Conformity assessment and the CE mark

Conformity assessment procedures

Here we set out in broad terms the conformity assessment routes to be followed by manufacturers to demonstrate that their devices meet the essential requirements of the Medical Devices Directive (MDD). The routes depend on the classification of the device.

The conformity assessment routes

Class I devices

The manufacturer is responsible for ensuring that their product complies with all the relevant essential requirements of the MDD and must draw up a written statement to this effect (self-declaration).

Additionally, manufacturers of sterile products and devices with a measuring function must apply to a notified body for certification of the aspects of manufacture relating to sterility or metrology. Once the manufacturer is satisfied that their products meet all the relevant essential requirements, they must register with the Competent Authority (the MHRA in the UK) by completing and returning form RG2. They may then CE-mark the products and place them on the market.

Class IIa devices

The manufacturer declares conformity with the provisions of the MDD and the Medical Devices Regulations 2002 and ensures that their products comply with relevant essential requirements. However, for Class IIa products, this declaration must be backed up in all cases with conformity assessment by a notified body. The manufacturer can choose the assessment from these options:

1. Examination and testing of each product or homogenous batch of products (Annex IV)

   or

2. Audit of the production quality assurance system(Annex V:) ISO 13485:2003(excluding Design)

   or

3. Audit of final inspection and testing (Annex VI:) ISO 13485:2003 (excluding Design & Manufacture)

   or

4. Audit of the full quality assurance system (Annex II) ISO 13485:2003 Once the manufacturer has received certification from the notified body he may CE mark his products and place them on the market.

Class IIb devices

There are two routes: a notified body must carry out either an Annex II audit of the full quality assurance system (ISO 13485:2003), or a type-examination (Annex III) plus one of the three options given in items 1-3 above for Class IIa (i.e. Annex IV, V or VI). Once the manufacturer has received certification from the notified body they may CE mark the products and place them on the market.

Class III devices

Class III controls are similar to those for Class IIb devices but additionally require the manufacturer to submit the design dossier to the notified body for approval under Annex II and do not allow the Annex III/Annex VI option. Once the manufacturer has received certification from the notified body they may CE mark the products and place them on the market.

The flow charts to illustrate these conformity assessment routes.

Clinical investigations

In some cases manufacturers may need to carry out a clinical investigation (clinical trial) to demonstrate compliance with the essential requirements of the Directive. Our page on clinical trials gives more details.

Standards

Compliance with a harmonised standard will give a presumption of conformity with the Regulations. The European Commission website lists these for each directive:
Under Directive 93/42/EEC medical devices
Under Directive 90/385/EEC Active implantable medical devices
Under Directive 98/79/EC In vitro diagnostic medical devices
UK Notified Bodies are listed on the list of UK Notified Bodies page.

The CE marking

What the CE marking means

The CE marking means that a manufacturer is declaring, on his own responsibility, that his product conforms with the relevant essential requirements in the Directives, and that it is fit for its stated, intended purpose. Once satisfied that the device meets the relevant provisions of the Directives and that the relevant assessments have been carried out, the manufacturer signs a ‘Declaration of Conformity’ prior to affixing the CE marking to his product before it is placed on the market.

Does the CE marking mean that a device is safe?

The CE marking is seen as a declaration by the manufacturer that the product meets all the appropriate provisions of the relevant legislation including those relating to safety and where required has been assessed in accordance with these. The CE marking also means that the product can be freely marketed anywhere in the EU without further control. The CE marking does not indicate the origin of the product.

What devices should not be CE marked

The following devices are exempt from the CE mark:

- custom-made devices
- devices undergoing a clinical investigation
- in vitro diagnostic medical devices (IVDs) for performance evaluation
- non-complying devices used in exceptional circumstances.

Do these devices still have to meet the essential requirements?

Although custom-made devices are exempt from carrying the CE marking they must conform with all the relevant essential requirements of the Directives.

Devices intended for clinical investigation must also conform with the relevant essential requirements as far as possible, and with regard to the aspects under investigation every precaution must be taken to protect the health and safety of patients.

IVDs for performance evaluation are not subject to the normal conformity assessment/CE marking procedures.

By their very nature humanitarian use devices do not conform with the requirements of the Directive.

Although third party conformity checks are not required for these products, manufacturers have to draw up a statement of compliance on their own responsibility for custom made, clinical investigation and performance evaluation devices. This statement is subject to control by the national competent authorities (the MHRA in the UK). Custom-made devices must be clearly marked as such and all devices for clinical investigation must bear the wording ‘exclusively for clinical investigation’.

Manufacturers of custom-made devices are required to register with the competent authority where they have their registered place of business.

Free movement

Unless there are grounds for suspecting that a device may pose a risk to public health, member states must not ‘create any obstacles to the placing on the market or the putting into service of any medical devices as defined under the Directive bearing a legitimate CE marking’. This means that a CE-marked device may have access to the whole of the European Economic Area market (the 27 member states of the EU and EFTA countries, Iceland, Norway and Liechtenstein) and manufacturers are not

required to comply with any national schemes when exporting their devices to other countries. Once placed on the EEA market CE-marked medical devices are subject to inspection by the market surveillance authorities of the relevant member states.

Notified body identification

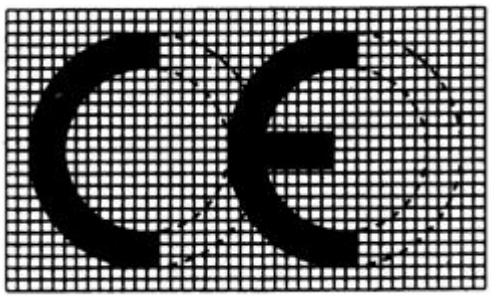
Where a notified body has been involved in conformity assessment, the identification number assigned to it by the Commission must be applied below the CE mark.

Commission guidance on the CE marking

The European Commission has produced guidance that includes six steps to CE marking a product. This is available on the European Commission website.

Form and dimensions of the CE marking

The CE conformity marking shall consist of the initials ‘CE’ taking the following form:



It should be at least 5mm in size, and should appear on the packaging and on the device itself where this is practicable. Instruction leaflets should also carry the CE mark. If the marking is reduced or enlarged the proportions given in the above graduated drawing must be respected.

The various components of the CE marking must have substantially the same vertical dimension, which may not be less than 5 mm. This minimum dimension may be waived for small-scale devices.