Ensuring excellence ***safeguarding people***

kiwa

A complete service portfolio for the ***medical sector***

Medical devices are a heterogeneous category of products, such as active equipment, implants, reusable instruments, substances and materials, softwares, and more, intended for use on humans and therefore their safety and performance are of vital importance. To be put on the market and traded in EU, medical devices must comply with pertaining European legislations.

With a worldwide presence and a wide and in-depth experience in the medical field with several thousand certified devices in over 25 years of activity, Kiwa can provide complete and reliable information on the appropriate medical devices certification process to undertake, and deliver trusted conformity assessment activities and related services.

Member of TEAM-NB

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

Our Notified Bodies for medical devices

Kiwa Cermet Italia (NB 0476) in Italy, Kiwa Belgelenddirme Hizmetleri (NB 1984) in Turkey and Kiwa DARE NB (1912) in The Netherlands, are the Notified Bodies within the Kiwa Group, boasting a wide and in-depth experience in medical devices certification, with thousands of products already certified.

CE 0476 CE 1984 CE 1912

A global network

Kiwa has a worldwide network of offices and laboratories, allowing us to provide local support wherever you operate. We help you navigate international markets effortlessly.

Kiwa can provide complete and reliable information on the appropriate medical devices certification process to undertake, and deliver trusted conformity assessment activities and related services. Together we create trust.

Ensuring excellence, safeguarding people

Certification isn't just about compliance; it's about trust. Patients, healthcare professionals, and regulatory authorities all rely on certified medical devices for safety and effectiveness. Kiwa helps you build that trust.

CE Marking - Medical devices conformity assessment

Kiwa Medical, through its Notified Bodies, performs conformity assessment activities for the issuance of EU certification in accordance with Regulation (EU) 2017/745 (MDR). Thanks to the presence of a high number of qualified professionals in different countries, Kiwa Medical is able to deliver the assessment activities at a global level.

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 implantable), the intervention of the Notified Body is always required.

ISO 13485 standard - mangement system certification

People rely on medical devices to survive; if your organization operates in the medical devices field, quality is vital. ISO 13485 certification can help you demonstrate your ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements.

ISO 13485 specifies the requirements for a quality management system that any organization operating in the medical devices sector needs to demonstrate. Kiwa as international Accredited Body for Management System Certification is your eligible and trusted partner for ISO 13485

Laboratory services

Medical device testing services aim to demonstrate reliability and safety of the devices during their use. For this, medical devices must undergo rigorous testing to meet the highest quality standards. Kiwa Group laboratories offer to organizations the opportunity to carry out electrical safety, electromagnetic compatibility and functional tests with respect to the harmonized standards.

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Get in touch!

Do you want more information about our services in the field of medical devices? Contact us via **medical@kiwa.com** or visit our website:

kiwa.com/medical

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