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Current Trends in Pharmacy and Pharmaceutical Chemistry

Journal homepage: https://www.ctppc.org/

Review Article

CE marking – An insignia for medical devices in european union

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ARTICLE INFO

Article history:
Received 21-11-2021
Accepted 09-12-2022
Available online 04-04-2023

Keywords:
Medical devices
Technical file
Combination products
IVD selfcertified devices
Quality

ABSTRACT

Now a day's medical devices are being used at greater extent in many countries. Medical devices are marketed according to the compliance with the requirements of various regulatory bodies. For commercialization of medical devices in the European Union, a CE Mark certificate is needed. CE is a "European Conformity" is the translation of the French term "Conformité Européenne". It also significantly reduces the time and resources need to compile application for registration, easy in the self-declaration for medical devices, simplifies exchange of regulatory information between regulatory authorities and playing field good for export market CE marking is the medical device manufacturer's claim that product meet all regulatory requirements for all relevant European Medical Device Directives. The CE mark is a legal requirement to place a device on the market in the EU. The intension of this presentation is to know about the regulatory requirements and to analyze the requirements for obtaining CE marking for medical devices and simplifying CE marking procedures for various medical devices. It is given based on the description of research design. The marking certification process undergoes six steps to affix the CE mark. At present system Notified bodies issues CE certificates valid for 3 years. For some High — risk devices validity period may only one year. However, the status of your CE certification is dependent on maintaining your quality system certification.

1. Introduction

The products or equipment known as medical devices are utilised in the medical field. They need to undergo a conformity evaluation within the European Union (EU) to prove that they adhere to safety and performance standards. They are governed by EU Member States, however, the (EMA) European Medical Agency is involved in regulatory process. The CE (Conformité Européenne) mark can be applied to medical devices once they have completed a conformity assessment. According to the type of device, the manufacturer's technical documentation on the device's performance and safety may also be examined as part of the conformity assessment. Accredited notified bodies are chosen by EU Member States to conduct conformity assessments. Before issuing a CE certificate, the notified authority may be required to obtain a scientific opinion from EMA in particular situations.[1] The notified body is required to consult an expert panel before issuing a CE certificate for specific high-risk medical device. While preparing to export your medical devices to the EU market, it is critical to confirm whether your items will fall under the scope of medical device' under EU regulation. If they do qualify as medical devices, you must also decide the right classification before deciding on the most acceptable and suitable conformity assessment procedure. The legal

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https://doi.org/10.18231/j.ctppc.2023.002

framework has drawn attention from all around the world as a result of the Medical Device Directive 93/42/EEC to the Medical Device Regulation 2017/745/EC.[2,3]

The European medical device market accounts for around 30% of the global market, trailing only the market in the United States (42%). From an estimated USD 48.9 billion in 2020, the European medical device market is expected to grow by 4.7% CAGR to USD 61.4 billion by 2025., as depicted in Figure 1.[4,5] In EU medical devices were classified based on the risk factor as given in Table 1. The European Union approves medical devices based on their safety and technical performance rather than their utility by the patients. As proof for medical device approval, limited data, such as laboratory tests, literature studies, or small-scale clinical trials, is necessary. Following a thorough examination of the data, permission is provided by recognised bodies: Profit organisations chosen and employed by the producers. Any notified body's approval enables marketing within the EU. In EU IVD's were classified as given in Table 2.

2. Approval Process of Medical Devices in EU

The approval of medical devices in EU having the following steps as shown in Figure 3, the timeline required is Class I devices not require approval, Class IIa requires 1 to 3 months, Class IIb — 3 to 6 months and class III — 6 to 9 months. The approval process was depicted in Figure 2 as given below.

1. Local representative must be employed by a foreign manufacturer.
2. The sponsor is responsible for determining the device's category.
3. A QMS is not formally necessary for class I, non-sterile, and non-measuring. Nevertheless, even if it is not audited by a Notified Body, a PMS procedure is still required (NB).
4. The majority of businesses ask for ISO 13485 certification in order to achieve QMS compliance, which is necessary for devices of Class II & III. To demonstrate compliance, the applicant must create a technical file.
5. A dossier must be produced for class III devices. A notified body needs to conduct an audit of the QMS and technical file. (Which is more difficult in the case of a class III device). A technical file or audit is needed for class I, non-sterile, and non-measuring materials.

2.1. Approval process of IVD's in EU

The approval of IVD's in EU having the following steps as depicted in Figure 3 and given below,

1. Local representation is required for a foreign manufacturer.
2. Prior to implementing QMS programme, the sponsor is responsible for determining the IVD device's category.
3. QMS is necessary for various kinds of IVD devices, to achieve QMS compliance, the majority of firms ask for ISO 13485 accreditation.
4. A technical file must be created by the sponsor, who must also provide proof of compliance.
5. Dossier must be provided for List — A IVD's
6. A notified body must audit the QMS and the technical file (which is more difficult in list A IVD's).
7. No audit or technical file is required for general IVD self-certified devices.
8. Create a compliance declaration[6]

3. CE (Conformite Europeenne) Marking

In EU, medical devices must undergo a conformity assessment to verify that they adhere to safety and performance standards. The products which meet the EU criteria must bear the CE marking. The CE (Conformite Europeenne) mark can be placed on medical devices once they have completed a conformity assessment. The EU Member States have the authority to appoint accredited notified entities to perform conformity evaluations. Typically, compliance evaluations include

1. Technical dossier demonstrating compliance
2. Deciding whether you need to involve a recognised body in your product evaluation or whether you can do it yourself.
3. Creating and acknowledging a declaration of EU compliance.

The requirements for marketing medical devices are now governed by three major European Directives. The first two directives are related to the active implantable devices and IVD medical devices. In this article focusing mainly on the process of gaining a CE mark under the third directive, which applicable to other medical devices.[7]

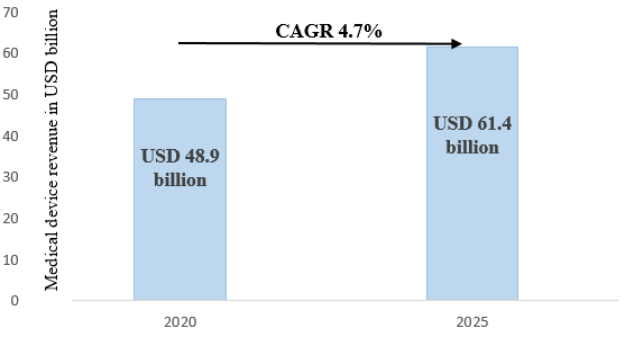

Fig. 1: Market size of medical device industry in Europe

Table 1: Medical devices classification as per EU

Class	Risk	Examples
I (Non-Sterile, Non-Measuring)	Low	Corrective glasses
I (Sterile, Measuring)	Low	Hospital beds, Bed pans
II a	Medium	Thermometers, hearing aids, ultrasonic diagnostic equipment
II b	Medium	Ventilators, surgical lasers
III	High	Implanted cerebella simulators, Silicon gel-filled breast implants

Table 2: IVD's classification as per EU

S.NO	Class	Examples
1	List A	ABO blood typing
2	List B	Blood glucose monitoring
3	Devices for self-testing	Pregnancy tests
4	Self-declared devices	Clinical chemistry analyser

Table 3: CE marking directives

S.NO	Title	Directives
1	Machinery	2006/42/EC
2	Low Voltage	2014/35/EU
3	EMC	2014/30/EU
4	Medical Devices	93/42/EEC
5	Personal Protective Equipment	89/686/EEC
6	Constructive Products	(EU) No 305/2011
7	Pressure Equipment	2014/68/EU
8	Reach	(EC) No 1907/2006
9	Restriction of Hazardous Substances	2011/65/EU
10	Waste Electrical and Electronic Equipment	2012/19/EU
11	Atex	2014/34/EU
12	Toy	2009/48/EU
13	Radio Equipment	2014/53/EU
14	Recreational Craft	2013/53/EU
15	Active Implantable Medical Devices	90/385/EEC
16	Explosive for Civil Use	93/15/EEC
17	Noise Emission in the Environment	2000/14/EC
18	Gas Appliances	2009/142/EC
19	Lifts	2014/33/EU
20	Pyrotechnic	2007/23/EC
21	Measuring Instruments	2004/22/EC

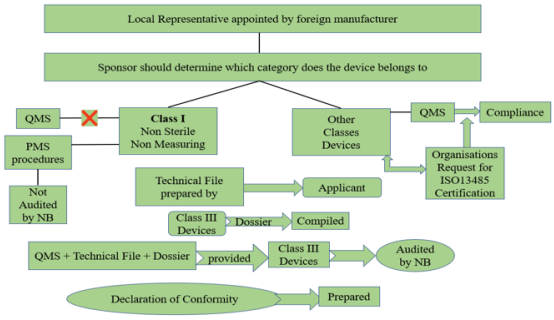

Fig. 2: Approval process of medical devices in EU

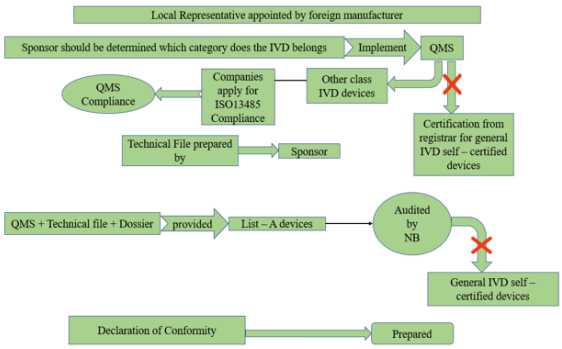

Fig. 3: Approval process of IVD's in EU

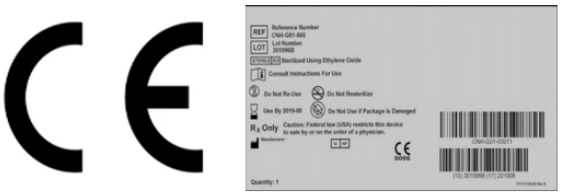

Fig. 4: CE mark & CE mark on the label

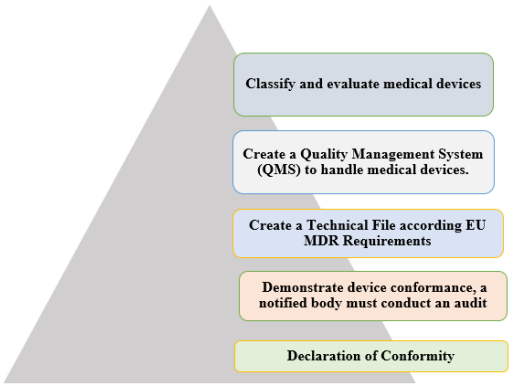

Fig. 5: Steps for getting CE marking with EU MDR requirements

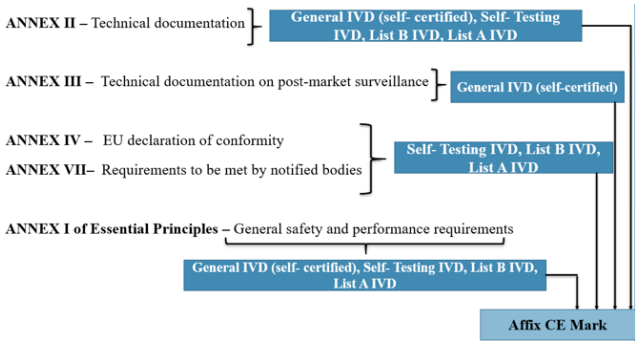

Fig. 6: Conformity assessment procedure for IVD'S[8]

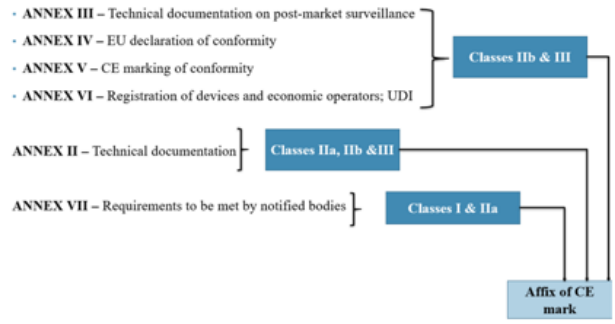

Fig. 7: Conformity assessment procedures for medical devices[9]

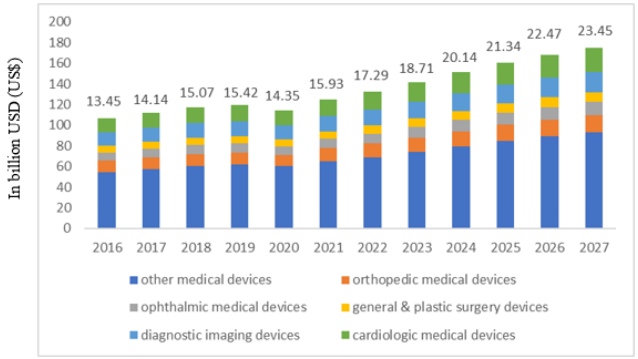

Fig. 8: Various medical devices revenew in Europe

4. Countries that demand CE marking

If a manufacturer sells their goods in the EEA (European Economic Area), which includes the 26 EU countries and 3 EFTA countries, they must have the CE mark on those products. European Union members include the following countries viz., Germany, Austria, Cyprus, Estonia, Italy, Luxembourg, Poland, Belgium, Czech Republic, Finland, Greece, Romania, Spain, Latvia, Malta, Portugal, Hungary, Slovakia, Sweden, Bulgaria, Denmark, and France, Lithuania, Netherlands, Republic of Ireland, Slovenia, United Kingdom. Iceland, Norway, Liechtenstein, Switzerland are the EFTA countries, also require the CE mark.[10] The regulations and directives of CE marking was given in Table 3.[11]

5. Need of CE Mark for Medical Devices

It can be difficult to determine the proper regulatory strategy and classification for a combination device that contains both medication and device components. Whether a product is regulated as a device or a medicine ultimately depends on the fundamental method which is achieved by its intended use. A pre-filled syringe is an example for a product whose main function is to deliver a substance that is controlled as a drug. A drug-eluting stent is an example of a product that is regulated as Class III medical device and calls for CE mark. All software marketed in the European Union with a medicinal purpose must have a CE marking. Software used as an accessory to an existing device could need its own CE certification, but all software intended to enhance the healthcare delivery process is regarded as Medical Standalone Software (Software as a Medical Device).

6. Cost Associated with CE Marking

The type of goods and the certification process will affect the pricing. When estimating your costs, you should take into account a number of aspects, including:

1. What is the product's intended use?
2. What are the product's characteristics and level of risk?
3. Which directive, if any, applies to the product?
4. Which laws or regulations are relevant to the product?
5. What are the fundamental requirements for safety and health that apply to the product?
6. Will the process require the assistance of a third-party certification agency?
7. Can use the parts/ components of the device which are already CE marked?
8. If the manufacturer, able to carry out he conformity assessment by their own no need to pay amount to anyone. If the service of NB is needed, then need to pay the amount. NB is a third-party organization accredited by a European Competent Authority that reviews medical device technical documentation against the medical regulations and harmonized standards. Manufacturer having the choice to select the NB to assess their device.

6.1. How to affix CE marking

The CE marking must to be clear and readable. It must only have the letters "CE," and both letters must be at least 5mm tall and the same width. The manufacturer can extend or lower the size of letters, can be seen in numerous hues and even as hollow text if the initials are still visible. If the product itself cannot bear the CE label, it might be added to

the package or other related papers, the image was depicted inFigure 4.

The validity of CE certificate issued by the NB is three years but, for some High-risk devices validity period may be only one year. CE certification is active, if quality system certification is approve. As long as your product complies with the relevant directive's health, safety, and environmental criteria, the EC Declaration of Conformity and CE mark will remain in place. If any changes are made to the product related to use, characteristics, design or any other aspect need to retest the product.[12] The steps involved in providing CE marking should be as per EU MDR requirements as shown inFigure 5. They are;

6.2. Step 1: Classify and evaluate medical devices

1. Applying set of regulations based on type of device i.e., In Vitro Diagnostics Regulation (IVD 2017/746) or Medical Device Regulation (MDR 1017/745)
2. According to Medical Device Regulation (MDR), Annex VIII classifies medical devices based on their risk profile. Devices are categorised based on how long they interact with patients, how intrusive they are, and which parts of the body they affect.
3. In accordance with the related dangers, devices are classified as Class I, IIa, IIb, or Class III using 22 descriptive rules.

6.3. Step 2: Create a QMS to handle medical devices

1. Many medical device companies use ISO 13485 as a model for developing effective QMS because QMS standards are comparable to those of FDA and other organisations.
2. QMSs are groups of processes and policies that applies to and involve everyone at medical device company. This covers from document controller in charge of monitoring your QMS to workers who adheres to these policies and procedures on a daily basis to assure safety and effectiveness of your product processes and design.
3. eQMS is the effective way to ensure product quality and effectiveness in the medical device sector.

6.4. Step 3: Create a technical file to meet the EU MDR essential requirements

1. For the majority of medical devices, you must ensure that they meet the requirements of the Medical Device Regulation (MDR 2017/745) in terms of their suitability for the intended use, safety, labelling and packaging, impacts of transit and storage, and risk against benefit for the end user. The general performance and safety requirements were provided in Annexure I for affixing the CE mark.
2. If medical device falls into risk classifications I, IIa, or IIb, you must create a technical file that outlines the item's conformance and demonstrates the Essential Requirements to meet. Product descriptions and specifications, manufacturing data, design verification, risk management files, clinical evaluation, validation test reports and labelling details should all be included in the technical file.
3. A Design Dossier should be made for Class III devices that contains information from the technical file as well as an explanation of the design process.

6.5. Step 4: Demonstrate device conformance, a notified body must conduct an audit

1. QMS and paperwork audited by a notified authority.
2. This service is provided by a number of significant international auditing and standards bodies.

6.6. Step 5: Declaration of conformity

1. After completion of the audit, CE marking certificate is being issued for the product along with an ISO 13485 certificate that establishes that your QMS is compliant with European standards.[13]
2. The final step is to create a Declaration of Conformity. This is a legally binding document which declares that the device meets all of the essential requirements as laid out by EU MDR and any other applicable regulatory standards.
3. Affix the CE marking to the product, having established compliance with European regulations. In Figures 6 and 7, the Conformity Assessment process of IVD's and Medical Devices of different classes was depicted respectively.

7. Observations

In terms of global revenue, the United States will generate the most (US$159.80 billion in 2022). According to the graph, the revenue of medical equipment in 2016 was US$106.64 billion in Europe. In 2022, revenue in the Medical Devices segment is expected to reach US$132.40 billion in Europe.[14] Other Medical Devices is the market's largest section, with a projected market volume of US$69.20 billion in Europe in 2022. Revenue in Europe is expected to grow at a 5.75% annual rate (CAGR 2022-2027), resulting in a market volume of US$175.10 billion by 2027,[15]Figure 8 depicts the revenue of various medical device segments in Europe.

8. Conclusion

This article mainly delivers the information about how medical device approval is done Europe countries. It also discusses about the CE marking for the medical devices and IVD's in Europe which is important for the marketing of the devices in that country. It also consists the revenue

marketing of the two countries comparative to the US market which is globally on the top. It gives the information regarding the growth of medical device market in Europe from the year 2016 to 2027. From this article the approval process and CE marking and the directives of the Europe country for medical devices is clearly given. The CE marking process is required for the devices in Europe for marketing and gives a better option for the customer regarding the aspects of quality and safety attributes.

9. Source of Funding

None.

10. Conflict of Interest

None.

Acknowledgments

The authors would like to thank Shri Vishnu College of Pharmacy, Bhimavaram for their kind support during article writing.

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Cite this article: Teja P, Jeevan S, Varma TS, Raju KV, Nori LP. CE marking – An insignia for medical devices in european union. *Curr Trends Pharm Pharm Chem* 2023;5(1):4-9.