

What requirements should your medical and laboratory devices comply with to be allowed on the European market?

To place your medical devices on the European market, you have to comply with various requirements. Most importantly, you need to comply with the European Medical Devices Directives to obtain CE marking. Other important legal requirements concern restrictions on the use of substances, packaging and liability. Voluntary commitment to environmental and Corporate Social Responsibility policies is becoming increasingly standard on the European medical devices market.

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1. What legal and non-legal requirements must your product comply with?

Medical Devices Directives

Medical devices for the European market require [CE marking](#). To obtain this certification, your product must comply with [Directive 2007/47/EC](#) on the safety and performance of medical devices. This Directive aims to protect human health and safety, and ensures that medical devices can be freely and fairly traded throughout Europe. It consists of three specific Medical Devices Directives:

- [Medical Devices Directive 93/42/EEC](#);
- [In Vitro Diagnostic Medical Devices Directive 98/79/EC](#);
- [Active Implantable Medical Devices Directive 90/385/EEC](#).

To obtain CE marking, you should:

1. determine the [classification of your medical device](#) (Class I/II/III);
2. implement a quality management system, such as [ISO 13485](#);
3. draw up a [Technical File for Class I/II devices](#) or a [Design Dossier for Class III devices](#), with detailed information on their design, function, composition, use, claims and clinical evaluation;
4. appoint an [Authorised Representative](#) in the European Union;
5. apply for an audit by a [Notified Body](#) to receive a CE Marking Certificate;
6. draw up a Declaration of Conformity stating that your device complies with the relevant Directive;
7. affix the CE marking to your medical device.

Labelling

The Directives also include requirements for the labelling of medical devices. Labels must include:

- the name or trade name and address of the manufacturer and the authorised representative;
- information required to identify the device and the contents of the packaging;
- where appropriate, the word STERILE and the method of sterilisation;
- where appropriate, the batch code preceded by the word LOT or the serial number;
- where appropriate, the date by which the device should be used;
- where appropriate, an indication that the device is for single use;
- where appropriate, the statement “custom-made device”;
- where appropriate, the statement “exclusively for clinical investigations”;
- any special storage and/or handling requirements;
- any special instructions on how to use;

- any warnings and/or precautions to be taken;
- the year of manufacture for certain active devices.

Revision of the Medical Devices Directives

The European Commission is revising the three existing Directives. The aim is to “achieve a suitable, robust, transparent and sustainable regulatory framework” for the development of safe, effective and innovative medical devices.

Two European Regulations are replacing the above Directives:

- [Medical Devices Regulation](#);
- [In Vitro Diagnostic Medical Devices Regulation](#).

These Regulations are expected to be implemented by 2020.

The main changes in the Regulations for medical device manufacturers include:

- scrutiny procedure - before approval, a specially selected committee of authorities from European Union Member States will be able to review products during the CE marking process;
- Common Technical Specifications (CTS) - the European Commission will be able to create CTS for all medical devices;
- Unique Device Identification (UDI) - a UDI system to identify different types of devices will be implemented and the [European Databank on Medical Devices](#) (Eudamed) will be expanded;
- reclassification - certain devices will be reclassified as Class III devices, requiring a Design Dossier;
- reusability - all medical devices will be considered reusable, unless scientific evidence supports a designation as single use.

The most important changes in the Regulations regarding [Notified Bodies](#) include:

- Special Notified Bodies - the European Medicines Agency will designate Special Notified Bodies to issue CE marking certificates for high-risk devices such as implants;
- Assessment Committee for Medical Devices (ACMD) - the ACMD, a new expert body, will perform additional case-by-case checks of conformity assessments;
- unannounced audits - Notified Bodies will conduct unannounced audits of manufacturers;
- Notified Body audits - competent authorities will jointly perform audits of Notified Bodies to ensure compliance with the new regulation.

Tips:

For more information on how to implement the Medical Devices Directive, see their accompanying [guidance documents](#).

Consult the European Commission’s [Blue Guide](#), which explains how to implement European product rules on medical devices.

For details on CE marking, see BSI’s [Guide to Notified Bodies](#) and Emergo’s [CE Marking Process Chart](#).

Keep up to date on [the revision of the Medical Devices Directives](#).

For more information on the revision, see for example the whitepaper [Changes to EU Medical Device Legislation - What you need to know](#).

Contact [Open Trade Gate Sweden](#) if you have specific questions regarding access requirements in Sweden and the European Union.

Restricted substances

To prevent environmental damage and protect human health, the European Union has restricted the use of certain chemicals. Usually, your European buyer is responsible for compliance with the legislation on chemical substances. As a result, you need to provide your buyer with details on which substances you use in your products.

Tip:

Ask your buyer how they prefer to receive this information; for example, via [Material Safety Data Sheets](#) (MSDS) or by the use of software in which you declare the chemical content of your product.

Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (REACH)

The European Union restricts the use of certain chemicals via the [Registration, Evaluation, Authorisation and Restriction of Chemicals \(REACH\)](#) Regulation. This regulation defines “substance of very high concern” (SVHC), which are:

- category 1 or 2 Carcinogenic, Mutagenic or Reprotoxic (CMR);
- Persistent, Bioaccumulative and Toxic (PBT);
- very Persistent and very Bioaccumulative (vPvB); and/or
- raising “an equivalent level of concern”.

Medical devices must comply with the limits set for these substances. For example, REACH restricts the use of mercury in measuring devices such as thermometers and barometers.

Restriction of Hazardous Substances (RoHS)

If you produce electrical and electronic equipment (EEE), the [Restriction of Hazardous Substances \(RoHS\)](#) Directive applies to your medical devices. RoHS restricts the use of six hazardous substances: lead, mercury, hexavalent chromium, polybrominated biphenyls (PBB), polybrominated diphenyl ethers (PBDE) and cadmium.

The main difference between RoHS and REACH is that RoHS bans the aforementioned substances that are present in electrical equipment. REACH, however, covers all chemicals including those used to make a product. This can include materials, solvents, paints, chemicals, and more.

As with the Medical Device Directives, you prove your compliance with RoHS via [CE marking](#)..

Waste Electrical and Electronic Equipment (WEEE)

The [Waste Electrical and Electronic Equipment \(WEEE\)](#) Directive regulates the disposal of Electrical and Electronic Equipment (EEE). To prevent environmental effects of hazardous substances, it requires European producers of EEE to set up and participate in product take-back schemes. This requirement also affects you, because your product design for the European market should make reuse and recycling possible.

Devices whose recovery and recycling would carry a contamination risk are exempt from this legislation; for example, blood glucose monitors.

Tips:

Consider using tools for the registration of chemical substances. An example of a data collection tool

for compliance with legislation on chemical substances is [BOM check](#) (paid service). This is a collective data system developed to collect chemical composition information from suppliers.

To determine how REACH affects your business, see our [REACH study](#).

Check the REACH [candidate list of Substances of Very High Concern](#). These substances might be prohibited in the future, so you might do better to stop using these substances.

Check your buyer's chemicals policy, as some companies have requirements regarding the use of chemicals that exceed legal obligations.

Read more about [REACH](#), [RoHS](#) and [WEEE](#) in the EU Export Helpdesk.

Packaging

Sterile packaging

Sterile packaging is a key requirement for medical devices. [ISO 11607 - Packaging for terminally sterilized medical devices](#) is the main standard in this area. It consists of two parts:

- 11607-1 - requirements for materials, sterile barrier systems and packaging systems;
- 11607-2 - validation requirements for forming, sealing and assembly processes.

ISO 11607 is a voluntary standard. However, the European medical device industry considers compliance a necessity to meet the requirements of the Medical Devices Directives.

Packaging material

The general European [Packaging and Packaging Waste](#) Directive also applies to medical devices. This Directive regulates the management of packaging and packaging waste. It prevents or reduces the impact on the environment; for example, by restricting the use of certain heavy metals.

In addition, European rules on [Wood packaging materials \(WPM\)](#) restrict the use of wooden packaging for transport; for example, packing cases, boxes, crates, drums, pallets, box pallets and dunnage.

Tip:

Read more about [European packaging legislation](#) in the EU Export Helpdesk, as well as ITC's additional information on [packaging for exporters](#).

Liability

The [Product Liability Directive](#) applies to all goods marketed in Europe. It states that European producers or importers have to provide compensation if a defective product causes damage to consumers or their property. Although your European buyers are responsible for your products, they may pass on a claim to you.

Tip:

For more information, see our study of [liability](#).

2. What additional requirements do buyers often have?

Compliance with voluntary product standards for quality and safety

Buyers often ask their suppliers to deliver products according to voluntary standards. The large number of different standards makes it hard to determine which ones are applicable and relevant. The standards are often harmonised, overlap and/or complement each other. Which one is the best to follow depends on your specific situation; for example, the product and market(s) that you want to target. In Europe, [ISO standards](#) and [EN standards](#) are the most prevalent.

Tips:

Be sure that you understand all standards applicable in a country, or mentioned in an inquiry, before making an offer.

For more information about specific standards, see our factsheets about specific products; for example, [Exporting electro-diagnostic apparatus to Europe](#).

Consult the websites of the [EU standardisations bodies](#) to determine which quality standards are most suitable for the product and market(s) that you want to target.

[Search for ISO standards](#) for your specific products.

Environmental management

The European medical devices industry is committed to sustainability. This commitment is reflected both in European legislation and in voluntary measures. As buyers wish to minimise the environmental impact of their business, they are looking for green manufacturing methods and energy-saving concepts.

A popular category of standards among European buyers is [ISO 14000 - Environmental management](#). These standards provide practical tools for companies to manage their environmental responsibilities.

Especially relevant standards are:

- [ISO 14001](#) - framework for an environmental management system (EMS), certification to which assures buyers that you measure and improve your environmental performance;
- [ISO 14971](#) - risk management system for medical device manufacturers, to protect patients as well as operators, other people, other equipment and the environment.

Tips:

Study the possibilities and benefits of [ISO 14000](#) in general, as well as [ISO 14001](#) and [ISO 14971](#).

Stay updated on environmental developments in the medical devices industry; for example, via [MedTech Europe](#).

Corporate Social Responsibility

European buyers are increasingly selecting suppliers on their ethical and social responsibility measures. This development drives the popularity of [Corporate Social Responsibility](#) (CSR) in the medical device industry. CSR focuses on a responsible policy regarding the three Ps: Planet, People and Profit.

Socially responsible European buyers require you to adhere to their code of conduct, but you may also have your own CSR policy in place. [ISO 26000 - Social responsibility](#) provides guidance on how to incorporate CSR into your business.

For a competitive advantage, you can obtain certification in CSR-related fields; for example:

- [SA8000 - Social Accountability](#);
- [OHSAS 18001 - Occupational Health and Safety Management](#).

Tips:

Read more about [Corporate Social Responsibility in practice](#) on the website of the European Commission.

Use the [CSR Risk Check](#) to study what international CSR risks apply to your product and country. The tool also provides options to manage these CSR risks.

Set up a good-quality CSR policy for your company, covering your impact on society as well as the environment.


Clearly advertise your commitment to CSR; for example, on your website and in your brochures. Use quotes from your CE audit report.

Discuss with your buyer whether they have additional CSR requirements to which you should adhere.


For a [full overview of certification schemes in the medical devices industry](#), consult the ITC Standards Map.

Please review our [market information disclaimer](#).

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