Affixing a CE mark to a product means that the manufacturer is declaring that the product meets all legal requirements as well as conforming to relevant product safety directives in the EU.

An identification number for a notified body needs to be placed below the CE mark to show it has been involved in the conformity assessment. It shows that the device has been checked and meets EU health and safety legislation. It also shows the product can be freely marketed anywhere in the European Union without further control.

CE marking is mandatory, but only applies to products that are covered by the subject matter of one or more of the New Approach Directives. The aim of this research was to clarify the process and requirements for gaining a CE mark.

Each one encompasses guidelines relating to an individual product and whether it is required to bear a CE mark.

Medical devices are categorised by type (class) and the registration will include the type of device you sell. There are several classifications of medical devices—Class I, Class IIa, Class IIb and Class III (Figure 2). Class III contains the highest risk products.

The classification rules are based on different criteria such as:

- the duration of contact with the patient
- the degree of invasiveness
- the part of the body affected by the use of the device

Once a CE mark has been obtained from a notified body a ‘declaration of conformity’ must be signed before you can place the CE mark on your product. It states that the manufacturer takes sole responsibility for the conformity within all the legal requirements to achieve a CE mark. CE marking (Figure 3) means that the product can be marketed anywhere in the EU.

A CE mark states that a product has been assessed before being placed on the market and satisfies legislative requirements of the applicable EC directives. It ensures that a product has ‘free-movement’ within the EU.

More and more medical devices are required to have a CE mark if they want to gain access to the EU market. In order to get a medical device to market a conformity assessment must be carried out. This proves that the medical device meets the essential requirements laid out in annex I of the Medical Devices Directive.

Guidelines set down by MEDDEV and rules shown in simple flowchart designs (Figure 2) help the manufacturer to determine the type of classification the device will fall under, as well as assisting in general navigation through the system.

Once the assessment has been successful, a CE mark can be placed on the product to show it has met the necessary requirements. Companies should be aware that some of these directives may change in the coming months due to a review of the regulations.

References:

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