Kiwa Medical

Safeguarding People with our Services for the Medical Devices Industry

Notified and Certification Bodies for the Medical Devices Sector

We Create Trust

A complete service portfolio for the Medical Sector

Kiwa Medical is the ideal partner able to provide complete and reliable information about the most appropriate certification and notification path with respect to the type of device, ensuring impartiality and trusted conformity assessment activity.

Member of TEAM-NB

Kiwa Cermet Italia, Kiwa Turkey and Kiwa DARE!! are members of TEAM-NB, the European Association of Notified Bodies in the medical devices field.

CE 0476 CE 1984 CE 1912

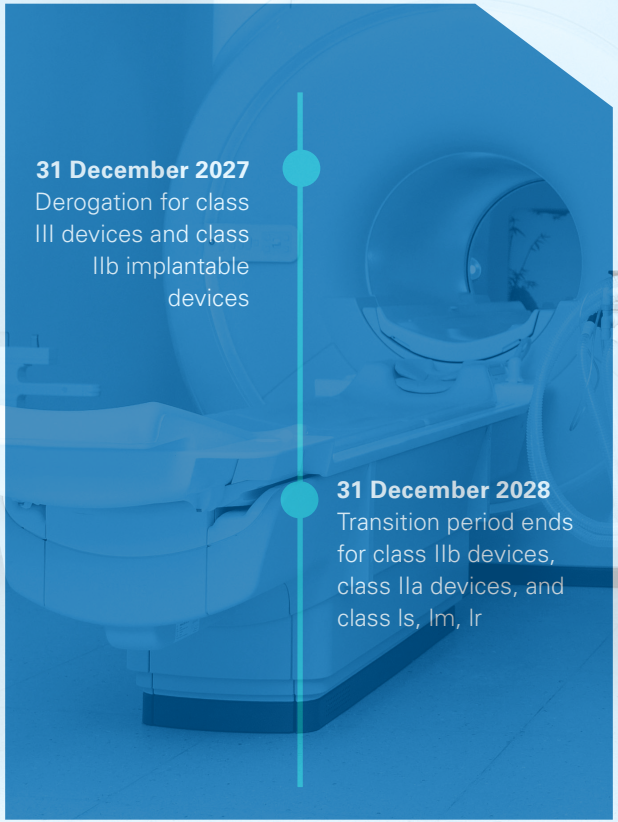
MDR Deadlines

26 May 2024
Transition period ends for legacy devices. No later than 26 May 2024, the manufacturer or the Authorized Representative has lodged a formal application with a Notified Body

26 September 2024
No later the Notified Body and the manufacturer have signed a written agreement

26 May 2026
Derogation for class III custom-made implantable devices

Kiwa's Notified Bodies for Medical Devices



31 December 2027
Derogation for class III devices and class IIb implantable devices

31 December 2028
Transition period ends for class IIb devices, class IIa devices, and class Is, Im, Ir

Kiwa Cermet Italia (NB 0476) in Italy, Kiwa Belgelenddirme Hizmetleri (NB 1984) in Turkey, and DARE!! Services (NB 1912) in The Netherlands, are the Notified Bodies within the Kiwa Medical.

Kiwa Cermet Italia and Kiwa DARE!! have been designated as notified bodies for the Medical Device Regulation (EU) 2017/745 (MDR).

Focus on Kiwa

Find out more on our dedicated Medical Service portfolio at https://bit.ly/3SvUEye

Medical Devices Conformity Assessment

Kiwa, through its Notified Bodies, performs **conformity assessment activities** for the issuance of EU certification **in accordance with Regulation (EU) 2017/745 (MDR)**.
Due to the high number of technical and clinical experts in different countries, Kiwa is able to deliver the assessment activities worldwide ensuring a high level of competence.
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.

Laboratory Services

Testing services for medical devices are functional to demonstrate products will be performing. Therefore, medical devices must undergo rigorous testing to meet the highest quality standards. Kiwa Group laboratories, such as Kiwa Creiven (Italy) Kiwa Primara (Germany) and Kiwa DARE!!, offer to Organizations the opportunity to carry out electrical safety, electromagnetic compatibility and functional tests with respect to the EU harmonized Standards. Our experience makes us leader in the branding market of active medical devices for several applications: **Diagnosis and Therapy, Surgery, Rehabilitation and Physiotherapy and Dentistry.**

ISO 13485 Standard Quality Management System Certification

For medical devices organizations, compliance with ISO 13485 can support conformity assessment that are used in different regulatory authorities, but a quality management system on its own will not necessarily lead to an improvement of work processes or to improvements of your product. Kiwa Medical can answer to your need.

Training Courses

Understanding international standards, EU regulations and directives is vital to put medical devices on the market.

Through its training companies, such as Kiwa Idea, offers a range of medical device training courses carried out in line with the company strategies and the latest updates.

Contact Us

Do you want more information about our services in the Medical Devices field?

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