



The Medical Device Directive

93/42/EEC

Background

In order to ensure free movement and acceptable level of safety for selected products within the internal EEA¹⁾ market, the European Community (EC) has, over the years, developed a number of common “technical harmonization directives”, also referred to as “new approach directives”. These individual directives apply to various product groups and/or phenomena. They are mandatory for products which are intended to be put into service or placed on the EEA market, and it is a legal responsibility of the manufacturer or his authorized representative in the EEA to identify relevant directives and to document and declare conformity with applicable requirements.

¹⁾ EEA = Extended Economic Area, Countries of the EU and EFTA



The CE mark

The CE mark indicates conformity to the essential health and safety requirements of applicable directives. The CE mark is affixed under the sole responsibility of the manufacturer or his authorized representative in the EEA. A CE mark followed by a number indicates that an independent body, a Notified Body²⁾, has additionally carried out an assessment of the manufacturing phase of the product.

Compliance with European harmonised standards provides presumption of conformity to the applicable essential requirements of the directive. DNV recommends the manufacturer to use harmonised standards, when available.

The Medical Device Directive 93/42/EEC

The Medical Device Directive 93/42/EEC entered into force 1st of January 1995. It became mandatory from 13th of June 1998 and describes the requirements as applied to medical devices.

The Medical Device Directive and other relevant information is available electronically at the European Union website at:

http://europa.eu.int/comm/enterprise/medical_devices/index_en.htm.

The way to the CE mark

Major steps towards CE marking, with references to the directive, are:

Major steps to CE marking	Reference to the directive
Is this a medical device?	Article 1
Classification according to rule?	Annex IX
Conformity route(s)	Article 11
Essential requirements of the device	Annex I
Technical documentation needed	Annex VII
Vigilance/Post Market Surveillance	Annex VII
Evaluation by Notified Body	Annex II – VI
Determine European Entity	Annex I, 13.3, Article 14
Declaration of Conformity	Annex VII
CE marking	Article 17
Register with competent authority	Article 14

²⁾ *Notified Body: An independent organisation appointed by a national authority within the EEA to undertake a third party conformity assessment prior to allowing the manufacturer to CE mark their products.*



The risk classes of medical devices are defined in annex IX of the Directive. For medical devices having a medium to high degree of risk, the Medical Device Directive requires conformity assessment by a Notified Body to be carried out before the CE mark can be affixed.

Based on the classification, the manufacturer selects the relevant Conformity Assessment procedure.

DNV as a Notified Body

Since 1995, Det Norske Veritas (DNV) has been appointed as a Notified Body to carry out conformity assessment according to Annex II, IV and V of the Medical Device Directive 93/42/EEC. Manufacturers of medical devices in all parts of the world can thus benefit from the experience of DNV's worldwide network of highly qualified auditors and medical experts supported by product specialists. Before placed on the market all DNV certified medical devices shall be marked as follows:



DNV's CE mark services

As a Notified Body, DNV offers CE marking services according to the following directives:

- Medical Device Directive (MDD) 93/42/EEC
- Radio Equipment and Telecommunications Terminal Equipment Directive (R&TTE) 1999/5/EC
- Pressure Equipment Directive (PED) 97/23/EC
- Lift Directive 95/16/EC
- Machinery Directive 98/37/EC
- Directive on electromagnetic compatibility (EMC) 89/336/EEC
- Low Voltage Directive (LVD) 73/23/EEC
- Directive for equipment intended for explosive atmospheres (ATEX) 94/9/EC

When using DNV for CE marking and accredited quality management system certification according to ISO 9001 and ISO 13485, the audits will be carried out as fully integrated processes.



Why place your trust in DNV?

Established in 1864, DNV is an independent foundation with the objective of safeguarding life, property and environment and is a leading international provider of services for managing risk.

DNV is a knowledge-based organisation. Our prime assets are the creativity, knowledge, and expertise of our employees. Most of our more than 6,000 employees are highly qualified engineers and technical personnel.

DNV is an international company with about 300 offices in 100 different countries. Headquartered in Oslo (Høvik), Norway, DNV's global network is linked by efficient information technology enabling us to create value for our customers in a coherent and consistent manner worldwide.

DNV is one of the world's leading certification bodies/registrars offering the latest in management systems and product certification services. With more than 50,000 management system certificates issued worldwide, our name evokes a strong commitment to safety, quality, and concern for the environment.

With the following qualities we are well-equipped to satisfy your organisation's certification needs:

- We have offices all over the world that can provide local service to you. Our employees speak your language and know your local needs, customs and market. Wherever you are, our auditors make it a point to know the business you are in.
- We are one of the few global certification bodies actively involved in the development of new international standards.
- We provide a "one stop shopping" concept by offering a range of both single and integrated certification services that enhance the effectiveness of the certification process.
- We offer Risk Based Certification™ as the standard way of conducting all management system certification. With our risk-based approach to certification you get more than just a certificate. Our auditors will also evaluate how your management system handles risks, i.e. identifying strengths, weaknesses and improvement opportunities.
- We have one of the most stringent auditor training and qualification programmes in the business.

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