DEPARTMENT OF HEALTH

MEDICAL DEVICES DIRECTORATE

DIRECTIVES BULLETIN

CONFORMITY ASSESSMENT PROCEDURES

Introduction

This bulletin is the fourth in a series and sets out in broad terms the conformity assessment routes likely to be available, under the Medical Devices Directive, for manufacturers to demonstrate that their devices meet the Essential Requirements. This will permit affixation of the CE mark in accordance with the Directive (see earlier bulletins for details).

The classification rules

Annex IX of the Medical Devices Directive sets out a system of classification rules. Each device is taken through a set of rules which classify it according to its properties, function and intended purpose.

Level of control

The system's main purpose is to allow the strictest controls to be applied only to those devices which present the greatest risk to health or safety. This is known as the "principle of proportionality".

Details under negotiation

The details of the classification system are still being negotiated, and we are therefore unable to say at present how particular devices will be classified.

Four classes

Devices will be assigned to one of four classes: broadly, these are Class I for low-risk devices, Classes IIa and IIb for medium-risk devices and Class III for high-risk devices.

The conformity assessment routes

The conformity assessment routes available to the manufacturer of devices in each of the four classes will be along the following lines:

Class I

The manufacturer declares conformity with the provisions of the Directive, including compliance of the product with all relevant Essential Requirements. This means that the manufacturer is legally obliged to meet those Essential Requirements.

Additionally, sterile products and measuring devices are expected to be subject to a limited degree of Notified Body intervention. The intention is that this should be limited to those aspects of manufacture relating to sterility and/or metrology.

Class IIa

As for Class I, the manufacturer declares conformity with the provisions of the Directive (including the compliance of the product 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.

This assessment may, at the manufacturer's choice, consist of:

- audit of the production quality assurance system; or
- audit of final inspection and testing; or
- examination and testing of sample products.

Alternatively, the manufacturer may follow the full quality assurance route as for Class IIb devices.

Class IIb

A Notified Body will carry out either an audit of the full quality assurance system or type-testing plus some form of production audit or sample examination.

Class III

Class III controls are broadly equivalent to the controls applied under the Active Implantable Medical Devices Directive. They are similar to those for Class IIb devices but additionally require the manufacturer to submit the design dossier to the Notified Body for approval.

In vitro diagnostic medical devices (IVDs)

Work has only recently begun on the third Directive. There is expected to be a classification system, with most IVDs in Class I. Some IVDs whose performance is crucial in terms of patient health and safety, will be subject to some kind of Notified Body controls.

Conformity assessment charts

The charts on page 3 of this bulletin show in more graphic detail how the conformity assessment routes will operate.

Further information

Future bulletins will go into more detail on each of the Directives areas of specific interest such as notified bodies, European Standards and clinical investigations.

Further information, and copies of the first three bulletins in our series about the medical devices Directives, can be obtained from:-

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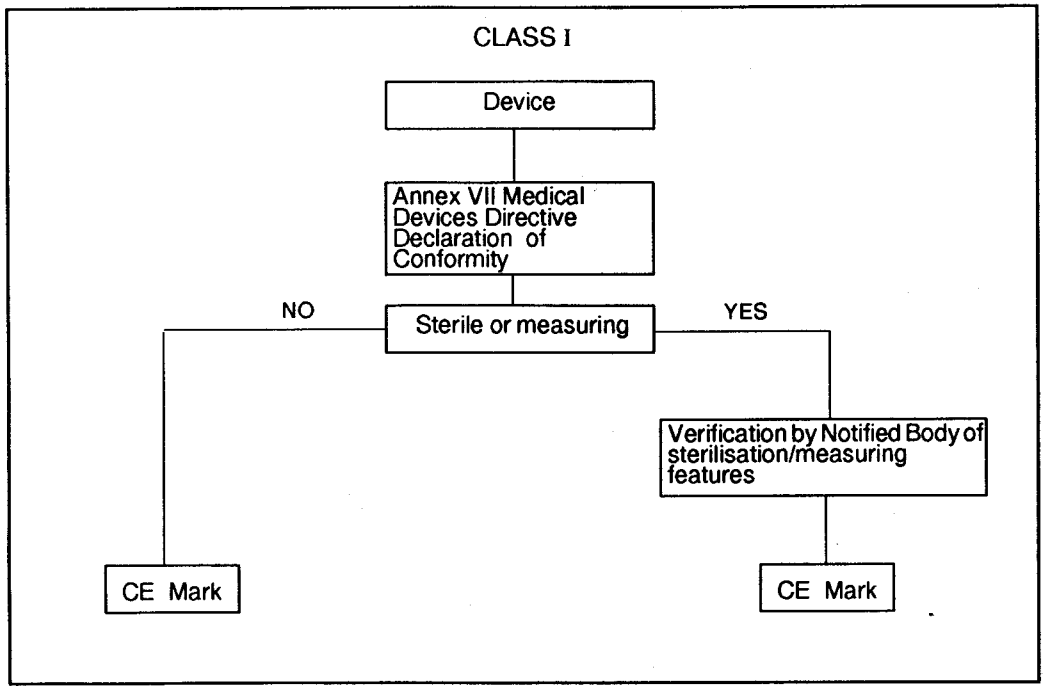
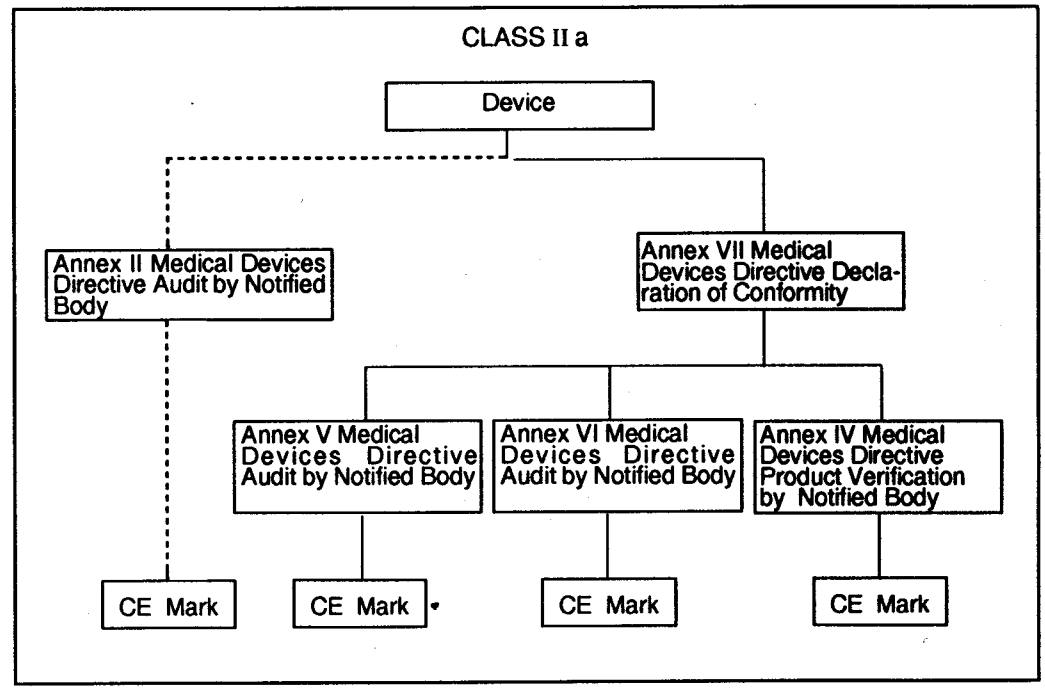
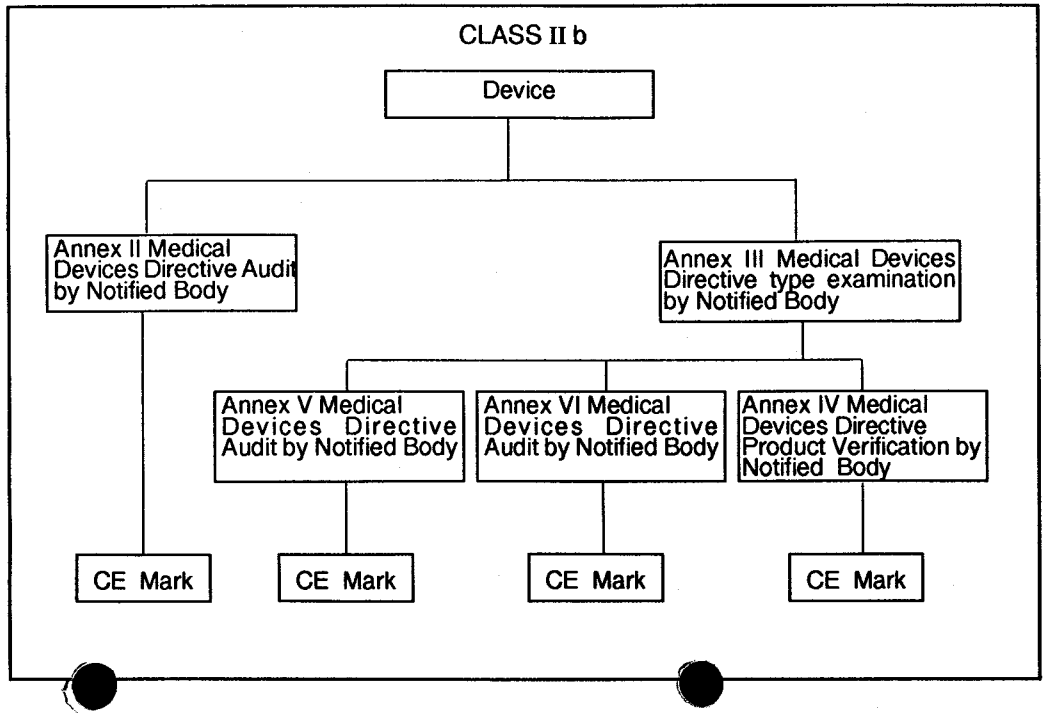
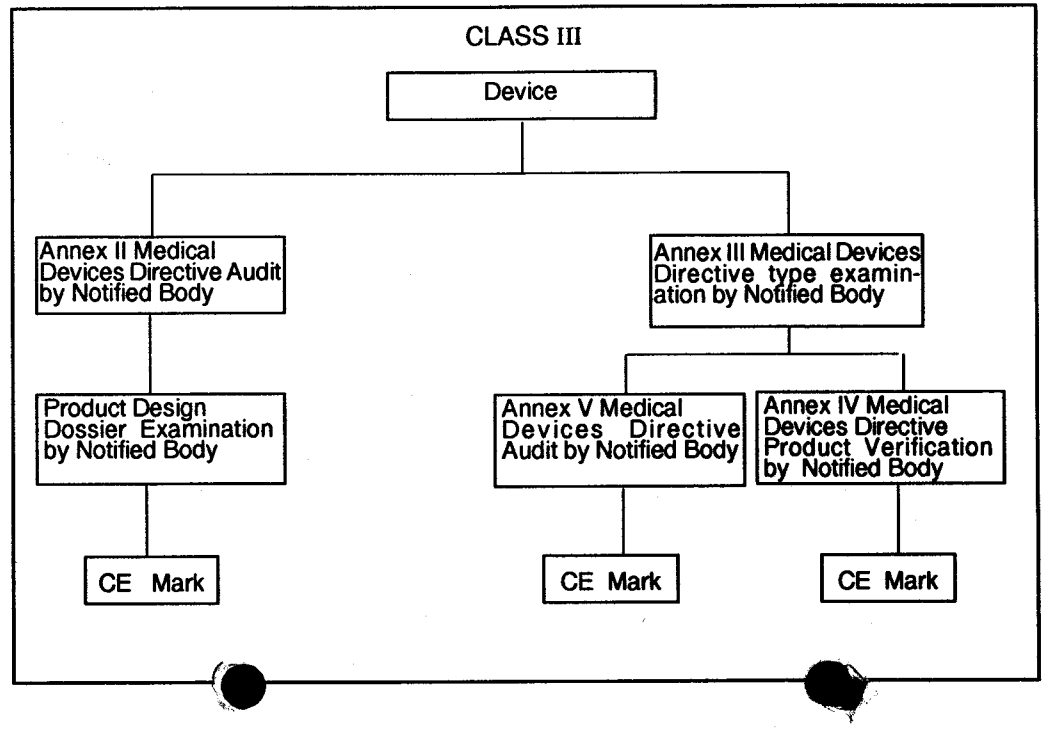

CLASS I
Device
Annex VII Medical Devices Directive Declaration of Conformity
Sterile or measuring
NO
YES
Verification by Notified Body of sterilisation/measuring features
CE Mark
CE Mark


CLASS II a
Device
Annex II Medical Devices Directive Audit by Notified Body
Annex VII Medical Devices Directive Declaration of Conformity
Annex V Medical Devices Directive Audit by Notified Body
Annex VI Medical Devices Directive Audit by Notified Body
Annex IV Medical Devices Directive Product Verification by Notified Body
CE Mark
CE Mark
CE Mark
CE Mark


CLASS II b
Device
Annex II Medical Devices Directive Audit by Notified Body
Annex III Medical Devices Directive type examination by Notified Body
Annex V Medical Devices Directive Audit by Notified Body
Annex VI Medical Devices Directive Audit by Notified Body
Annex IV Medical Devices Directive Product Verification by Notified Body
CE Mark
CE Mark
CE Mark
CE Mark


CLASS III
Device
Annex II Medical Devices Directive Audit by Notified Body
Annex III Medical Devices Directive type examination by Notified Body
Product Design Dossier Examination by Notified Body
Annex V Medical Devices Directive Audit by Notified Body
Annex IV Medical Devices Directive Product Verification by Notified Body
CE Mark
CE Mark
CE Mark