

INFORMATION ABOUT THE EC MEDICAL DEVICES DIRECTIVES

BULLETIN No. 8

COMPETENT AUTHORITY(UK)
Amended January 2006

INTRODUCTION

This bulletin is intended as general guidance and should not be regarded as an authoritative statement of the law, nor as having any legal status. It follows that manufacturers and others should not rely on the bulletin but should consult the legislation referred to, making their own decisions on matters affecting them 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 the bulletin whether negligent or otherwise. An authoritative statement could be given only by the courts.

BACKGROUND

A series of three Directives regulating the safety and marketing of medical devices throughout the European Union started to come into effect from 1 January 1993. This bulletin sets out in broad terms:

- ◆ *why we need the Directives*
- ◆ *how patients and users are expected to benefit*
- ◆ *type of devices covered by each Directive*
- ◆ *implementation in the UK*
- ◆ *some key points in the Directives*

WHAT IS A MEDICAL DEVICE

For the purposes of the Directives, a medical device is defined as:-

"any instrument, apparatus, appliance material or other article, whether uses alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used on human beings for the purpose of:

- ◆ *diagnosis, prevention, monitoring, treatment or alleviation of disease,*
- ◆ *diagnosis, monitoring, treatment, or alleviation of or compensation for an injury or handicap,*
- ◆ *investigation, replacement or modification of the anatomy or of a physiological process,*
- ◆ *control of conception*

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means".

WHY DO WE NEED THE DIRECTIVES?

Before the introduction of the medical devices Directives, each Member State in the European Union would control the safety and marketing of medical devices on its territory in different ways.

The Directives benefit manufacturers by harmonising controls within a single system and avoid the need for manufacturers having to comply with 15 different sets of rules. Purchasers and users can also be reassured that devices manufactured in the UK or anywhere in the Union should meet common standards of performance and safety.

The Directives benefit patients and users, by setting out **essential requirements** that products must meet. These make it clear that devices must not compromise the health or safety of the patient, user or any other person, and that any risks associated with the device are compatible with patient health and protection. Any side effects must be acceptable when weighed against the intended performance of a device. Devices meeting these requirements generally carry the "CE" mark to show that they comply.¹

THE DIRECTIVES

The Medical Devices Regulations 2002 consolidates all the existing medical devices regulations into a single piece of legislation and came into force on 13 June 2002.

THE ACTIVE IMPLANTABLE MEDICAL DEVICES DIRECTIVE

SCOPE AND IMPLEMENTATION

This first Directive covers all powered implants or partial implants that are left in the human body. Heart pacemakers are the most common example of powered implants.

THE MEDICAL DEVICES DIRECTIVE

SCOPE AND IMPLEMENTATION

The second Directive covers most other medical devices, ranging from, for example, first aid bandages, tongue depressors, hip prostheses, X-Ray equipment, ECG and heart valves.

THE IN VITRO DIAGNOSTIC MEDICAL DEVICES DIRECTIVE

SCOPE AND IMPLEMENTATION

The third Directive covers any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system intended for use in-vitro for the examination of specimens, including blood and tissue donations, derived from the human body. Examples of in-vitro diagnostic devices are blood grouping reagents, pregnancy test kits and Hepatitis B test kits.

KEY POINTS IN THE DIRECTIVE

CE MARKING

The CE mark that appears on a medical device or on its packaging means that the device satisfies the relevant essential requirements and is fit for its intended purpose as specified by the manufacturer. Eventually all devices, (except custom-made devices, those intended for clinical

investigations and devices for performance evaluation) whether used in private or public hospitals and nursing homes or sold in retail outlets, will have to carry the CE marking.

CLASSIFICATION

The Medical Devices Directive and the In Vitro Diagnostic Medical Devices Directive include a classification system whereby the level of regulatory control applied to devices is proportionate to the degree of risk associated with the device. The strictest controls therefore apply only to high-risk products.

THE COMPETENT AUTHORITY

The Competent Authority is the body responsible for implementing the requirements of the Directives in each Member State. In the UK, the Competent Authority is the Secretary of State for Health acting through the MHRA. The Competent Authority's main role is to ensure that manufacturers comply with the Regulations, to evaluate adverse incident reports received from manufacturers, and carry out a pre-clinical assessment of devices intended for clinical investigation.

(Footnote 1 - Exceptions are devices intended for clinical investigations, custom-made devices, devices for performance evaluation)

NOTIFIED BODIES

The Competent Authority is also responsible for designating the independent certification organisations (Notified Bodies) that check that manufacturers of medium and high risk medical devices have followed the requirements. Once they are satisfied, manufacturers may apply the CE mark to their products and place them on the market.

CLINICAL INVESTIGATIONS

The Directives require all devices intended for clinical investigation in the EU to be formally assessed on the risks such investigations might pose to the health and safety of patients. For most medical devices (except in-vitro diagnostic devices) manufacturers have to inform the relevant Competent Authority if they intend to start a clinical investigation at least 60 days before it is due to begin. The investigation may start after the 60-day period unless the Competent Authority notifies the manufacturer of a decision to the contrary on grounds of public health. All proposals for clinical investigations must be referred to the Local Research Ethics Committee (LREC). The LREC opinion must be submitted to the Competent Authority.

ADVERSE INCIDENT REPORTING (VIGILANCE)

Arrangements for reporting adverse incidents have changed under the Regulations. Manufacturers are required by law to report **serious** incidents to the Competent Authority. Information about these is collected and evaluated centrally and, where necessary, made available to other Member States. The overall aim of the new system is to improve the safety of



patients, users and others by trying to prevent incidents similar to those reported occurring elsewhere in the Union.

MEDICINES & HEALTHCARE PRODUCTS REGULATORY AGENCY ADVERSE INCIDENT CENTRE

MHRA's voluntary system operated by its Adverse Incident Centre (AIC), based on user reporting of all device-related adverse incidents, continues alongside the new vigilance system.

COPIES OF DIRECTIVES AND REGULATIONS

Copies of the following Directives and UK Regulations are available by writing, telephoning or faxing:-

Stationery Office Books
Scanfax Department
Publications Centre
51 Nine Elms Lane
London, SW8 5DR

Tel: 020 7873 8372
Fax: 020 7873 8247

TITLE	REFERENCE
Medical Devices 1993 Directive (93/42/EEC) quote no: 31993L0042	Official Journal L169-
The In Vitro Diagnostic Medical Devices Directive (98/79/EC) quote no: 31998L0079	Official Journal L331-1998
The Active Implantable Medical Devices Directive (90/385/EEC) quote no: 31990L0385	Official journal L189-1990

(access for Official Journal documents on the European Commission Website: <http://europa.eu.int/eur-lex/en/index.html>)

For Regulations:-

The Stationary Office Ltd
PO Box 29
Norwich
NR3 1GN

Tel: 0870 600 5522
Fax: 0870 600 5533

TITLE	REFERENCE
The Medical Devices Regulations 2002	SI 2002/618 ISBN 011042317



The Medical Devices
(Amendment)
Regulations 2003

SI 2003/1697
ISBN 011046763-9

FURTHER INFORMATION

Further information, copies of guidance documents and copies of other bulletins in our series can be obtained on our website at <http://www.mhra.gov.uk> or by leaving a message on 020 7084 3203 (24 hours). For more detailed enquiries ring 020 7084 3300, send a fax to 020 7084 3112 or write to;

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