Ensuring excellence
Safeguarding people

Services for the Medical Sector

Kiwa Medical

Partner for Progress

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

Kiwa's Notified Bodies for Medical Devices

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 Group, boasting a wide and in-depth experience in medical devices certification, with thousands of products already certified. Kiwa Cermet Italia and Kiwa Dare!! have been designated as notified bodies for the Medical Device Regulation (EU) 2017/745 (MDR).

CE 0476 CE 1984 CE 1912

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.

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) and Directive 93/42/EEC (MDD). Thanks 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.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.

Please contact us to discuss which conformity assessment procedure applies to your device and to find out more about the Kiwa certification process.

ISO 13485 Standard - Quality Management System Certification

The Management System Certification in accordance with ISO 13485 is a value of Reliability for the Organization, proving that they have correctly applied all management and technical requirements to guarantee the safety and quality of the products placed on the market. Kiwa as international Accredited Body Certification is the eligible and trusted Partner to comply with worldwide market requirement.

Laboratory Services

Testing services for medical devices are functional to demonstrate products will be performing in use reliably and safely, for a preventive protection of end-users.

Therefore, medical devices must undergo rigorous testing to meet the highest quality standards. Kiwa Group laboratories, such as Kiwa Creiven (Italy) and Kiwa Primara (Germany), offer to Organizations the opportunity to carry out electrical safety, electromagnetic compatibility and functional tests with respect to the EU harmonized Standards.

Moreover, Kiwa's laboratory supports Companies during the whole process, from the initial "Risk Analysis" phase up to the "Compliance" one.

Our experience makes us leader in the branding market of active medical devices for several applications: Diagnosis and Therapy, Surgery, Rehabilitation and Physiotherapy and Odontology.

Training Courses

Understanding international standards, EU regulations and directives is vital to put medical devices on the market. That is why Kiwa, through its training companies, such as Kiwa Idea, offers a comprehensive range of medical device training courses carried out in line with the company strategies and the latest updates.

Find out more on our dedicated Medical Service portfolio at

https://www.kiwa.com/en/markets/medical-devices/

Contact our experts for further information

medical@kiwa.com

Kiwa Global
Sir Winston Churchill-laan 273
2288 EA Rijswijk

PO Box 70
2280 AB Rijswijk
The Netherlands

Phone +31 (0)88 998 44 00
E-mail info@kiwa.com

www.kiwa.com