DEKRA

DEKRA SEAL & CE MARK

Promote Your Certification — DEKRA Seal

ISO 13485 & ISO 9001

Congratulations on your certification! One of the reasons you pursued certification is to demonstrate your commitment to high standards. Your certificate shows that an independent party has audited and approved your systems and processes. To support you in communicating this to customers and stakeholders, DEKRA offers the DEKRA Seal.

Important Note for ISO 13485

Under ISO 13485 (Medical Devices – Quality Management Systems), certification seals, logos, or marks may not be applied to individual products, packaging seen by end users, or product-related advertisements in a way that suggests product certification or conformity.

Seal Formats

Examples of Proper Seal Usage

- Plexiglass display at your reception
- On your website or social media, with a note like: “Organization/Process is certified by DEKRA in accordance with ISO xxxx.”
- For more information, please check www.dekra-seal.com

Seal Formats

Seal formats are shown below. To obtain an official copy of the seal, please contact your Support Officer or Project Manager.

Seal Usage Guidelines

Do’s and don’ts

Do's

- Use on printed materials (e.g., letterhead, brochures), provided it’s clear the Seal refers to the certified management system
- You may resize the Seal as long as proportions remain unchanged
- Color can be changed from DEKRA green to black

Don'ts

- Please ensure the Seal is not placed on products, their packaging, or in product-related advertising
- Please use the Seal in a way that does not suggest product certification
- Please avoid any graphic or marketing use of the Seal that could imply the device itself is certified by DEKRA
- Please use the Seal in its original colors, without recoloring it to match corporate branding

CE Marking Requirements Overview

CE marking is a certification mark that indicates conformity with health, safety, and environmental protection standards for products sold within the European Economic Area (EEA). For medical devices, CE marking is mandatory and signifies that the device meets EU regulatory requirements.

Steps to Obtain CE Marking for Medical Devices

1. Determine the applicable EU directive/regulation (e.g. Regulation (EU) 2017/745 on Medical Devices (MDR) and/or Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Devices (IVDR)
2. Classify your device (MDR: Class I, Im, Is, Ir, IIa, IIb, or III) (IVDR Class A, As, B, C or D)
3. Identify applicable conformity assessment procedure.
4. If required: Involve a Notified Body.
5. Perform conformity assessment procedure.
6. Sign an EU Declaration of Conformity.
7. Once compliance to the MDR/IVDR is demonstrated, affix the CE mark to the device and maintain compliance.

Important Notes

- The CE mark must appear clearly, be easy to read, and be permanent on the device, its packaging, or the instructions for use (IFU).
- CE marking is not a quality mark, but a declaration of compliance with EU legislation.
- Misuse of the CE mark or use without conformity can lead to penalties or product recall.
- **Only use the CE mark on the device, its packaging, or the instructions for use (IFU).**

CE Marking Requirements Overview

References to MDR and IVDR

Medical devices in the EU are regulated under the following legal frameworks:

- Regulation (EU) 2017/745 on Medical Devices (MDR)
- Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Devices (IVDR)

Compliance with MDR or IVDR is required before a product can be CE marked and legally placed on the European market.

Adding the Notified Body (NB) Number

If your medical device requires the involvement of a Notified Body (NB), the NB number must appear next to the CE mark.

The CE mark should be accompanied by the four-digit identification number of the NB that performed the conformity assessment. Example:

CE0344

Where '0344' is the number assigned to DEKRA Certification B.V., a designated Notified Body.

Rules for displaying the CE mark with NB number:

- The mark should be affixed to the product, its packaging, or the IFU, as applicable
- Please ensure it is clearly visible, easy to read, and indelible throughout the product's lifetime
- It must be at least 5 mm in height (see MDR/ IVDR Annex V).
- The CE mark and the Notified Body number should be placed together, without any other markings between them
- **The CE mark and NB number together may not be used on promotional material. The combination is only allowed on the device, its packaging, or the instructions for use (IFU).**

Referencing CE Marking on Marketing Material

MDR and IVDR Requirements

The MDR (Article 20) and IVDR (Article 18) both require:

Where applicable, the CE marking shall be followed by the identification number of the notified body responsible for the conformity assessment procedures set out in Article 52 (MDR)/ 48 (IVDR).

Referencing the Notified Body Number on promotional material

Under the MDR and IVDR, if promotional material states that a device complies with CE marking requirements, the Notified Body identification number must also be mentioned.

However, the CE mark itself and the Notified Body number are **not allowed to appear together on promotional** materials. This combination may only be used on the **product itself and its official labelling**, in line with the EU Blue Guide.

Rules for referencing the Notified Body identification number on promotional material:

- If promotional material **does not** claim that the device fulfils the CE marking requirements, no mention of the Notified Body identification number is required.
- If the promotional material **does** claim that the device fulfills the CE marking requirements the following are examples of appropriate referencing of the Notified Body number:

❖ *The following devices fulfil the requirements for CE marking certified at Notified Body 0344*

❖ *This device is CE-marked under Regulation (EU) 2017/746. Notified Body: 0344”*

❖ *Product table entry: CE-marked***
*Footnote: **Notified Body: 0344*

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