DARE!!
Measure the Difference!!

Medical Certifications

Certification of Active Medical Devices

Efficient · Effective · High Quality

DARE!! Medical Certifications is a Notified Body (NB1912) for the Medical Devices Directive 93/42/EEC. We have a broad scope with regard to active medical devices. European and International Authorities have set forward a large number of requirements specific for medical devices. For many start-ups and small and medium sized businesses these requirements may represent a barrier to enter the international market of medical devices.

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 as 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

DARE!! Medical Certifications assists in overcoming obstacles and acts as a Notified Body for the classes I-measure, IIa and IIb. 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 of the European Economic Area. Our experienced technical, clinical and certification engineers have the required knowledge and experience with regard to the latest developments in this field and can therefore counsel you on the applicable harmonized standards. Examinations and tests are performed with a high degree of quality and in accordance with these standards.

Application Review

Before the formal assessment takes place, an Application Review is performed. During this assessment the total 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 ensures that the total project can be performed in a fluent way and prevents surprises that will lead to a delay of the formal assessment and thus to the time to market.

Notified Body

The Dutch department of health (VWS) has designated DARE!! Medical Certifications as a Notified Body for the European Medical Devices Directive 93/42/EEC for the annexes III and IV, non-sterile active (electronic) equipment for a wide scope of medical devices. See the rear of this leaflet for our complete scope.

Quality

It is the responsible task of DARE!! Medical Certifications engineers 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 Medical Devices Directive 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!

DARE!! Medical Certifications

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The Standard for product certification in EMC, Product Safety & Medical Devices

CE 1912

Medical Certifications

Product / Product Group	Certifications Scheme	Standard / Normative document
MD 1100: General active medical devices MD 1101: Devices for extracorporeal circulation, infusion and hemapheresis MD 1102: Respiratory devices, devices including hyper baric chambers for oxygen therapy, inhalation anesthesia MD 1103: Devices for stimulation or inhibition MD 1104: Active surgical devices MD 1108: Active rehabilitation devices and active protheses MD 1109: Active devices for patient positioning and transport	European Directive 93/42/EC (Medical Devices) • EC type examination – annex III • EC verification – annex IV	European Directive 93/42/EC Annex I and XI
MD 1200: Devices for imaging MD 1202: Imaging devices utilizing non-ionizing radiation		
MD 1300: Monitoring devices MD 1301: Monitoring devices of non-vital physiological parameters MD 1302: Monitoring devices of vital physiological parameters		
MD 1400: Devices for radiation therapy and thermotherapy MD 1402: Devices utilizing nonionizing radiation		

CE 1912

CB Scheme

RvA TESTING RvA L 279

RvA PRODUCTS RvA C 447

For more information contact
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