

THE CE MARK

BULLETIN No. 2

COMPETENT AUTHORITY(UK)

Amended September 2007

INTRODUCTION

This bulletin replaces the earlier version printed in August 1999. It is intended as general guidance only and should not be regarded as an authoritative statement of the law, or as having any legal status. Manufacturers and others should not rely solely on the information in this bulletin but should also consult the legislation referred to, making their own decisions in conjunction with their lawyers and other professional advisers. The Medicines & Healthcare products Regulatory Agency (MHRA) does not accept liability for any errors, omissions, misleading or other statements in this bulletin, whether negligent or otherwise.

THE CE MARK

This information bulletin is the second in a series and explains in broad terms:-

- what the CE mark means
- which devices are exempt from the CE mark
- how manufacturers of devices can gain the CE mark

THE MEDICAL DEVICES DIRECTIVES

There are three European Directives concerning medical devices:-

- the Active Implantable Medical Devices Directive (90/385/EEC)
- the Medical Devices Directive (93/42/EEC): as amended in Directives 2000/70 and 2001/104 on medical devices incorporating stable derivatives of human blood or human plasma
- the In Vitro Diagnostic Medical Devices Directive (98/79/EC)

These have been implemented into UK legislation by the Medical Devices Regulations 2002, which consolidates all the existing medical devices Regulations into a single piece of legislation and which came into force on 13 June 2002. The main purpose of these Regulations is to bring about the completion of the single market by introducing harmonised and statutorily based controls to regulate the safety and performance of devices throughout the European Union. The Directives replace any existing national systems in Member States and include provisions for mandatory CE marking of products within their scope, except for certain specific exclusions.

WHAT THE CE MARK MEANS

The CE mark means that a manufacturer is satisfied that his product conforms with the relevant Essential Requirements in the Directives and that it is fit for its intended purpose.

DOES THE CE MARK MEAN THAT A DEVICE IS SAFE?

The CE mark 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 mark also means that the product can be freely marketed anywhere in the EU without further control.

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

DO THESE DEVICES STILL HAVE TO MEET THE ESSENTIAL REQUIREMENTS?

Although custom-made devices are exempt from carrying the CE mark they must conform with all the relevant Essential Requirements. 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.

Although third party conformity checks are not required for these products, manufacturers have to draw up a statement of compliance on their own responsibility. This statement is subject to control by the national Competent Authorities (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".

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



Community market and manufacturers are not required to comply with any national schemes when exporting their devices to other countries in the EU.

FORM AND DIMENSIONS OF THE CE MARK

The CE mark is reproduced at Annex A. 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.

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.

FURTHER INFORMATION

Copies of guidance documents and other bulletins in our series can be obtained from our website

<http://www.mhra.gov.uk>

or by leaving a message on 020 7084 3203. (24 hour answer phone).

Address & Telephone Numbers are as follows:

Write: European & Regulatory Affair
Medicines and Healthcare Products
Regulatory Agency
8th Floor
Market Towers
1 Nine Elms Lane,
London SW8 5NQ

Tel: 020 7 084 3300

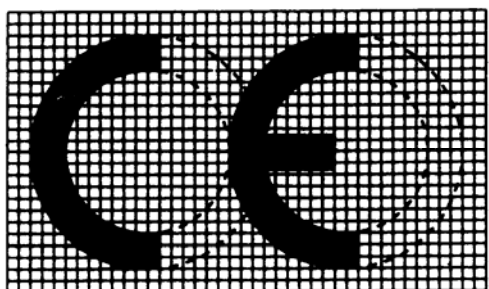
Fax: 020 7 084 3112

E-mail: era@mhra.gsi.gov.uk

ANNEX A

The CE Mark of Conformity

The CE conformity marking shall consist of the initials 'CE' taking the following form.



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.

In line with the requirements of the Hampton Report on Reducing Administrative Burdens - Effective Inspections and Enforcement, MHRA keeps its guidance documents under constant review. If you have any feedback, particularly on the presentation, accessibility or clarity of any of our guidance notes or bulletins please inform the contact person indicated at the end of the individual document.