The CE marking

A CE mark is a logo that is placed on medical devices to show they conform to the requirements in the directives. It shows that the device is fit for its intended purpose stated and meets legislation relating to safety. It shows the product can be freely marketed anywhere in the European Union.

The manufacturer must sign a ‘declaration of conformity’ before they can place the CE mark on their product.

The CE marking also means that the product can be freely marketed anywhere in the EU and in India. The mark does not indicate the origin of the product.

Only CE marked medical devices can be placed on the market. The CE mark shows that the device meets the legal requirements for medical devices. To place a CE mark on a medical device, the manufacturer must document the product's quality, safety and performance.

Why do medical devices have to be CE marked?

The CE marking shows that medical devices meet the current EU legislation. The CE marking means that medical devices can be marketed in the EU, provided that the devices meet the national requirements.

However, there is no legal requirement for CE marking of custom-made devices, system and medical treatment packages and devices for clinical investigation.

How to place a CE marking on a product

Before placing a CE marking on a medical device, the device must be covered by the definition of medical devices and be classified correctly in accordance with the classification rules laid down.

Conformity assessment

When the product is in compliance with the requirements for safety and performance, and the technical documentation has been established, the manufacturer must date, sign and keep a declaration of conformity to show that the product complies with the requirements of the executive order.

CE marking

Once the manufacturer has signed the EU declaration of conformity, the CE mark can be placed on the device. The CE mark should be placed visibly, legibly and

indelibly on the instructions for use and is a symbol that the product complies with the legal requirements.

The CE mark must also be affixed to the packaging and on the device. On sterile devices, the CE mark should be placed on the package that ensures sterility of the device. The identification number for a notified body has to be placed below the CE mark.