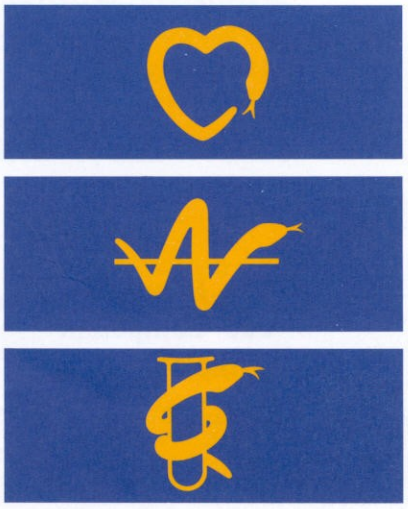
DEPARTMENT OF HEALTH

MEDICAL DEVICES DIRECTORATE

DIRECTIVES BULLETIN



THE COMPETENT AUTHORITY

Bulletin number 7

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DEPARTMENT OF HEALTH

Introduction

This information bulletin is the seventh in a series and sets out in broad terms the role and functions of **The Competent Authority**.

The Competent Authority

The Competent Authority is the body which has the authority to act on behalf of the government of a Member State to ensure that the requirements of the medical devices Directives are carried out in that particular Member State. **The Competent Authority** in the UK is the Secretary of State for Health who has delegated responsibility for day to day running of **The Authority** to The Medical Devices Directorate.

The Role of The Competent Authority

The role of **The Competent Authority** is determined by the Directives and consequent national Regulations. Its primary aim is to ensure that all medical devices sold in the UK meet the Essential Requirements laid down in the Directives and in so doing, do not compromise the health and safety of patients, users and, where appropriate, any other persons.

The Functions of The Competent Authority

The general responsibilities of **The Competent Authority** include

* negotiating the Directives on behalf of the UK Government,
* putting in place the necessary Statutory Instruments to give effect to the Directives,
* liaising and consulting with interested parties within the Department of Health, other Government Departments, the National Health Service and other bodies, including the UK healthcare industry,
* participating in EC Working, and other, Groups,
* publicising the provisions of the Directives and issuing appropriate guidance to device users and manufacturers in the UK,
* advising on the medical devices Directives eg interpretation of the Articles, conformity assessment routes and the classification of devices, and
* monitoring the effectiveness of the Regulations and their burdens on business.

More specific tasks of **The Competent Authority** include

* enforcing the Regulations using powers under The Consumer Protection Act,

* liaising with the EC Commission if it considers that harmonised standards do not meet the Essential Requirements,

* membership of the Standing Committees set up under the Directives to provide opinions, advice and guidance to Member States,

* undertaking appropriate measures to withdraw unsafe devices from, or prohibit or restrict their being placed on, the market,

* resolving disputes eg between manufacturers and Notified Bodies,

* ensuring that adverse incidents are reported within the appropriate timescales and are recorded and evaluated centrally,

* maintaining registers of Class I devices, custom-made devices and systems or procedure packs,

* handling all applications for clinical investigations including arrangements for evaluation by expert assessors, and

* designating Notified Bodies within the UK to carry out conformity assessment procedures.

Some of these tasks, such as **The Authority's** role in carrying out pre-clinical assessment procedures, designating Notified Bodies and operating a vigilance system, are dealt with in more detail in other information bulletins. The implications of some of the other tasks are described more fully below.

Enforcement

The Competent Authority must ensure, except for custom-made devices and those intended for clinical investigation, that

* all devices carrying the CE Marking meet the Essential Requirements,

* devices not meeting the Essential Requirements are not allowed to carry the CE Marking, and

* except for devices marketed under transitional arrangements, only devices carrying the CE Marking are placed on the market.

For the purposes of The Active Implantable Medical Devices Directive, **The Competent Authority** will enforce the Regulations. For The Medical Devices Directive, however, it may be necessary to enlist the help of other dedicated enforcement authorities.

Medical devices bearing the CE Marking when placed on the market are presumed to conform to the appropriate Essential Requirements unless there is reason to believe otherwise. If **The Competent Authority** becomes aware that a particular medical device bearing the CE Marking does not conform to the Essential Requirements or is a risk to public health it will take appropriate measures to verify this and, if necessary, withdraw the device from the market.

Liaison with the EC Commission, other Member States and non-EC countries

The Competent Authority will inform the EC Commission of any enforcement action taken within the UK. It will also provide observations on any notifications received from the Commission about enforcement action taken in other Member States. Countries in the European Free Trade Area (EFTA) have agreed to accept the provisions of the Directives. **The Competent Authority** will notify the appropriate government when enforcement action is taken against any medical devices originating in any of those countries.

Further information

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

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