CE Marking of Medical Devices in accordance with MDR

Medical devices manufactured or traded in the EU must comply with EU legislation in the area of safety and health. This means they have to be conform to the Medical Device Regulation (EU) 2017/745 (MDR) and must be CE marked. Kiwa Cermet Italia and Kiwa Dare (based in The Netherlands) have been designated notified bodies for the Medical Device Regulation. They can help you with certification of your products according to the MDR.

Medical Devices are an heterogeneous category of products, such as active equipment, orthopaedic implants, reusable instruments, substances and materials, software, and more, intended to be used in or on humans for medical purposes, performing their main action through means other than pharmacological, immunological or metabolic. To be placed on the market, devices must comply with applicable legislation and be CE marked.

The Regulation (EU) 2017/745 – MDR

The Medical Device Regulation (EU) 2017/745 (MDR) replaced the current Directive 93/42/EEC (MDD) and also the Directive 90/385/EEC on Active Implantable Medical Devices (AIMD), to regulate the new conditions for placing Medical Devices on the market with the aim of ensuring the safety and health protection of patients and users.
The MDR was officially published on May 5, 2017 and entered into force on May 25, 2017, but as subsequently established by Regulation (EU) 2020/561, it found its full application on May 26, 2021.
In accordance with Article 120.3 of the MDR and the subsequent corrigendum, medical devices that possess a valid CE certificate in accordance with the MDD and AIMD Directives, and Class I medical devices that are up-classified by the MDR and possess a valid Declaration of Conformity, may continue to be placed on the market until May 26, 2024 and put into service until May 26, 2025.
By May 27, 2024, all medical devices must be MDR-compliant in order to be placed on the European market. Medical companies are therefore challenged to address the changes and requirements that the MDR has introduced, planning and implementing strategies in good time to ensure their devices comply with the new requirements. Key changes include:

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- greater emphasis on a life-cycle approach to safety, supported by clinical data (Art. 61);
- new rules for classification of devices with more rigorous and precise criteria (Annex VIII);
- new economic operators (agent, importer and distributor) for which specific obligations are defined (arts. 11, 13 and 14);
- need for financial coverage (art. 10) and a person responsible for compliance (art. 15) for the manufacturer;
- drafting of specific documents such as a summary of safety and clinical performance;
- (SSCP, art. 32) for implantable and class III devices, periodic safety update report (PSUR, art. 86) for class IIa, IIb and III devices and finally the card for patients with implantable devices (art. 18);
- inclusion of products that do not have a medical purpose such as products with aesthetic purposes (Annex XVI);
- new system of unique identification of devices (UDI, art.27) for the traceability and effectiveness of activities related to post-marketing safety and new European Database (EUDAMED, art. 33) that will play a central role in increasing both the quantity, quality and availability of data;
- strengthening of external consultation procedures with Competent Authorities for medical devices based on substances, drugs and animal tissues and introduction of a new clinical evaluation consultation for some class IIb, implantable and class III devices by a group of independent experts appointed by the European Commission (art.54);

Kiwa Notified Body for MDR

Within the Kiwa group, Kiwa Cermet Italia (NB 0476) and Kiwa Dare (Netherlands) (NB 1912) have been designated a notified body for the MDR.
Kiwa Cermet Italia has successfully achieved designation as a Notified Body by the Italian Ministry of Health and the European Commission for Conformity Assessment activities according to the Medical Device Regulation (EU) 2017/745 (MDR). The designation is included in the Nando Database of the European Commission. Thanks to the presence of a high number of experts in different countries, Kiwa Cermet Italia is able to deliver the assessment activities at a global level.
Kiwa Dare, part of Kiwa since March 2021, has been appointed by the Dutch Ministry of Health, Welfare and Sport (VWS) as Notified Body for the Medical Devices Regulation (EU) 2017/745 (MDR). The designation is included in the Nando Database of the European Commission.
Kiwa operates by statute in an independent, objective and impartial way during conformity assessment activities, ensuring high levels of competence, professionalism and absolute integrity of its experts, so as not to influence in any way the judgment or the results of the EU certification process. Furthermore, Kiwa has internal procedures in place to ensure absolute confidentiality of information received during the assessment activities.
Through the association to Team NB (European Association of Notified Bodies in the field of medical devices), Kiwa actively participates in the technical working tables for the development of the main documents and guidelines of the medical sector and has quick access to all updated information and new approaches applicable to medical devices.

Procedure for EU Certifications of Conformity

The procedure to be followed to obtain the EU Conformity Certificate differs based on the risk class of the medical device according to art. 52 of the MDR.
For Class I sterile devices (Is) or with measurement function (Im) or reusable surgical instruments (Ir), IIa, IIb and III (including custom implantables), the intervention of the Notified Body is always required.

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Please contact us to discuss which procedure applies to your product.

For more information about the Italian tariffs click here.

For more information about the Dutch tariffs from Kiwa Dare click here.

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