

COMPETENT AUTHORITY (UK)

**9 EC MEDICAL DEVICES
DIRECTIVES**

**GUIDANCE NOTES FOR
MANUFACTURERS OF
CUSTOM MADE DEVICES**

Updated January 2006

CONTENTS	PAGE
<hr/> <u>Introduction</u>	<u>3</u>
<hr/> <u>Definition of Custom-Made Devices</u>	<u>4 - 5</u>
<hr/> <u>The Medical Devices Legislation with reference to Custom-Made Devices</u>	<u>5 - 6</u>
<hr/> <u>The Essential Requirements for Custom-Made Devices</u>	<u>6 - 7</u>
<hr/> <u>Annex VIII Statement concerning Custom-Made Devices</u>	<u>7 - 9</u>
<hr/> <u>Contact point</u>	<u>9 - 10</u>
<hr/> <u>Appendix I: Examples of some products which might be considered as Custom-Made</u>	<u>11 - 12</u>
<hr/> <u>Appendix II: Bibliography</u>	<u>13 - 14</u>

INTRODUCTION

The Medical Devices Directive (93/42/EEC) was adopted by the European Council of Ministers on 14 June 1993, (Official Journal of the European Communities, ref. L169, 12 July 1993). This directive has been implemented in the United Kingdom by the Medical Devices Regulations 2002 (SI 2002 No 618) which came into force on 13 June 2002. The Regulations regulate the safety and marketing of medical devices whether used in the public or private sectors.

This guidance aims to present the Department of Health's current views on the interpretation of the Medical Devices Regulations where enquiries from medical device manufacturers and others have shown that there is uncertainty as to what the requirements are.

This guidance is intended as general guidance and should not be regarded as an authoritative statement of the law, nor as having any legal consequence. It follows that manufacturers and others should not rely on the guidance but should consult the legislation referred to and make their own decisions on matters affecting them in conjunction with their lawyers and other professional advisors. The Department of Health does not accept liability for any errors, omissions or other statements in this guidance whether negligent or otherwise. An authoritative statement could be given only by the courts.

The purpose of this document is to provide guidelines* to assist manufacturers of custom-made devices in meeting the requirements of the Regulations.

A manufacturer, as defined in the Regulations, is:

“the person who is responsible for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party”.

these guidelines may also help in understanding compliance requirements for manufacturers of any custom-made active medical device under the Active Implantable Medical Devices Directive (90/385/EEC) implemented by the Medical Devices Regulations 2002 SI 2002 No 618.

For the purpose of the Regulations, a medical device is defined as:

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

- *diagnosis, prevention, monitoring, treatment or alleviation of disease;*
- *diagnosis, monitoring, treatment, 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, even if it is assisted in its function by such means.”*

DEFINITION OF CUSTOM-MADE DEVICES

According to the Regulations,

“custom-made” means, in relation to a device -

- a) *that it is manufactured specifically in accordance with a written prescription of a duly qualified medical practitioner or a professional user which gives, under his responsibility, specific characteristics as to its design; and*
- b) *that it is intended for the sole use of a particular patient.”*

For the purpose of this guidance document the term “qualified person” will be used to cover medical practitioners and professional users.

Examples of professional users are:

Ophthalmologist, Optometrist, Orbital Prosthetist, Ocularist, Audiology Technicians, Orthotist, Dentist, Hearing Aid Dispenser, Orthopaedic Shoefitter.

A written prescription may be a letter from a qualified person or a moulded impression of the shape of the required device together with the order specifying customer details, and a request to “make as pattern”.

It is the qualified person who is responsible for specifying the particular design characteristics of the product.

The manufacturer of a custom-made device must meet the particular requirements of the Medical Devices Regulations which relate to custom-made devices. These requirements are not intended to interfere in any way with the professional and clinical responsibilities of the prescriber. The activities carried out by the healthcare professional in supplying or fitting a custom-made device (e.g. preparation, impression taking, prescribing, final fitting and any adaptation), are not considered to fall within the scope of the Medical Devices Regulations.

It should be noted that mass-produced devices which need to be adapted to meet the specific requirements of a healthcare professional (and which are supplied for the sole use of a particular patient) are not considered to be custom-made devices (e.g. contact lenses and stock footwear).

THE MEDICAL DEVICES LEGISLATION

WITH REFERENCE TO CUSTOM-MADE DEVICES

A manufacturer of custom-made devices must refer to Regulations 5 to 19 of the Medical Devices Regulations and identify those requirements applicable to his products.

Points to note are:

Regulation 8

Essential requirements for general medical devices.

The manufacturer should comply with the relevant essential requirements (defined in Annex I of the Directive).

Regulation 15

Procedures for custom-made general medical devices.

Custom-made devices which would fall into Class II(a), II(b) or III shall be *accompanied* by the statement referred to in Annex VIII of the Medical Devices Directive. These devices shall not bear the CE Marking.

Regulation 65 (Article 10)

Information on incidents occurring following placing of devices on the market.

There is no legal requirement for manufacturers of custom-made devices to report incidents, serious or otherwise, to the Competent Authority. However, manufacturers are asked to report any serious incident to the relevant manufacturer where a CE

marked device used in the manufacture of the custom-made device has played a part in causing the incident. The voluntary user reporting system will continue to apply and the MHRA will investigate incidents.

Regulation 18

UK notified bodies and the conformity assessment procedures for general medical devices

To comply with the Medical Devices Regulations, a manufacturer of custom-made devices must follow the procedures referred to in Annex VIII of the Medical Devices Directive. Manufacturers of custom-made devices do not require the intervention of a Notified Body.

Regulation 19

Registration of persons placing general medical devices on the market.

A manufacturer of a custom-made device with a registered place of business in the United Kingdom who places the device on the market under his own name shall inform the Secretary of State of the address of that registered place of business and supply a description of the devices concerned. The Medicines & Healthcare products Regulatory Agency has prepared form RG2 and guidance for its completion (*Guidance Note 8*) to simplify this process. This registration must *not* be made *until* the manufacturer claims compliance with the Regulations.

Where a person who has a registered place of business in the United Kingdom is designated as the person responsible for marketing a device placed on the market by a manufacturer who does not have a place of business in the European Economic Area, that person must register with the Secretary of State as described above.

Regulation 16

Procedures for general medical devices for clinical investigations

It is possible that custom-made devices will be the subject of a clinical investigation, e.g. investigation into the use of novel materials used in dental appliances. For further information see MHRA's Guidance Documents on Clinical Investigations.

THE ESSENTIAL REQUIREMENTS FOR CUSTOM-MADE DEVICES

Although a custom-made device is manufactured to the prescribed requirements of the healthcare professional, if it is to be fit for its intended purpose, it must meet all the relevant essential requirements. These are set out in Annex I of the Medical Devices Directive, with the general requirements listed at paras 1-6.

The manufacturer should consider whether the following are relevant.

- a) chemical, physical and biological properties of the device (*Annex I paragraph 7*);
- b) infection and microbial contamination (*Annex I paragraph 8*);
- c) construction and environmental properties (*Annex I paragraph 9*);
- d) protection against radiation (*Annex I paragraph 11*);
- e) requirements for medical devices connected to or equipped with an energy source (*Annex I paragraph 2*);
- f) information supplied by the manufacturer, including labels (*Annex I paragraph 13*);

As a minimum requirement the labels on a custom-made device must include (*Annex I paragraph 13.3*):

- the name or trade name and address of the manufacturer or, for devices imported into the European Economic Area (EEA), the name and address of a representative based there;
- the details strictly necessary for the healthcare professional to identify the device and the contents of the packaging (e.g. patient name/description of device);
- the words “custom-made device”.

The manufacturer must also review the requirements regarding other information that is to be supplied with the device and determine what is appropriate for his products.

ANNEX VIII

STATEMENT CONCERNING CUSTOM-MADE DEVICES

The manufacturer of a custom-made device must comply with Annex VIII of the Directive which contains provisions relating to the drawing up of a statement containing the information detailed below and the keeping of documentation relating to the device (*see Regulation 15*).

If the device would not fall into Class I (*see the classification criteria in Annex IX of the Directive*), the statement must accompany the device (*see Regulation 9(5)*).

It is the responsibility of the manufacturer of the device to review all the requirements of the Directive and Regulations against his procedures. This statement must include:

- a) data allowing identification of the device in question, i.e. description, serial number, order number, generic name;
- b) a statement that the device is intended for exclusive use by a particular patient, together with the name of the patient (this may be an identification number if patient confidentiality needs to be maintained, provided it can be traced through records to the named patient);
- c) the name of the qualified person, medical practitioner or other authorised person who made out the prescription and, where applicable, their place of work;
- d) the particular features of the device as specified in the relevant prescription, i.e. the written prescription with its special features extracted to define the particular device;
- e) a statement that the device in question conforms to all the relevant essential requirements set out in Annex I and, where it does not, the grounds for believing it is safe for use.

Additionally, the manufacturer must:

- a) retain and, upon request, make documentation available to the Competent Authority, allowing an understanding of the design, manufacture and performances of the product -including the expected performances - so as to allow assessment of conformity with the requirements of the Regulations;
- b) take all measures necessary to ensure that the manufacturing process produces products which are manufactured in accordance with the documentation mentioned in (f) above.

Procedures to ensure requirements are met generally would include:

- a) *a review of the qualified person's written prescription* to ensure that adequate information has been supplied and to document the manufacturing requirements, e.g. choice of materials, processing parameters and considerations of cleanliness and infection control;

- b) *manufacturing under controlled conditions*, e.g. following defined/documented processes and have some method of demonstrating that they are being followed (e.g. records); using suitably trained personnel; where appropriate, undertaking calibration and maintenance of equipment; considerations of cleanliness and infection control; defined handling activities and packaging;
- c) *a review of the final product* against the qualified person's written prescription before it is placed on the market. The review should be documented.

NOTE:

The nature and extent of the documentation required depends on the type of custom-made device. For example, hearing aid inserts, which are manufactured in large numbers using a common technique, may be supported by standard manufacturing procedures and records and a prepared common statement completed for each device supplied. On the other hand, a custom-made joint replacement may require individual specifications, procedures and test reports. Written justification for key decisions or interpretations, appropriate records and statements are generally necessary.

The Competent Authority has the power (under Section 29 of The Consumer Protection Act 1987) to check control systems to ensure conformity with Annex VIII. There is no statutory requirement for the manufacturer to have a formal quality system. However, the manufacturer is expected to have developed or referenced documentation to meet all the relevant requirements. This includes the prescription review, manufacturing, inspection and test procedures.

Annex VIII also requires that all the specified information be held in safe keeping for a period of not less than five years from the date when the custom-made device was placed on the market.

CONTACT POINT:

Further information about the Medical Devices Regulations can be obtained from:-

Medicines & Healthcare products Regulatory Agency
European & Regulatory Affairs
Market Towers
1 Nine Elms Lane
London
SW8 5NQ



Telephone: (020) 7084 3090/3300
Fax: (020) 7084 3112
Email: era@mhra.gsi.gov.uk
<http://www.mhra.gov.uk>

APPENDIX I

EXAMPLES OF PRODUCTS WHICH MIGHT BE CONSIDERED AS CUSTOM-MADE

The following products are listed for *guidance* only and must not be considered as an exhaustive list.

Some of the products listed below will also be available as mass produced, rather than custom-made medical devices and must be classified according to the rule in Annex IX of the Medical Devices Directive.

DEVICE	PRESCRIBER	MANUFACTURE	COMMENT
DENTAL APPLIANCES	Dentist	Dental Laboratories	See Guidance Notes No. 10
PRESCRIBED OPHTHALMIC SPECIALIST	Ophthalmologist Optometrist Dispensing Optician (in part)	Glazing Shop	Custom-made device only if lenses or frames are not mass produced. Otherwise refer to Regulation 11
ARTIFICIAL EYES/ COSMETIC SHELLS	Ocularist/Orbital Prosthetist	Ocularist or Ocular Technician	Patient specific
MAXILLOFACIAL PROSTHESIS	Medical Consultant or Prosthetist	Prosthetist	Patient specific
HEARING AID INSERTS/MOULDS	Medical Consultant or Audiology Technician or Hearing Aid Dispenser	Insert Maker	Patient specific
IN-THE-EAR AIDS	Medical Consultant or Audiology Technician or Hearing Aid Dispenser	Aid Manufacturer	Patient specific
ORTHOPAEDIC FOOTWEAR*	Orthotist or Shoe Fitter	Shoemaker	Patient specific
JOINT REPLACEMENT IMPLANTS (<i>Designed for a specific individual</i>)	Orthopaedic Surgeon	Implant Manufacturer	No two implants alike but some parts the same. Basic principle of function the same.

PROSTHETICS AND ORTHOTICS	Rehabilitation Consultant or Orthopaedic Consultant Also private sector Prosthetists and Orthotists	Prosthetic and Orthotic Service Companies and Manufacturers or NHS	See Guidance Notes NO. 16 Guidance for Manufacturers of Prosthetic and Orthotic Devices.
---------------------------	--	--	--

*The Footwear Labelling Directive is aimed at footwear offered for retail sale. It may not apply to bespoke footwear made under contract for the NHS.

APPENDIX II

BIBLIOGRAPHY

Council Directive 93/42/EEC (Medical Devices Directive) 1993. Official Journal of the European Community No L169 - publication date 12 July 1993.

The Medical Devices Regulations implementing the Directives Reference SI 2002 No 618.

Council Directive 90/385/EEC (Active Implantable Medical Devices Directive) 1990. Official Journal of the European Community No L189 - publication date 20 June 1990.

All available from
Stationery Office Books (Scanfax Department)
Publications Centre
51 Nine Elms Lane
London
SW8 5DR

Tel: 020 7873 8372

Fax: 020 7873 8247

MHRA GUIDANCE NOTES on the EC MEDICAL DEVICES DIRECTIVES

Guidance Document Number 1
EC Medical Devices Directives - Guidance Notes for Manufacturers on Clinical Investigations to be carried out in the UK.

Guidance Document Number 8
EC Medical Devices Directives - Guidance Notes for the Registration of persons responsible for placing devices on the market.

Guidance Document Number 10
EC Medical Devices Directives - Guidance Notes for Manufacturers of Dental Appliances (Custom-Made Devices).

Guidance Document
European Commission Guidelines on a Medical Devices Vigilance System April 2001
- MEDDEV 2.12-1 rev 4 see Europa website:
<http://europa.eu.int/comm/enterprise/medical-devices/guidelinesmed/baseguidelines.htm>



Directives Bulletin Number 18
Activities of Healthcare Establishments (In-House Manufacture) in the UK.

MHRA FORMS

Form RG2

Medical Devices Regulations 2002: Regulation 19 form RG2 - Registration of persons responsible for placing devices on the market.

All MHRA publications and forms are available from

MHRA website at

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

Or:

MHRA European and Regulatory Affairs

Market Towers

1 Nine Elms Lane

London

SW8 5NQ

Tel: (020) 7084 3300

Fax: (020) 7084 3112