Healthcare equipment

Optimising the approval process

You get test reports according to international standards for safety, EMC, telecom and environmental requirements to demonstrate conformity with national requirements.

We perform quality management audits as joint audits for several countries.

Contact us for our approval support services for countries in Europe, Asia and America

We are your local partner

By contacting your local Nemko team you get access to our experts. They are handling your projects and following up the delivery. Nemko has test facilities for healthcare equipment in America, Europe and Asia.

- IEC 60601-1 (General requirements for safety), IEC 60601-1-xx (Collateral) and IEC 60601-2-xx (Particular) series of standards. In addition, Nemko can assist you to ensure product compliance within more than 50 part 2 (Particular) standards
- CB certificates , 52 participating countries
- ISO 13485 and 9001 certificates
- EMC and telecom testing
- RoHS testing
- Reach and WEEE services
- Climatic and environmental testing

Notified Body for Europe

DNV Nemko Presafe has been appointed a Notified Body for Medical Device Directives and issues CE-certificates.

- European Directive for medical devices 93/42/EC
- European Directive for in vitro diagnostic medical devices 98/79/EC

More about how we can improve your regulatory processes

- Early contact with our experts for pre-compliance evaluation
- Establishing a test and audit plan based on your market plan
- Consider regulatory changes in near future

Related services

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Product testing [1]

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