Ensuring excellence
Safeguarding people

Services for Medical Devices

Kiwa Italy

Trust
Quality
Progress

Kiwa Services for Medical Devices

The theme of product safety is now a priority gained for each manufacturer, as well as the importance of the knowledge of laws and regulations, to ensure the ultimate purpose: the "preventive safeguard" of users.

Kiwa Cermet Italia boasts a wide and in-depth experience from over 20 years in Medical Devices certification, with thousands of products already certified, providing all the necessary services to get complete answers and reliable information on medical devices certification services.

Thanks to **Kiwa Cermet Italia** expertise, Medical Companies can demonstrate effective compliance with requirements related to the products, in both mandatory and voluntary certification.

93/42/EEC Directive - Medical Devices Certification

The 93/42/EEC Directive defines the essential requirements that all Medical Devices have to be met in order to obtain a CE Mark that allow them to be legally place on the European market, safeguarding patients and users.

Kiwa Cermet Italia is a leading and independent Notified Body (N.0476), designated by the Italian Ministery of Health, for the CE Certifications of several types of Medical Devices, both active and non-active, for the following risk categories:

- Class I with measurement function
- Class I sterile
- Class IIa
- Class IIb
- Class III*

**only non active implantable orthopedic and surgical medical devices in direct contact with the Central nervous system for transient use.*

Kiwa Cermet Italia has created a series of integrated procedures, so that the Certification can actually be a tool that will advantage the manufacturer and protect the market.

Kiwa Cermet Italia provides worldwide conformity assessment services as Notified Body number 0476.

Kiwa Cermet Italia as Accredited Body by ACCREDIA for Management System Certification according to ISO 9001 and ISO 13485 standards.

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 007A
SGA N° 010D
PRD N° 069B
SSI N° 006G
FSM N° 004I
PRS N° 089C
LAB N° 0001
LAT N° 052

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

CE
0476

Conformity assessment procedure for Medical Devices

1. **Initial Study** - evaluation of Manufacturer's application requests and identification of all necessary actions and conformity evaluation route to start with CE certification.
2. **Documental Analysis** - technical evaluation through the assessment of complete technical file, including if applicable design dossiers, and related quality management system procedures.
3. **On-site Audit for initial certification** - evaluation of quality system assessed during documental analysis applied to product lifecycle: concept, design, production, final control and post-market surveillance.
4. **Issue of CE Certificate** - issuance of the CE Certificate following the positive results obtained by documental analysis and on-site audit.
5. **On-site Audit for the maintenance of the certification** - annual assessment to guarantee continuous fulfillment of the requirements of the Medical Devices Directive.
6. **Unannounced Audits** - on-site audits that, following the European Commission Recommendation 2013/473/EU, of 24 September 2013, shall be carry out at any time, in addition to periodical ones, to verify the day to day compliance with legal obligations.

ISO 13485 Standard - Quality System Certification

The ISO 13485 Standard specifies the Quality Management System requirements, which an Organization operating in Medical Devices field needs to demonstrate.

This Quality Management Standard also proves Company's commitment and abilities to provide design, manufacture and sale services for medical devices, that consistently meet customers and regulatory requirements. 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 Cermet Italia as international Accredited Body for Management System Certification is the eligible and trusted partner to comply with worldwide market requirement.

Laboratory Services

Kiwa Cermet Italia offers to Organizations the opportunity of employing its laboratory for carrying out electrical safety, electromagnetic compatibility and any functional test, with respect to the 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 Odontology.

Kiwa laboratory goes closed to Companies for all the way along the process, from the initial "Risk Analysis" phase up to "Compliance" one, through all trials and testing needed to assess conformity with active requirements.

Electrical Safety

- Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance (EN 60601-1)
- Medical electrical equipment - Part 2-52: Particular requirements for basic safety and essential performance of medical beds (CEI EN 60601-2-38)
- Electrical Equipment For Aesthetic Use - General Requirements For The Safety (CEI 62-39)
- Photobiological Safety Of Lamps And Lamp Systems (EN 62471)

Electromagnetic Compatibility

- Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (EN 60601-1-2)
- Electrical Equipment for Measurement, Control and Laboratory Use - EMC Requirements Part 1: General Requirements (EN 61326-1)

Trust Quality Progress

Kiwa Italy offers a wide range of services in the TIC domains, supporting organizations in innovation and growth challenges.

With more than 30 years of activity, Kiwa Italy operates as an independent body for the certification of goods, services, systems and persons, and for the verification, testing and calibration of products and equipment, offering a complete and comprehensive range of services, that can take into account specific needs also at the local level.

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