Directive 93/42/EEC that sets technical requirements for medical devices. There are a few medical devices that do not need to obtain the CE mark but their number is limited. Typically customized medical devices or medical devices designated for clinical trials.
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). The Declaration of conformity must contain the following information: product identification; the EU directives with which the product complies; standards used to verify compliance with the directives; name of the Notified Body used (if its use is required by applicable directives); signature on behalf of the manufacturer or the authorized representative; and the manufacturer's name and address. Declaration of Conformity applies to all EU countries.
4. The Czech importer has a **notification duty at Ministry of Health** (forms are available on www.mzcr.cz/kat/67).

The same procedure and rules apply for the importation of new, used and refurbished medical equipment. Eastern Europe has been considered a potential market for use of refurbished equipment. However, there is a lack of awareness amongst customers of the advantages refurbished systems have over used systems in the Czech Republic. Recently, it seems that the Czech Republic prefers top-level new technologies. This can be the case especially in connection with preparation of International Clinical Research Center project in Brno. There are cases of repeated use of single-use medical devices (however, mainly in cases where this is indicated as an option by the manufacturer).

There are no restrictions for public health institutions with regard to purchasing of refurbished medical devices. All health institutions can only purchase medical devices and equipment that are certified by the Czech Ministry of Health for sale in the Czech Republic.

Labeling and Marking Requirements:

Labeling must be in the Czech language. Information must include the name of the product, names of producer and importer, country of origin, and information necessary for the safe use of the medical device. Instructions for use are obligatory except for medical devices of class 1 and 11a unless instructions for use are necessary for safe use of the medical device. In addition, international norms for warning labels apply. Czech importers/distributors are responsible for the correct labeling of products that are put on the Czech market, and can typically advise the U.S. exporter of specific requirements regarding labeling and marking.

Customs Duties:

The Czech Republic is an open, highly developed market with liberal policies and intense competition. While imports from the EU are exempt, products from non-EU countries are subject to import duties. Customs duty rates are updated annually and are harmonized within EU countries. Duty on medical equipment is, in most cases, zero percent. The value-added tax (VAT) applies to all goods, both domestic and foreign, sold within the Czech Republic. The majority of medical equipment falls into the 5 percent VAT category, the remainder has a 19 percent VAT.

The metric system of weights and measures is standard in the Czech Republic. Czech is the official language in the Czech Republic. More than half of the company representatives are able to communicate in English or in German.

Market Entry:

A recommended strategy for a U.S. company interested in penetrating the Czech medical equipment market would be to find a local partner/representative or to open an office in the country. Without a local representative and regular contact with customers, insurers and government representatives, it is very difficult to succeed in the market. A U.S. company can stimulate further sales by working with Czech partners to create effective marketing campaigns. U.S. firms can spur sales through trade shows, in-country promotions, and advertising. Main competitive factors are price, quality of products, and quality of service. Personal contacts with customers are extremely important.

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Legal rules:

EU Directive 90/385/EEC on active implant medical device – In Czech law, government ordinance n.154/2004 Coll.

EU Directive 93/42/EHS on medical device – In Czech law, government ordinance n.336/2004 Coll.

EU Directive 98/78/EEC on in-vitro diagnostic medical device – In Czech law, government ordinance n. 453/2004 Coll.

Other EU directives information can be found under EU section of the report.