



Medical Device Directive 93/42/EEC CE-Marking What Manufacturers Need to Know & Do

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Conformity with Medical Device Directive 93/42/EEC is mandatory all devices that fit the definition of a 'medical device' and its accessories.. **This directive is in the process of being replaced by a Regulation. Approval of the Regulation remains pending.**

Before starting the compliance process a manufacturer needs to be able to answer the following four basic questions:

1) Does the device meet one of following 2 definitions?

a) 'medical device' means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological,

immunological or metabolic means, but which may be assisted in its function by such means;

or

b) 'accessory' means an article which whilst not being a device is intended specifically by its manufacturer to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device;

2) Who is the manufacturer?

The definition of a manufacturer is stated as follows: 'manufacturer' means the natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.

In plain English, if you place your company name on the device or label, you are the manufacturer.

Only one name is allowed and is to be preceded by the EU Symbol for manufacturer.

3) What is the device risk classification?

The determination of a device risk classification must be justified on a risk rule found in Annex IX of the Directive and/or its support documents meddev 2.4/1 latest Rev and the Border Line manual latest version.

There are 6 risk classifications not to be compared with the US-FDA classifications:

- a) Risk Class I,

Note: this is the only classification that qualifies for the self-certification compliance route in the directive.

- b) Risk Class I plus measuring function
- c) Risk Class I plus sterilization
- d) Risk Class IIa
- e) Risk Class IIb
- f) Risk Class III

Risk Classifications b) through f) all require assessment and certification by a European Notified Body.

Notified Bodies are for profit certification agencies that charge for their services. Only European agencies can be Notified Bodies.

4) Guidance documents for Medical Device Directive 93/42/EEC

Harmonized European Standards, available for a fee. They are considered the 'state of the art', and are considered 'not mandatory' but in reality you will be unable to CE-mark a device without the use of harmonized EU standards. Use of non-EU standards is possible only in the absence of an EU standard.

EU Meddev documents – available at no cost

Consensus statements – no cost

Notified Body Operations Group (NBOG) documents – no cost

Once you have determined that: 1) the product is a medical device, 2) your company is the manufacturer, 3) device risk classification and have located the 4) applicable support documents, you are ready to start the compliance process.

Starting the compliance process

Directive Article 11 titled: Conformity assessment procedures provides the options available based on the Risk Classification of the device, provided they are not custom made or intended for a clinical investigation:

Risk Class III devices:

Annex II or III coupled with Annex IV or Annex V

Risk Class IIa devices:

Annex VII coupled with Annex IV **or** Annex V **or** Annex VI or Annex II.

Risk Class IIb devices:

Annex II (minus point 4) or Annex III coupled with Annex IV or Annex V or Annex VI.

It is recommended that you discuss the preferred annexes with your Notified Body of choice. A recent study shows that a majority of Notified Bodies prefer use of Annex II coupled with one of the other Annexes.

In plain English, compliance requires an 1) Quality Management System (ISO 13485); 2) Technical file, including a design file for the highest risk classifications; 3) Hiring of a Notified Body for assessment and certification; 4) Appointing of an EU authorized representative for regulatory affairs not sales and marketing (see: <http://www.ce-authorizedrepresentative.eu/arfaq.pdf>))

Risk Class I devices: Annex VII

A special note about Risk Class I device CE compliance

The compliance requirements for Risk Class I devices far exceed what is required by the US-FDA.

The manufacturer shall:

1) Compile a technical file, using EU standards, which needs to include the following documentation:

- a) Classification justification;
- b) General Information about device and suppliers and sub-contractors;
- c) Translated Labels and Instructions for use and use of EU Symbols;
- d) Risk assessment in accordance with ISO14971 latest issue;

- e) Essential requirements may include biocompatibility, flammability, EMC/LVD, software standards and other test reports;
- f) Evaluation of clinical data;
- g) Procedures: for vigilance, post marketing review, translations etc.
- h) Declaration of Conformity; etc.

2) Appoint an EU authorized representative, who must register the devices in the EU and keep the technical file available to the Competent Authorities. (<http://www.ce-authorizedrepresentative.eu/>)

Selecting a Notified Body

Every manufacturer creates its own criteria, some of the Notified Body (NB) criteria that turned out to be the very important to US manufacturers (often in hindsight) includes:

- Accreditation in the EU and Canada, if you export to Canada,
- Accreditation to include the manufacturer's specific medical devices.
- Accepts English language technical files.
- Has auditors that can explain the requirements in American English and are domiciled in the USA.
- Accept manufacturer's crucial suppliers/vendors ISO 13485 certificates issued by other EU Notified Bodies.
- Auditors trained to include good people skills.
- Have accreditation in directives that can cover other than medical devices for a specific manufacturer i.e. IVDD, Machinery and PPE etc.
- Have a reasonable Notified Body transfer policy

Update: - Have the capacity and scope to Accept new clients/devices.

- a) EU Notified Bodies shall:
 - Be an accredited EU based agency
 - Adhere to the: IAF MD9:2011 Mandatory Document for the Application of ISO/IEC17021 in Medical Device Quality Management Systems (ISO13485).
 - Meet the requirements outlined in the Medical Device Directive.
 - Offer 3 year agreements consisting of: 1 assessment certification audit, annual maintenance audits and unannounced audits

- Membership in the Notified Body Operations Group. <http://www.nbog.eu/index.html>

In plain English, EU Notified Bodies are for profit agencies, not government agencies. Their 3 year contracts are not negotiable and transfer to another Notified Body has been made very expensive and difficult. Shopping for a Notified Body is impossible because their application form contains text limiting application to one Notified Body only.

We **strongly** recommend that you obtain references from other manufacturers and especially your supplier/vendors before making a decision.

Special Notes:

- Electrical/Electronic medical devices must also comply with the Rohs Directive. This does not require Notified Body certification.
- Control the device performance claims in marketing and online brochures, as this may cause a change in (higher) Risk Classification.
- Unannounced auditors cannot be turned away due to personnel vacations etc. Make sure you have a backup team.
- The often misunderstood words 'shall' and 'should' in the directive text stands for 'must'.
- Yes translations are required.

QNET LLC is a quality assurance and CE compliance consulting firm specializing in cost effective CE marking in accordance with Medical Device, Rohs, PPE, Machinery, ATEX and Pressure Equipment Directives since 1996.

QNET BV - Netherlands - delivers EU Authorized Representative services in accordance with the Medical, Machinery, PPE, RoHS, Medical and IVD directives since 1997.

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