

# GUIDANCE DOCUMENT

## CE MARKING OF STERILE BARRIER SYSTEMS

Sterile Barrier Systems are subject to the [Council Directive 93/42/EEC on Medical Devices](#) (referred to as the MDD) and under the directive are considered to be 'accessories' to medical devices as defined as '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'. The Directive defines the essential requirements i.e. the legal requirements that devices have to meet when they are put on the market or put into service. For the purposes of the Directive, accessories are treated as medical devices in the requirement to comply with the essential requirements as set out in Annex 1 of the Directive.

Medical Devices considered to meet the essential requirements must bear the CE marking of conformity when placed on the market.

The CE marking indicates a product's compliance with EU legislation and so enables the free movement of products within the European market. By affixing the CE marking to a product, a manufacturer declares, on his sole responsibility, that the product meets all the legal requirements for the CE marking, which means that the product can be sold throughout the European Economic Area (EEA, the 28 Member States of the EU and European Free Trade Association (EFTA) countries Iceland, Norway, Liechtenstein). This also applies to products made in other countries which are sold in the EEA.

CE marking does not indicate that a product was made in the EEA, but merely states that the product has been assessed as satisfying the applicable legal requirements before being placed on the market.

It means that the manufacturer\* has:

- verified that the product complies with all relevant essential requirements laid down in the applicable directive(s) and
- if stipulated in the directive(s), had it examined by an independent conformity assessment body.

It is the manufacturer's responsibility to:

- carry out the conformity assessment
- set up the technical file
- issue the declaration of conformity and
- affix the CE marking to a product.

Distributors must check that the product bears the CE marking and that the requisite supporting documentation is in order.

Importers of products from outside the EEA, have to verify that the manufacturer has undertaken the necessary steps and that the documentation is available upon request.

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To demonstrate conformity with the essential requirements assessments must be carried out. Generally, sterile barrier systems are taken into account as an accessory or part of the device in the overall conformity assessment process carried out by a device manufacturer on the final product. However, sterile barrier systems sold directly to the hospitals are considered as Class 1 devices (generally regarded as low risk) under the Directive and the responsibility for the conformity assessment lies with the sterile barrier manufacturer.

Before proceeding with the assessment procedure, it is important to establish whether you, the manufacturer, can assess your product by yourself or whether you have to involve a Notified Body. The involvement of a Notified Body is not necessary for Class 1 medical devices unless they have a measuring function or are placed on the market in a sterile condition.

For Class 1 devices, other than devices which are custom-made or intended for clinical investigations, the manufacturer must, in order to affix the CE mark, follow the procedure referred to in [Annex VII of the MDD](#) and draw up the EC declaration of conformity required before placing the device on the market.

**Since sterile barrier systems are taken into account as an accessory or part of the device in the overall conformity assessment process carried out by a device manufacturer on the final product they do not require their own CE mark. The CE mark which appears on the sterile barrier material will relate to the medical device and not to the sterile barrier system itself.**

**It is usual, in order to avoid confusion with the CE mark for the final product, for sterile barrier systems considered as Class 1 devices sold separately to the device prior to sterilisation to carry the CE mark on the sales packaging rather than on the individual bag, pouch or sheet.**

Further detailed information on the MDD and CE marking can be found on the [European Commission DG Growth website](#)

See also [Guidance notes for manufacturers of Class 1 medical devices](#)

\* The **Council Directive 93/42/EEC on Medical Devices** defines the manufacturer as:

*'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'.*

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