CE Marking Guide for Medical Devices in the European Union

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Contents

What is CE marking?

CE marking is a symbol that consists of "CE, " which is the abbreviation of the French phrase "Conformité Européene" meaning "European Conformity". The term initially used to describe "CE" was "EC Mark" but it has officially been replaced by "CE marking" according to the EU Directive 93/68/EEC. CE marking is used in all EU official documents, although you will still see "EC Mark" being used in common language. If you are using EC Mark in your documentation, you should change that terminology to CE marking in the future.

The letters 'CE' appear on many products traded on the Single Market in all the member states of the European Union plus Iceland, Liechtenstein, Norway and Switzerland. Simply put, The CE mark is a mandatory compliance mark, informing the consumer that the product is compliant with all applicable EU directives and regulations where the CE mark is required.

The Single Market was established in 1993 and is still considered one of the most significant achievements of the European Union. The main goal was to ensure the movement of goods and services freely within all the member states and to establish high safety standards for consumers. The CE mark indicates that goods and services do not need to be verified when shipping into another member country. To further support this movement, in April 2011, the Single Market Act was established to boost growth and strengthen confidence in the economy even further.

Why is CE marking important?

CE marking is required for many types of products, not just medical devices. The CE symbol can be found on bicycle helmets, toys, laptop batteries, wheelchairs, construction equipment, gas appliances and cell phone chargers - to name a few. CE marking is required for products manufactured anywhere that are sold in the EU, and only for those products for which EU specifications exist and require CE marking. The CE marking signifies that the product has been found to meet the general safety and performance requirements (GSPRs) of the European health, safety and environmental protection legislation and allows the product to be sold in the EU.

CE marking responsibilities

Manufacturer responsibilities for CE marking

Medical device manufacturers are responsible for properly and legally CE marking products before they leave the warehouse.

Most Class II and III medical devices, along with IVDs and some Class I devices, require a conformity assessment performed by a Notified Body to ensure that all legislative requirements are met before it can be placed on the market. Manufacturers of most Class I devices can self assess conformity. This process needs to demonstrate that all the legislative requirements are met, including any testing and inspections, and that all necessary certifications are obtained.

The European Commission lists 6 steps that manufactures should follow to affix a CE marking to their devices:

1. Identify the applicable directive(s) and harmonised standards - see the following:
    - Medical Devices
    - In Vitro Diagnostic (IVD) devices
    - Implantable Medical Devices

2. Verify product specific requirements using the essential principles identified in the above standards.

3. Identify whether an independent conformity assessment by a Notified Body is necessary. Notified bodies will be required to verify compliance with relevant Essential Requirements for most medical devices classified as IIa, IIb, or III - along with sterile class I devices. See the Notified and Designated Organisation (NANDO) database for available notified bodies.

4. Test the product and check its conformity.

5. Create and keep available the required technical documentation.

6. Affix the CE marking and create the EU Declaration of Conformity.

Importer responsibilities for CE marking

If you are importing medical devices into the EU, it is your responsibility to review all the technical documentation and maintain a copy, or to make sure that it's available to you upon request.

You should verify:

- That the device has been CE marked and that the EU declaration of conformity has been completed.
- That the manufacturer has designated and established an authorized representative.
- That the device is labeled appropriately and contains instructions for use (IFU).
- When applicable, that a UDI has been assigned to the product.
- Whether or not the product is registered in EUDAMED (registration is currently voluntary).

Take action:

- List your name and address on the device or packaging, in addition to the manufacturer's information.
- Keep records of complaints, non-conformities, recalls, etc. on file.
- Report any noticed non-conformity or product complaints from end users to the manufacturer and authorized representative immediately.
- Maintain a copy of the EU declaration of conformity and any other relevant certificates.

Distributor responsibilities for CE marking

If you are a distributor, you are responsible for reviewing the technical documentation provided to you so that you can verify the product is safe to put on the local market. You must also be sure the product is labeled correctly with the CE marking symbol clearly visible. The technical file documentation contains all of the information that is necessary to show conformity of the product to the applicable requirements.

You should verify:

- That the device has been CE marked and that the EU declaration of conformity has been completed.
- That the device includes all the appropriate labeling, including instructions for use.
- That if imported, the importer has complied with all the EU regulations.
- When applicable, that a UDI has been assigned to the product.

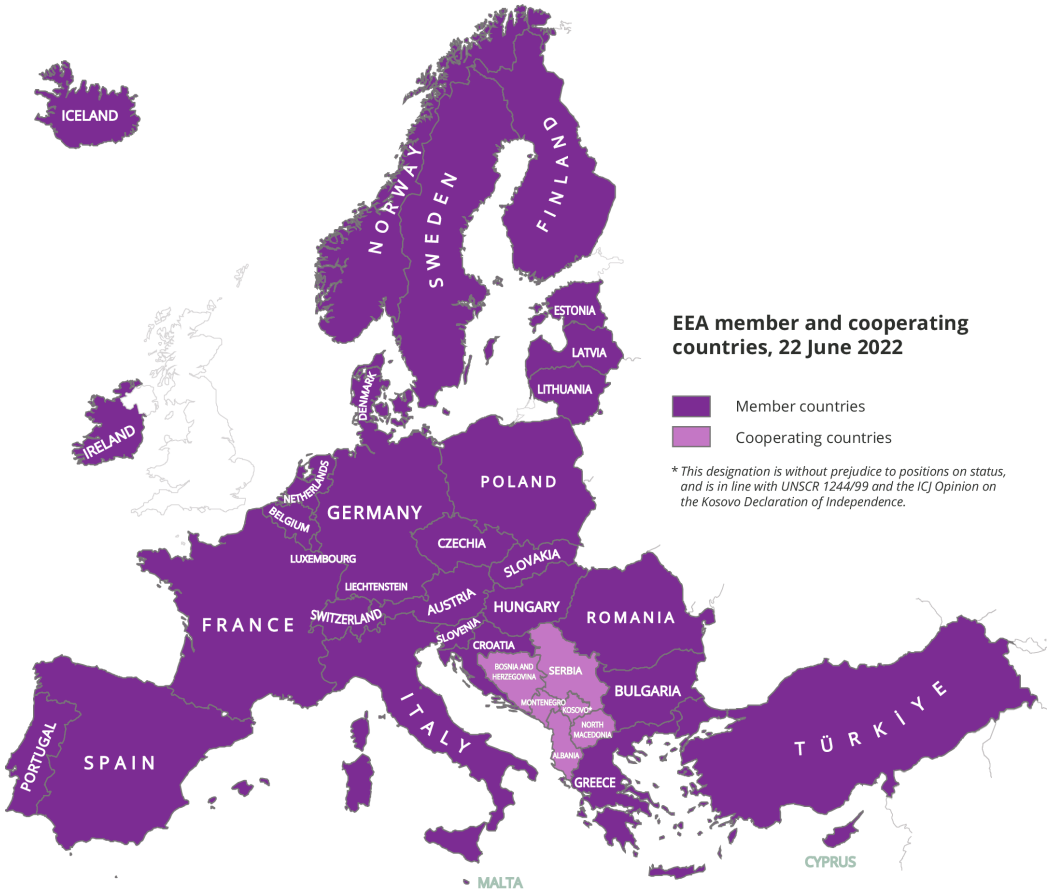
Take action:

- Report any noticed non-conformity to the manufacturer, importer, and authorized representative immediately.
- If a product appears to be out of compliance to the regulations and could pose a serious risk, the information should be reported to the Competent Authority, and to the manufacturer, importer and authorized representative.
- Any complaints or reports from end users about the product should be reported to the manufacturer and, if necessary, to the importer and authorized representative.

Important note: If the importer or distributor markets the product under their own company name, then they become responsible for CE marketing, and take over that role from the manufacturer.

What countries require or accept CE marking?

CE marking is mandatory when importing products into the European Union, which is part of the larger European Economic Area (EEA). The EEA Agreement, established in 1992 and made official in 1994, is an international agreement that enables the extension of the European Union's single market to non-EU members. It consists of the 27 EU countries plus the four European Free Trade Association (EFTA) countries - Iceland, Liechtenstein, Norway and Switzerland. Today, the EFTA has 29 Free Trade Agreements (FTAs) with 40 countries and territories outside the EU. Because these countries operate in the single market, this allows free movement of goods and services across all of the EEA.



Source: European Environment Agency (EEA).

Which medical devices require a CE mark?

All medical devices sold in the EU require a CE mark. While a CE mark is not required for items such as chemicals and pharmaceuticals, it can be required for combination devices and medical device software. For these two situations, how do you know if your product requires a CE mark?

- Determining the correct categorization and regulatory strategy for a combination device that includes both drug and device components can be complex. The primary mode used by the product in meeting its intended use ultimately determines whether the product is regulated as a device or as a drug. A product whose primary purpose is to deliver a drug, such as a pre-filled syringe, is regulated as a drug. A product in which a drug is ancillary to the purpose, such as a drug-eluting stent, is regulated as a Class III medical device requiring a CE mark.
- CE marking is required for all software sold in the European Union for a medical purpose. All software used for improving the healthcare delivery process is considered Medical Standalone Software (sometimes referred to as Software as a Medical Device), but software used as an accessory to an existing device may require its own CE mark.

If your product falls outside the CE marking scope of the regulations, you can still choose to voluntarily affix a CE marking as an indication that your product complies with the European legislation.

Technical documentation

What is technical documentation?

The manufacturer of a CE-marked product is required to create a technical file which contains all information necessary to demonstrate that the product complies with relevant directives and regulations. This technical documentation is required in order to ensure products traded in the EU meet high health, safety, and environmental standards. You can create your own technical document format that suits you, but you do need to list all the requirements, their applicability to your product, industry standards used for design, and the rationale used to decide if a regulation is a necessary requirement. With the implementation of EU 2017/745 (MDR) and 2017/746 (IVDR), essential requirements are now referred to as General Safety and Performance Requirements (GSPR's) in Annex I of both regulations. These GSPR's are a checklist with a set of requirements that must be followed for each medical device you want to bring to market. Read more in our EU MDR and IVDR general safety and performance requirements guide.

Who prepares the technical documentation?

According to the EU MDR 2017/745 and EU IVDR 2017/746, an EU representative is mandatory for non-European manufacturers wishing to sell medical devices and IVDs on the European market. The manufacturer (or hired consultant/agency) is generally responsible for compiling the technical documentation - often referred to as the "tech file" - which includes information on the design, manufacture, and operation of your product.

The tech file must be completed and available upon request to government authorities before the product is placed on the market. If you don't have an established company office in Europe, you must appoint an Authorized Representative (AR) who would then be responsible for assisting you in the CE marking process. At a minimum, they will be required to keep a current copy of the tech file or have immediate access to it electronically. The AR is also known as an EC REP and acts as the main point of contact between the manufacturer, Notified Body, and national Competent Authorities. If a Notified Body assessment is carried out, the CE marking must be accompanied by the identification number of the respective Notified Body. Contact information for your authorized representative must be displayed on your labeling, instructions for use, or outer packaging to show the shared ownership.

You will need to compile a technical file for each product that you intend to market and sell. For example, if you want to register a Class IIa CPAP mask and a Class III x-ray machine, you will need to create two separate technical files because they fall into different classifications and are two entirely different products. However, you may be able to create one technical file for all your CPAP masks, but only if they share the same intended use, are in the same classification, and meet the same requirements. As an example, you manufacture a gel CPAP mask, the same gel CPAP mask with a head strap, and also offer three sizes of each one. Since they are the same mask, but one comes with a head strap, both could be in the same technical file, as long as the head strap does not change the intended use, classification, or design of your product.

Since you will most likely be placing products on the market at different times, you need to be very detailed in documenting the effective market "start date." Color coded Excel sheets are the most common method used to track registrations, not only in Europe but for other countries as well. This can quickly become extremely time-consuming and challenging to maintain. More and more, medtech companies are turning to Regulatory Information Management (RIM) systems to manage product registrations, country-by-country. For example, you may have a spreadsheet that looks something like this:

	A	B	C	D	E
1	**Market Entrance Date**	**Certification expires**	**Product**	**Where Registered?**	**When to start renewal?**
2					
3	February 1, 2021	Feb 1 2025	Gel CPAP Mask	Europe	January 1, 2025
4	January 14, 2018	Jan 14 2022	Gel CPAP Mask	Canada	December 14, 2021
5	March 17, 2018	March 17, 2022	Gel CPAP Mask	USA	February 17, 2022
6					
7	March 17, 2021	March 17, 2025	Super Gel CPAP Mask	Europe	February 17, 2025
8					
9	January 1, 2022	January 1, 2026	Plastic CPAP Mask	Europe	December 1, 2025
10	May 5, 2018	May 5, 2022	Plastic CPAP Mask	USA	April 5, 2022
11					

How do you keep track of all your products in that table, and know when you need to start the renewal process before one expires and puts your company at risk of a non-conformance? It's very easy to make a manual mistake each time you update the file, and it's also creating risks for your company. RIM systems will track registration information and ensure that required changes due to regulatory or standards updates don't fall through the cracks.

What does technical documentation include?

GSPR	Description	Applicable?	Methods Appliced	Standards & Solutions	Evidence
7	Devices shall be designed, manufactured and packaged in such a way that their characteristics and performance during their intended use are not adversely affected during transport and storage, for example, through fluctuations of temperature and humidity, taking account of the instructions and information provided by the manufacturer.	Yes	Design considers packaging requirements. Packaged product has been verified through shipping and transit testing. Product was stored at extremes of temperature and humidity.	EN ISO 13485 QMS EN ISO 15223-1 Labeling ISTA 2A Testing	Design procedure XXXXXX, rev XX located in document management system QMS certificate XXXXXXX Package design drawings XXXXXXX, rev XX located in document management system Product label XXXXXXX, rev XX found in section XX of Tech File XX ISTA 2A test report title XXXXX, dated XX/XX/XX found in section XX of Tech File XX Storage condition test report title XXXXX, dated XX/XX/XX found in section XX of Tech File XX
11.5	Devices labeled as sterile shall be processed, manufactured, packaged and, sterilised by means of appropriate, validated methods.	No	N/A - This does not apply to this device (device id XXXXX) as it is not a sterile device and cannot be sterilised.	N/A - This does not apply to this device (device id XXXXX) as it is not a sterile device and cannot be sterilised.	N/A - This does not apply to this device (device id XXXXX) as it is not a sterile device and cannot be sterilised.

Technical documentation must be kept from the first date of placing your product on the market until several years after the last product is sold as follows:

- Implantable device = 15 year retention period
- In vitro device = 10 year retention period
- Medical device = 5 year retention period

Again, this is the responsibility of the manufacturer or the Authorized Representative, depending upon who has the established business in the EU.

What are the costs associated with CE marking?

One of the biggest issues that a medical device manufacturer will face is the cost of doing business in Europe. You have determined that you want to distribute to Europe and that your product needs a CE marking, so now what? Finding the true cost of the process is not easy and has many variables. The costs will depend on the kind of product and the certification procedure process.

Some of the factors to consider when estimating your cost are:

- What is the intended use of the product?
- What is the nature and risk level of the product?
- Which directive (or directives) apply to your product?
- Which legislation/regulation(s) apply to your product?
- What are the Essential Safety and Health Requirements related to your product?
- Do you have the internal regulatory resources to support the process?
- Will a third-party certification agency be required to assist with the process?

As the manufacturer, you should also consider additional questions that may incur costs such as:

- Can you self-certify your product, or do you need to hire a Notified Body? (See the EU Commission's information for manufacturers)
- Can any of the testing be done in-house as opposed to sending it to a vendor?
- Can you use parts / components that are already CE marked?

If you, as the manufacturer, are able to carry out the conformity assessment yourself, you won't have to pay any fees to apply CE marking to your product. However, if you are required to use the services of a Notified Body, then you will have to pay the Notified Body for any services they provide.

A Notified Body is a third-party organization accredited by a European Competent Authority, that reviews medical device technical documentation against the medical regulations and harmonized standards. As a medical device manufacturer, you can select which Notified Body you want to do the assessment for you. See the NANDO database for a list of Notified Bodies.

Once you have determined that you need a conformity assessment from a Notified Body and/or the services of an Authorized Representative, you should evaluate multiple options and gather quotes. Compare these quotes to help you decide if you will also need consultants, test labs, government agencies, etc. But do your due diligence and evaluate the specific capabilities of each provider, along with their ability to provide the services you need in a timely manner. Remember, the CE mark is about providing evidence that your product complies with all the applicable requirements. If your CE compliance ever gets challenged, regulatory authorities will resort to the reliability of test certificate(s) and reports.

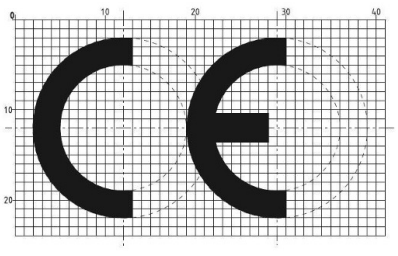
How do you apply the CE marking?

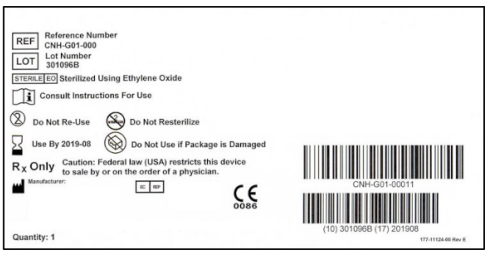
The CE marking must be visible and legible. It must consist of the initials "CE" and both letters should have the same vertical dimension and be no smaller than 5mm (unless specified differently in the relevant product requirements).

If you want to reduce or enlarge the CE marking on your product, you need to respect the proportions of the two letters. If the initials remain visible, the CE marking can be displayed in different colors and even hollow text.

If the CE marking cannot be placed directly on the product itself, you can add it to the packaging or on any accompanying documents. If your product is subject to several EU directives/regulations which require CE marking, then the accompanying documents must state that your product conforms to all applicable EU directives/regulations. A CE mark is accompanied by the 4 digit code of the applicable Notified Body. In the case of Class I devices that are self-certified, no NB code is included.

You can download the CE marking image files directly from the EU webpage.





Product label with CE mark

Does the CE mark expire?

CE certificates issued by Notified Bodies are generally valid for three years, but the validity period may only be one year for some high-risk devices. Nonetheless, the status of your CE certification is dependent on maintaining your quality system certification. Ultimately, it is your responsibility to manage your product registrations.

The EC Declaration of Conformity and CE mark are valid for as long as your product meets the applicable health, safety, and environmental requirements of the applicable directive(s). If you have changes in product design or intended use or characteristics (among others), you may be required to have the product retested (or at a minimum perform a gap analysis) to ensure it is still in compliance with the appropriate directive(s). It's always best to check with the European Union website for the most up-to-date information.

Do I need to CE mark my software?

If you want to do business in Europe, you must first assess if your software qualifies as a medical device. Since medical device software (MDSW) is now classified as an active medical device, you will need to apply the same steps you would use for a device. As a manufacturer of medical device software, regardless of whether you outsource the manufacturing process or choose to do that in-house, you are responsible for acquiring the CE marking.

Where do I put the CE mark on software?

According to Decision No 768/2008/EC, Chapter R3, Article R12:

"The CE marking shall be affixed visibly, legibly, and indelibly to the product or to its data plate. Where that is not possible or not warranted on account of the nature of the product, it shall be affixed to the packaging and to the accompanying documents, where the legislation concerned provides for such documents."

Final steps

Once you have successfully passed your audit, you should be issued a CE marking certificate along with an ISO 13485 certificate that establishes that your quality management system (QMS) is compliant with European standards.

The final step is to create a Declaration of Conformity. This is a legally binding document which declares that your device meets all the essential requirements as laid out by EU MDR or EU IVDR and any other applicable regulatory standards. There is no single format for Declarations of Conformity, but the document should be written on company letterhead and include the information described below.

EU DECLARATION OF CONFORMITY

Statement of Conformity:	Use a statement along the lines of "This declaration of conformity is issued under the sole responsibility of [manufacturer] in compliance with Article 19 of EU MR 2017/745. We hereby declare that the medical device specified below meets the provision of Annex IV of Regulation EU MDR 2017/745 for medical devices."
Manufacturer:	Manufacturer's name Manufacturer address
European Representative:	Authorized representative name Authorized representative address
Product:	Product name Product model number Product part number
Classification (MDR)	Product classification under MDR with reference to rule applicable rule number in Annex VIII.
Conformity Assessment route:	Annex IX, conformity assessment based on quality management system and on assessment of quality documentation. Mention the conformity route as per MDR article 52.
Notified Body:	Notified Body name Notified Body address
Harmonized Standards:	EN ISO 13485:2016 and any other applicable standards
Common Specifications:	List any applicable common specifications are note "N.A."
Certificates issued:	List name, number and validity dates for all certificates (use a table)
Signatures:	Include name, function, place and date of issue.

About Rimsys

Rimsys is bringing regulatory order to the medtech industry. The Rimsys Regulatory Information Management (RIM) platform digitizes and automates regulatory activities, freeing teams from inefficient administrative work, and helping them confidently establish and secure global regulatory compliance. Unlike complex spreadsheets, or expensive consultants, Rimsys centralizes all regulatory information, automates submission processes, and monitors relevant expirations, standards, and global regulations. Overburdened regulatory affairs teams struggle to keep pace with the increasingly complex global landscape. Rimsys streamlines all regulatory activities in an integrated platform, helping MedTech companies get to market more quickly and reduce risk of non-compliance, product recalls, and unexpected expirations. For more information about Rimsys or to get a free demo of our platform, please visit rimsys.io.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