Medical Certifications

Notified Body for Active Medical Devices

"Certification according to the Medical Device Regulation (MDR) EU 2017/745 and EN-ISO 13485"

Kiwa Dare is a Notified Body (NB 1912) under the MDR. We have a specific scope with regard to active non-implantable medical devices and software. The scope includes sterile accessories Class I and excludes devices working with ionizing radiation.

Importance of medical devices

Advanced medical devices play an ever-increasing role in the health care arena. Many new and innovative medical devices are developed by spin-offs of academic research. A reliable partner that can certify medical devices is of the utmost importance. Both to ensure a strong competitive position on the international market and maintaining a high level of quality of medical devices.

CE Marking

Kiwa Dare performs conformity assessments under the MDR and acts as a Notified Body for Class I-measure, I-sterile, IIa, IIb and III. For these classes a Notified Body is a requirement to obtain CE marking. The CE marking is mandatory to allow medical devices to be put on the market in the European Economic Area (EEA). Our experienced technical, clinical and certification employees have the required knowledge and experience with regard to the latest developments in this field. Audits, assessments and tests are performed with a high degree of quality and in accordance with the standards and regulations.

Conformity Assessment Procedure

Before the formal assessment takes place, an Application Review is performed. During this assessment, the complete project is reviewed including the proper classification, the applicable standards and the required documentation as well as the required time and competence to perform the certification process. The Application Review enables that the complete project can be performed in a fluent way and reduces the chance of surprises that will lead to a delay of the formal audit or assessment and thus to the time to market.

Quality

It is the responsible task of Kiwa Dare product reviewers, (lead) auditors and experts to perform the proper assessments. Not only with the goal to obtain the required CE marking but also to protect manufacturers against substantial claims or even prosecution. At the same time, a device in compliance with the MDR must be a reliable device, thus resulting in savings in the after sales cost. A reliable product also protects your reputation as a high-quality manufacturer!

Medical Certifications

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Scope for active medical devices

Certification Scheme MDR (EU) 2017/745 | EN-ISO 13485:2016

Product / Product Group
MDA 0202 Imaging devices (non-ionizing)
MDA 0203 Monitoring devices of vital physiological parameters
MDA 0204 Monitoring and diagnosis
MDA 0302 Devices utilising non-ioninzing radiation
MDA 0303 Devices for hyperthermia / hypothermia
MDA 0305 Devices for stimulation and inhibition
MDA 0306 Devices for administration or removal of substances
MDA 0307 Respiratory devices
MDA 0308 Devices for wound and skin care
MDA 0309 Ophthalmologic devices
MDA 0310 Devices for ear, nose and throat
MDA 0311 Dental devices
MDA 0312 Non-implantable surgical devices
MDA 0313 Rehabilitation devices and active prostheses
MDA 0315 Software
MDA 0316 Medical gas supply systems
MDA 0318 Other devices

For more information? Contact us!

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