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EU MDR & IVDR

REQUIRED STEPS FOR CE MARKING MDR AND IVDR DEVICES

One of the most frequent requests we get is for guidance on the steps required to obtain a CE marking for medical devices intended for sale in the EU and other regions requiring this designation. While there are variables involved depending on the specific type of device, there are similar core steps to be taken toward a CE marking that are detailed below. Let's begin with a general understanding of the CE mark itself and the manufacturer's responsibility for obtaining and affixing it to their devices.

GENERAL OVERVIEW

CE stands for "Conformité Européenne", the French for European conformity. A CE marking is a medical device manufacturer's declaration that their device complies with the requirements of all relevant European Medical Device Regulations and/or Directives, especially the new Medical Devices Regulation (2017/745/ EU) (MDR) and the In Vitro Diagnostic Medical Devices Regulation (2017/746/EU) (IVDR).

For the purposes of CE marking, here is the definition of a manufacturer:
"The natural or legal person with responsibility for the design, manufacture, packaging, and labelling of a device before it is placed on the market under its own name."

The MDR and IVDR outline the most current general safety and performance requirements (GSPR) for medical devices to be sold in the European Union (see Annex I of each regulation for specific requirements). For most classifications of medical devices, the manufacturer may require the services of a designated notified body (NB) to help with assessing the device's conformity and to certify it for sale in the EU. However, the manufacturer remains responsible for their conformity with all EU essential requirements.

A manufacturer established outside the EU will need to appoint an authorized representative (EC Rep) based in the EU to act on its behalf. Whether established inside or outside the EU, the manufacturer remains ultimately responsible for affixing the CE mark and its proper use.

Once the requirements are met and required steps are completed, the manufacturer affixes the CE mark to a device so that it can be sold in the EU.

The CE mark functions as a visual representation that the manufacturer takes responsibility for compliance with all applicable European health, safety, performance, and environmental requirements.

The CE mark is a requirement for the commercialization of most devices in the 27 member states of the EU as well as the European Economic Area (EEA), which includes Iceland, Norway, and Liechtenstein. Additionally, Switzerland accepts the CE mark for some devices and Turkey requires that many devices be CE marked as well.

The actual "conformity assessment route" may vary by device, but here are the general steps to prepare for the CE marking process for MDR and IVDR:

MDR

Step 1

Identify a person responsible for regulatory compliance (PRRC) to help manage completion and documentation of all relevant requirements. Having this individual on staff is itself a requirement of MDR (Article 15).

There is an exception granted for "micro and small enterprises within the meaning of Commission Recommendation 2003/361/EC" that the PRRC need not be on staff but that they "shall have such person permanently and continuously at their disposal."

Step 2

Determine the classification of the device using Annex VIII. The classification will dictate the conformity assessment route.

Step 3

Establish a quality management system (QMS) conforming to MDR requirements that includes plans for clinical evaluation and post-market surveillance (PMS) as well as post-market clinical follow-up (PMCF).

Following the EN ISO 13485 standard when creating a QMS is a common practice for companies, as it corresponds well to MDR.

Step 4

Assemble a technical documentation file containing information that is pertinent to the device classification. Generally, this will include the intended use, samples of the instructions for use (IFU), and other labeling, plus all relevant design, manufacturing, and testing information. Reference Annex II and III for detailed requirements.

Obtain a unique device identifier (UDI) for your device from an EU-designated entity (listed at the end of this article). The basic UDI-DI, a component of the UDI, acts as a main access key for the EUDAMED database and will need to appear on the device labeling and higher packaging, and should be referenced in the technical documentation.

Step 5

If your company does not have a business site in Europe, you will need to appoint an authorized representative (EC REP) that is based in the EU and has the necessary qualifications to assist with device registrations and serve as a liaison between your company and the national competent authorities. The EC REP should be identified on device labeling.

The authorized representative must also have a single registration number (SRN) that can be obtained through the actor registration module in EUDAMED.

Step 6

Have the QMS and technical documentation audited by an EU designated notified body. Class I (self-certified) devices are exempt from this requirement.

Upon successful completion of the audit, an EU CE marking certificate and ISO 13485 certificate will be issued.

Step 7

A declaration of conformity may now be created, which is a legally binding statement by the manufacturer that all relevant EU requirements for the device have been met and that it is compliant. See Annex IV for the information to be included in this document.

Step 8

A CE mark should now be affixed "visibly, legibly, and indelibly" to the device or its sterile packaging (Article 20). The CE mark must also appear in any instructions for use or sales packaging.

Step 9

The device and its associated UDI can now be registered in the EUDAMED database.

Step 10

With the exception of Class I (self-certified) devices, annual audits of ongoing MDR compliance by a notified body will be required to maintain a CE marking.

Be sure to perform post-market surveillance, post-market clinical follow-up (PMCF) and all other activities required to remain in compliance.

Class I (self-certified) devices will still require updates to technical documentation and performance of post-market activities.

IVDR

Step 1

Identify a person responsible for Regulatory Compliance (PRRC) to help manage completion and documentation of all relevant requirements. Having this individual on staff is itself a requirement of IVDR (Article 15).

There is an exception granted for "micro and small enterprises within the meaning of Commission Recommendation 2003/361/EC" that the PRRC need not be on staff but that they "shall have such person permanently and continuously at their disposal."

Step 2

Determine the classification of the device using Annex VIII. The classification will dictate the conformity assessment route.

Step 3

Establish a quality management system (QMS) conforming to IVDR requirements that includes plans for performance evaluation and post-market surveillance (PMS) as well as post-market performance follow-up (PMPF).

Following the EN ISO 13485 standard when creating a QMS is a common practice for companies as it corresponds well to IVDR.

Notified body audit and approval of the QMS is required for all device classes except for Class A (non-sterile).

Step 4

Assemble a technical documentation file containing information that is pertinent to the device classification. Generally, this will include the intended use, samples of the instructions for use (IFU), and other labeling and all relevant design, manufacturing, and testing information. Reference Annex II and III for detailed requirements.

Obtain a unique device identifier (UDI) for your device from an EU-designated entity (listed at the end of this article). The basic UDI-DI, a component of the UDI, acts as a main access key for the EUDAMED database and will need to appear on the device labeling and higher packaging, and should be referenced in the technical documentation.

Step 5

If your company does not have a business site in Europe, you will need to appoint an authorized representative (EC REP) that is based in the EU and has the necessary qualifications to assist with device registrations and serve as a liaison between your company and the national competent authorities. The EC REP should be identified on device labeling.

The authorized representative must also have a single registration number (SRN) that can be obtained through the actor registration module in EUDAMED.

Step 6

Have the QMS and Technical Documentation audited by an EU-designated notified body. Class A (non-sterile) devices are exempt from this requirement.

Upon successful completion of the audit, an EU CE marking certificate and ISO 13485 certificate will be issued.

Step 7

A declaration of conformity may now be created, which is a legally binding statement by the manufacturer that all relevant EU requirements for the device have been met and it is compliant. See Annex IV for the information to be included in this document.

Step 8

A CE mark should now be affixed "visibly, legibly, and indelibly" to the device or its sterile packaging (Article 18). The CE mark must also appear in any instructions for use or sales packaging.

Step 9

The device and its associated UDI can now be registered in the EUDAMED database.

Step 10

With the exception of Class A (non-sterile) devices, annual audits of ongoing IVDR compliance by a notified body will be required to maintain CE Marking.

Be sure to perform post-market surveillance, post-market clinical follow-up (PMCF) and all other activities required to remain in compliance.

Class A (non-sterile) devices will still require updates to technical documentation and performance of post-market activities.

CONCLUSION

Although CE marking can seem an arduous process at times, the bottom line is that successfully obtaining this marking grants access to the largest marketplace in the world.

HELPFUL LINKS

- **EU MDR/IVDR guidance documents and templates** - https://ec.europa.eu/health/md_sector/new_regulations/guidance_en
- **Database of EU notified bodies (NANDO) -** http://ec.europa.eu/growth/tools-databases/nando/
- **MDR technical file requirements overview -** https://www.bsigroup.com/contentassets/c48f4dd0aa8d4042987a2fbe72c3e086/white_paper__technical_documentation_web_v3.pdf
- **IVDR technical file requirements overview** - https://www.tuvsud.com/en-us/-/media/global/pdf-files/brochures-and-infosheets/tuv-sud-ivdr-technical-documentation-submission-requirements.pdf
- **SRN number registration** - https://ec.europa.eu/health/md_eudamed/actors_registration_en
- **Declaration of Conformity -** https://www.regulatory-affairs.org/en/regulatory-affairs/news-page/declaration-of-conformity-for-medical-devices/
- **EU PRRC guidance** - https://ec.europa.eu/docsroom/documents/36166
- Master link page to EUDAMED and UDI information - https://www.medical-device-regulation.eu/eudamed-documents/
- **UDI FAQ** - https://ec.europa.eu/health/sites/health/files/md_topics-interest/docs/md_faq_udi_en.pdf
- **Medtech UDI guidance** - https://www.medtecheurope.org/wp-content/uploads/2020/06/200602_MTE-Basic-UDI-DI-guidance-v1.1_final.pdf

EU designated UDI assignment entities:

- **GS1 AISBL** - https://www.gs1.org/industries/healthcare/udi
- **Health industry business communications council (HIBCC) -** https://www.hibcc.org/european-union-udi-requirements/
- **ICCBBA -** https://www.iccbba.org/subject-area/medical-devices/udi-labelers
- **Informationsstelle für Arzneispezialitäten — IFA GmbH** - https://www.ifaffm.de/en/ifa-codingsystem/udi.html

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