

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.



0476



1984



1912

Kiwa Medical Certification Bodies Testing Laboratories for Medical Devices

Medical Device Testing Services ensure device Reliability and Safety through rigorous testing to meet high-quality Standards. Kiwa Group laboratories enable organizations to perform electrical safety, electromagnetic compatibility, and functional tests in line with harmonized Standards.

Kiwa Medical CBTL perform the following tests:

- IEC/EN 60601-1 Medical Electrical Equipment
- IEC/EN 60601-1-11 Medical Care in Domestic Environment
- IEC/EN 60601-2-4 Defibrillators

...and many more.

Kiwa's Notified Bodies for Medical Devices

Kiwa Medical Testing Services for Medical Devices

Cybersecurity threats in healthcare are growing, especially with increased AI use in SaMD and AlaMD. Robust cyber security Testing helps prevent data breaches, safeguarding patient information and ensuring AI algorithms function accurately for better diagnostics and patient outcomes.

Kiwa Medical Testing perform the following tests:

- **IEC 62443 4-1 & IEC 62443 4-2**
- **Validation and Testing** (Interoperability Testing, Interface, Performance, Reliability, and Load Testing, ...)
- **Cyber Security** (Security Architecture Testing, Vulnerability Assessment, ...)

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

All 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://qr.cd.org/71F0>

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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