

# DGM Service

## CE Marking of Medical Devices

### Background

The European Union has published a number of New Approach Directives for the purpose of removing trade barriers within the member countries.

Today the manufacturers may therefore, without restrictions, market medical devices in Europe that comply with the requirements in the Directives without having the devices approved according to the various national rules first.

Medical devices placed on the market in the European Union must bear the CE marking as a visible sign of compliance with the requirements put down in Directive 93/42/EEC.

The medical device directive requires independent assessment of products and quality systems. For this purpose the member states has nominated a number of organizations, so-called Notified Bodies, to do third party assessments.

Danish Standards Association/ DGM is the Danish Notified Body guiding manufacturers of medical devices quickly and efficiently through the CE marking process. DGM is one of the few Notified Bodies able to offer all of the services required by the Directive.

### DGM offers

- Expert opinion on classification of medical devices
- Assistance in identifying most appropriate conformity assessment route
- Full quality system assessment (Annex II of the Directive)

- Production quality assessment (Annex V the Directive)
- Product quality assessment (Annex VI of the Directive)
- EC type-examination (Annex III of the Directive)
- EC design-examination (Annex II, section 4 of the Directive)
- EC verification (Annex IV of the Directive)
- Technical file evaluation
- Assessment of clinical data
- Assessment of labelling and IFUs
- EC certificate issue

### Essential Requirements

The Directive stipulates minimum essential requirements for medical devices to ensure the protection of the health and safety of patients, users and third persons.

As the essential requirements are described in general terms, you might find it useful to use special harmonized standards that offer interpretations of acceptable levels to fulfil the "Essential Requirements".

### Classification

The Directive divides medical devices into four risk classes (I, IIa, IIb and III). In addition, class I is subdivided into devices which are sold in a sterile condition and devices which are sold with a measuring function.

The classification reflects the risks involved in the use of the product, the vulnerability of the parts of the body on which the devices are to be applied and the duration of use.

## **Conformity Assessment Routes**

The Directive establishes different types of conformity assessment procedures. The principle is that the manufacturer can choose if he wishes to have his product and/or his quality system approved.

### **DGM's notification includes:**

#### **Active medical devices**

- suction equipment
- dental equipment
- hearing aids and audiometers
- electrocardiographs and electroencephalographs
- sterilizers for medical devices
- ultrasound equipment
- X-ray equipment
- CT scanners
- patient monitoring equipment
- equipment for registration of life-supporting functions
- defibrillators
- blood gas analyzers and anaesthetic monitors
- electrosurgical equipment
- surgical lasers
- heart-lung machines
- equipment for planning radiation therapy
- software for planning radiation therapy
- equipment for stimulators
- neonatal equipment

#### **Non-active medical devices**

- infusion equipment incl. accessories
- bandages and wound dressing materials
- drains, probes and suction equipment
- surgical equipment
- dental materials
- dental implants
- disinfectants
- sutures and adhesives
- contact lens fluids
- contraceptive devices

- surgical implants (excluding orthopedical implants and bone cement)
- single-use devices
- cardiovascular implants
- contact lenses
- medical devices for in vitro fertilization

#### **More information**

For more information about CE marking of medical devices, please contact DGM at +45 39 96 64 00 or [dgm@ds.dk](mailto:dgm@ds.dk).

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