

COMPETENT AUTHORITY (UK)

16
DIRECTIVES

EC MEDICAL DEVICES

**GUIDANCE NOTES FOR
MANUFACTURERS OF
PROSTHETIC AND ORTHOTIC
DEVICES**

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INTRODUCTION

This guidance sets out the Medicines & Healthcare products Regulatory Agency (MHRA)'s views on the interpretation of the Medical Devices Regulations. It should not be treated as an authoritative statement of the law in any particular case as it is intended as guidance only. Manufacturers and others should consult the relevant Directive and appropriate Regulations on matters affecting them. If you require a legal interpretation of the Regulations, you should consult your own legal advisers. MHRA does not accept liability for any errors, omissions or other statements in the guidance, whether negligent or otherwise.

The document covers those issues which appear to need further clarification based on enquiries received from prosthetic and orthotic device manufacturers and others concerned with these products. The guidance has been drawn up in collaboration with the International Society for Prosthetics and Orthotics (ISPO) and the British Healthcare Trades Association (BHTA), and should be read in conjunction with other relevant publications produced by MHRA (*see Bibliography at Appendix II*).

The Medical Devices Directive (Directive 93/42/EEC) was adopted by the European Council of Ministers on 14 June 1993 (Official Journal of the European Communities 12 July 1993 ref L169). This Directive was implemented in the UK by the Medical Devices Regulations 2002 (SI No 618), which consolidates all the existing medical devices Regulations into a single piece of legislation and which came into force on 13 June 2002.

Manufacturers and others placing medical devices on the Community market should consult the Medical Devices Regulations and the Medical Devices Directive to check whether their products fall within the definition of a medical device.

1. GENERAL

Under the Medical Devices Regulations, devices covered are classified into one of four categories (Class I, IIa, IIb or III) according to the definitions, implementing rules and classification rules set out in Annex IX of the Medical Devices Directive. Custom-made devices are subject to the same classification criteria.

Where the terms 'prosthetic devices' and 'orthotic devices' are used in this guidance they refer only to external prostheses and orthoses.

The majority of prosthetic and orthotic devices are Class I medical devices which carry the CE marking, custom-made devices as defined in Regulation 2 or systems consisting of an assembly of devices as defined in Regulation 14. *Appendix I* gives examples of prosthetic and orthotic devices according to the category in which MHRA considers they belong.

The European Standard 12523:1999 "External limb prostheses and external orthoses - requirements and test methods" will provide a means of satisfying

some of the Essential Requirements for external limb prostheses and external orthoses listed in Annex 1 of the Medical Devices Directive.

The professional activity of prosthetists and orthotists aligning or fitting prostheses/orthoses for individual patients is *outside* the scope of the Regulations.

A prosthetic or orthotic device manufactured by a healthcare establishment eg in an NHS workshop and by NHS technicians, and given or attached to a patient under its care (even if that patient has been referred from another NHS Trust) is *outside* the scope of the Regulations. However, healthcare establishments and prosthetists and orthotists who decide that their activities are not subject to the Regulations should also be aware of their responsibilities under the general law (including consumer protection and product liability) and ensure the safety of patients, users and any relevant third party.

Manufacturers and healthcare establishments supplying devices with the intention of placing them on the market ie “the first making available in return for payment or free of charge of a new or fully refurbished device other than a device intended for clinical investigation, with a view to distribution, use, or both, on the Community market” come *within* the scope of the Regulations. A commercial company/private contractor working within a healthcare establishment, eg a Disablement Services Centre, is considered to be a separate legal entity. A device manufactured by the company/contractor therefore falls *within* the scope of the Regulations, irrespective of ownership of the workshop equipment and facilities.

MHRA’s Bulletin No 18 “The Medical Devices Regulations: Implications on Healthcare and Other Related Establishments” provides further guidance on this aspect.

2. PROSTHETIC DEVICES

Modular prostheses are constructed from mass produced components, which are considered to be Class I medical devices requiring CE marking (*see Appendix I*), assembled (*see section 6*) in accordance with the manufacturer’s instructions. These prostheses are then adapted for individual patients.

Conventional prostheses are fabricated and shaped by technicians and adapted/aligned by prosthetists for individual patients. They are custom-made medical devices as they are manufactured for individual patients (although CE marked devices, eg a moulded foot, may be included in the construction).

MHRA considers an external prosthetic device to comprise two separate parts:

- *an assembly of hardware*

This comprises all the components up to the socket interface, all of which could be CE marked devices, or otherwise a mix of CE marked and custom-made devices (guidance on the assembly of systems is given in

Section 6 and on the manufacturer of custom-made devices in Section 5 of this document). It is a medical device.

- *a prosthetic socket*

This may be an accessory to the medical device (accessories are treated as devices in their own right and therefore subject to the Regulations) which is manufactured for attachment to the assembly of hardware to enable it to be used for its intended purpose. Alternatively, the socket may be custom-made in accordance with instructions from the Rehabilitation Consultant (termed medical practitioner or other healthcare professional in the Regulations), prosthetist or prescribing officer, the specific requirements of the patient and any manufacturer's instructions for the correct manufacture of the socket. The assembly of hardware and prosthetic socket are joined together in accordance with the manufacturer's instructions. Assemblers performing the activity of joining the hardware to the socket may be considered exempt from the obligations of being defined a manufacturer (Regulation 13(2)).

3. ORTHOTIC DEVICES

MHRA considers that the majority of orthotic devices are classified as follows:

CLASS I

- ◆ *mass produced orthotic kits or parts (eg swivel walkers) which are assembled with adjustments for height, width, weight, etc*
- ◆ *reciprocating gait orthoses*
- ◆ *mass produced or stock item orthotic devices which do not impart energy to the user, such as cervical and cervico thoracic orthoses*
- ◆ *mass produced footwear and insoles or segments for making insoles*

See also Appendix I.

NOTE: INSOLES PLACED ON THE MARKET WHICH ARE NOT INTENDED BY THE MANUFACTURER TO HAVE A MEDICAL FUNCTION ARE *OUTSIDE* THE SCOPE OF THE REGULATIONS.

CLASS IIA

- ◆ *orthotic devices with functional electrical stimulation (FES) to support mobility (where energy is imparted to the user)*

CUSTOM-MADE

- ◆ *general orthoses (eg lower limb callipers) which are a mix of Class I CE marked devices (such as knee joint side members) and custom-made devices designed for individual patients*
- ◆ *bespoke orthoses (eg cervical, cervico thoracic, orthotic splint, bespoke footwear) which are made direct from casts or lasts*

4. CE MARKING

The Regulations require all medical devices, with the exception of custom-made devices, devices intended for clinical investigation (see MHRA's Guidance Document No 1) and systems comprised only of CE marked parts, to display the CE marking of conformity (Regulation 10) when placed on the market.

Manufacturers (as defined in Regulation 2) of batch/mass produced prosthetic and orthotic devices, or their authorised representatives, must affix the CE marking to their devices in accordance with Regulation 10.

The CE marking must appear in a visible, legible and indelible form on the device or its packaging where practicable and appropriate, on the instructions for use (ie manufacturers' build/adjustment instructions) and where applicable on the sales packaging (Regulation 10).

MHRA's Guidance Notes for Manufacturers of Class I Medical Devices (Document No 7) gives further guidance on this aspect.

5. CUSTOM-MADE DEVICES

Custom-made devices are subject to the classification rules (Annex IX of the Medical Devices Directive) but should not be CE marked. Manufacturers of custom-made devices must meet the particular requirements of the Regulations which relate to custom-made devices (Regulation 15). See also Appendix I.

Regulation 2(1) states that if manufacturing is carried out in accordance with a duly qualified practitioner's written prescription for the sole use of a particular patient and the appliance is not an adaptation of a mass produced device, then the product is considered to be a custom-made device. In the manufacturing cycle of some "one-off" prosthetic/orthotic appliances, it is the practitioner (consultant, prosthetist, orthotist) who undertakes the design of the product and the technician manufactures it to a predefined specification.

The requirements are not intended to interfere in any way with the professional and clinical responsibilities of the prosthetist/orthotist. The professional activities carried out by practitioners in the supply and fit of appliances (eg preparation, cast-taking, prescribing, final fitting and any adaptation/aligning) are *outside* the scope of the Regulations and for those purposes the professionals are not considered to be manufacturers.

For each custom-made device, the manufacturer must draw up a statement under Regulation 15 covering the following information:

- ◆ *data allowing identification of the device in question, eg name of patient and hospital reference number, limb order number, name of manufacturer, date of manufacture, where made*
- ◆ *a statement that the device is intended for exclusive use by a particular patient, together with the name of the patient*
- ◆ *the name of the Rehabilitation Consultant, prosthetist or orthotist who made out the prescription and, where applicable, the name of the clinic or Disablement Services Centre*
- ◆ *the particular features of the device as specified in the relevant medical prescription/limb order and measure chart*
- ◆ *a statement that the device conforms to all the relevant essential requirements, as set out in Annex I of the Directive, or an explanation if any essential requirements have not been fully met*

For custom-made devices in Classes IIa, IIb and III (see classification criteria in Annex IX of the Directive), the statement must accompany the device (Regulation 9(5)).

The manufacturer must be able to demonstrate that work is being carried out under controlled conditions. This should include:-

- ◆ *a documented review of the requirements of the Rehabilitation Consultant/prosthetist/orthotist to demonstrate an understanding of the manufacturing requirements for the design, eg an assurance that suitable equipment and personnel are available and any training requirements (professional and product specific) have been met to facilitate construction of the prescribed device. (The processing parameters must be defined together with the choice of materials or components used. This will probably already be documented in the limb order or orthotic prescription and/or measure charts, etc.)*
- ◆ *defined manufacturing processes (eg work instructions)*
- ◆ *suitably qualified personnel*
- ◆ *where appropriate, calibration and maintenance of equipment (eg measuring instruments)*
- ◆ *defined handling activities and packaging requirements, such as workshop storage and methods of packing for postal deliveries*

- ◆ *a documented review of the final prosthetic or orthotic device against the Rehabilitation Consultant's/prosthetist's/orthotist's initial requirements before it is supplied*

Records should be kept available for a minimum of 5 years to demonstrate manufacturing control. The records should include:

- ◆ *the statement about custom-made devices (Regulation 15 - Annex VIII of the Directive)*
- ◆ *the review of the Rehabilitation Consultant's/prosthetist's/orthotist's requirements and final product, identification of the materials used*
- ◆ *production process monitoring*
- ◆ *maintenance*
- ◆ *calibration which for practical reasons may be recorded on relevant orders/prescriptions and measure/build charts*

MHRA's "Guidance Notes for Manufacturers of Custom-Made Devices" (Document No 9) gives general guidance in this area.

6. SYSTEMS AND ASSEMBLIES

In the prosthetic and orthotic device sector, a system is an assembly of components bearing the CE marking which are put together within their intended purpose and limits of use specified by their manufacturer.

Regulation 14(1) states that subject to paragraph (3), no person shall supply a system or procedure pack (if that supply is also a placing on the market, or if that supply is of a system or procedure pack that has been placed on the market) unless -

- (a) the medical devices in that system or procedure pack are for use within their intended purpose and within the limits of use specified by their manufacturer,
- (b) the person who places or has placed it on the market has drawn up a declaration that -
 - (i) he has verified the mutual compatibility of the medical devices in that system or procedure pack in accordance with the manufacturers' instructions, and he has carried out his operations in accordance with these instructions,
 - (ii) he has packaged the system or procedure pack and supplied relevant information to users incorporating relevant instructions from the manufacturers, and
 - (iii) his production of the system or procedure pack is subjected to appropriate methods of internal control and inspection,

and that declaration is true at the time it is made and continues to be true.

Where a system is made up of devices which all bear the CE marking and which are intended by the manufacturer(s) to be put together, Regulation 14(5) applies:

(5) Where a conformity assessment procedure is carried out in respect of a relevant device (including a device which is a system or procedure pack) pursuant to this regulation -

(a) no person shall affix a CE marking to that device as a result of that procedure; and

(b) no person shall supply that device (if that supply is also a placing on the market, or if that supply is of a device that has been placed on the market) unless it is accompanied by the information referred to in Section 13 of Annex I, which shall include, where appropriate, the information supplied by the manufacturers of the devices which have been put together.

Assemblers of systems under Regulation 14 must register with the Competent Authority (Regulation 19).

Where a system incorporates any device (other than a socket) without a CE mark, then it shall be treated as a device in its own right and be subject to the relevant procedure (see Sections 4 and 5). This also applies where the chosen combination of devices is to be put to a different use from that intended by the manufacturer of each device, eg the construction of 'hybrid' modular prostheses.

7. REFURBISHMENT

Anyone who fully refurbishes prostheses and orthoses and does not follow the original manufacturer's instructions becomes a manufacturer within the definition of Regulation 2. He must therefore meet the requirements of the Regulations and, where applicable, register as a Class I manufacturer (see Regulation 19 and Sections 9 and 11 of this document).

8. LABELLING

The minimum requirements for the labelling of devices are set out in Annex I paragraph 13.3 of the Directive and include:

- ◆ *the name or trade name and address of the manufacturer(s); for devices imported into the Community, the label, outer packaging, or instructions for use must also contain the name and address of either the person responsible referred to in Regulation 19(3), or the name of the authorised representative of the manufacturer established within the Community or of the importer established within the Community;*

- ◆ *the details strictly necessary for the user to identify the device and the contents of the packaging;*
- ◆ *where appropriate, the batch code, preceded by the word 'LOT', or the serial number;*
- ◆ *for devices intended for single use only, a statement to this effect;*
- ◆ *for custom-made devices, the words 'custom-made device';*
- ◆ *for devices intended for clinical investigations, the words 'exclusively for clinical investigations';*
- ◆ *any special storage and/or handling conditions;*
- ◆ *any special operating instructions;*
- ◆ *any warnings and/or precautions.*

It is for manufacturers to review all the information and labelling requirements against their practices. Manufacturers must also review the requirements for information to be supplied with the device and determine what is appropriate. Where appropriate, the instructions for use must contain the following particulars:

- ◆ *the details referred to above, with the exception of information about batch numbers*
- ◆ *if the device must be installed with or connected to other medical devices or equipment in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct devices or equipment to use to ensure a safe combination*
- ◆ *information about the risks of reciprocal interference posed by the presence of the device during specific investigations or treatment*
- ◆ *if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of sterilisation and any restriction on the number of reuses*
- ◆ *details of any further treatment or handling needed before the device can be used (eg final assembly)*

The instructions for use must also include details allowing medical staff to brief the patient on any contra-indications and any precautions to be taken. These details should cover in particular precautions to be taken:

- ◆ *in the event of changes in the performance of the device;*
- ◆ *regarding exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources, etc.*

9. OBLIGATIONS OF PERSONS OTHER THAN MANUFACTURERS

The obligations of a manufacturer under the Regulations extend to a person who assembles, packages, processes, fully refurbishes or labels one or more ready-made products or assigns to them their intended purpose as a device with a view to their being placed on the market under his own name (Regulation 2 Interpretation of "manufacture").

The above paragraph does not apply to a person who assembles or adapts devices already on the market to their intended purpose for an individual patient (Regulation 2 Interpretation of "manufacture").

10. INFORMATION ON INCIDENTS OCCURRING FOLLOWING PLACING ON THE MARKET

Annex VII requires manufacturers of devices bearing the CE marking, or authorised representatives, to notify the Competent Authority if they learn that a device has been involved in an incident that led to death, serious injury or deterioration in the health of the patient, user or other persons; or near incident that could have led to death or serious injury. For example, if there is a malfunction or deterioration in the characteristics and/or performance of a device, or inadequacy in the labelling or instructions for use of a device.

The Competent Authority must also be notified of any technical or medical reason relating to the characteristics or performance of a device which lead to systematic recall of devices of the same type of the manufacturer.

Further information on timescales and incident reporting is given in "The Vigilance System - Bulletin 3".

Manufacturers of custom-made devices are requested to report any serious incident to the relevant manufacturer where a CE marked device used in the manufacture of a custom-made device has played a part in causing the incident.

In addition to the requirements described above, the voluntary user reporting system will continue to apply and MHRA will investigate incidents.

11. REGISTRATION OF PERSONS RESPONSIBLE FOR PLACING DEVICES ON THE MARKET

Manufacturers of Class I and custom-made devices and assemblers covered by Regulation 19 (see section 6) must register with the Competent Authority using form RG2 available from MHRA and provide a description of the devices concerned and the business address(es).

Manufacturers of devices which do not fall into Class I (eg devices with Functional Electrical Stimulation which are Class IIa) need to approach a suitable Notified Body to obtain approval to cover the aspects of manufacturing concerned with

conformity of the product. MHRA's Bulletin No 6 "The Notified Body" gives further details.

Manufacturers of devices outside the European Economic Area must designate a representative within the Community. This representative must register with the Competent Authority of the Member State within which it has its business. The name and address of the representative must appear on the device label, outer packaging or on the instructions for use.

MHRA's "Guidance Notes for the Registration of Persons Responsible for Placing Devices on the Market" (Document No 8) gives general guidance on this aspect.

12. FURTHER INFORMATION

Information about the Medical Devices Directives and Regulations can be found in Publications/Regulatory on our website at <http://www.mhra.gov.uk>

Further information can also be obtained from:

MHRA
European & Regulatory Affairs
Market Towers
1 Nine Elms Lane
London
SE1 5NQ
Tel: 020 7084 3300/3090
Fax: 020 7084 3112
Email: era@mhra.gsi.gov.uk

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1 Nine Elms Lane
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SE1 5NQ
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APPENDIX I

CUSTOM-MADE/CE MARKED MEDICAL DEVICES

The items below are divided into CUSTOM-MADE or CE MARKED orthotic and prosthetic devices. This list is not exhaustive and the classes/groups shown are allocated for guidance purposes only. The Regulations place responsibility for classification on the manufacturer.

PROSTHETIC DEVICES

LIMB TYPE/COMPONENT	CUSTOM-MADE DEVICE	CLASS I CE MARKED DEVICE
<i>Lower Limbs:</i>		
Modular hip		4
Modular knee		4
Modular gain control (includes IP unit)		4
Modular shin		4
Modular ankle		4
Modular foot		4
Partial foot (Chopart)	4	
Non-modular limbs (conventional limbs)	4	
<i>Upper Limbs:</i>		
Hand (including myoelectric)		4
Terminal device (ie split hook)		4
Wrist		4
Forearm		4
Elbow		4
Shoulder		4
Partial hand	4	
Prosthetic Sockets	4 <i>when supplied on written prescription for the sole use of a particular patient</i>	4 <i>when considered 'accessories' within the definition of the Regulations</i>

ORTHOTIC DEVICES

TYPE OF ORTHOSIS	CUSTOM-MADE DEVICE	CLASS I CE MARKED DEVICE
Cervical orthosis (from a cast)	4	
Cervical orthosis (stock item)		4
Cervico thoracic (from cast)	4	
Cervico thoracic (stock item)		4
Cervico-thoraco-lumbo-sacral (CTLSO from cast)	4	
CTLSO (from stock items)		4
Footwear - bespoke (from cast/last)	4	
Footwear (stock item, Mass produced)		4 <i>when placed on the market principally for a medical purpose</i>
Shoulder, elbow, hand, wrist, knee, ankle orthoses etc	4 <i>when made direct from casts (eg ortholen splints) or from measure charts</i>	4 <i>when supplied as stock items</i>
Stock footwear/shoes		4 <i>when mass produced for a cross-section of users and adapted as necessary for individual patients (manufacturers should provide guidelines for acceptable adaptations)</i>
Stock inlays, insoles and mass produced segments for making insoles		4 <i>only when intended for a medical purpose</i>
Swivel walkers and standing frames		4 <i>these are supplied as a kit of parts and assembled in accordance with the component/kit manufacturer's instructions</i>
Reciprocating gait orthoses		4 <i>Note: the electrical stimulation equipment for Electrical Impulse Action is Class IIa as it imparts energy to the user</i>

APPENDIX II

BIBLIOGRAPHY

Council Directive 93/42/EEC (Medical Devices Directive), Official Journal of the European Community Reference No L169.
Published on 12 July 1993

The Medical Devices Regulations 2002 - Reference SI 2002
 No 618.

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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 7 EC Medical Devices Directives - Guidance Notes for Manufacturers of Class I Medical Devices

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 9 EC Medical Devices Directives - Guidance Notes for Manufacturers of Custom-Made Devices

MHRA DIRECTIVES BULLETINS

Directives Bulletin Number 3 The Vigilance System

Directives Bulletin Number 6 The Notified Body

Directives Bulletin Number 18 The Medical Devices Regulations: Implications on Healthcare and Other Related Establishments

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 on our website
<http://www.mhra.gov.uk>

or from:

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European and Regulatory Affairs
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