Medicines and Healthcare Products Regulatory Agency

Custom-made devices

These guidelines aim to help manufacturers understand compliance requirements for the manufacture of custom-made active implantable medical device or custom-made medical device.

As defined by the Medical Devices Regulations 5 (1):

- manufactured specifically in accordance with a written prescription of a registered medical practitioner, or other person authorised to write such a prescription by virtue of his professional qualification, which gives under his responsibility, specific characteristics as to its design; and
- intended for the sole use of a particular patient,

but does not include a mass-produced product which comprises a medical device and medicinal product forming a single integral product which needs to be adapted to meet the specific requirements of the medical practitioner or professional user;

Note as far as active implantable medical devices are concerned the requirement is that only a medical specialist may write the prescription. This is defined in the Regulations as 'a registered medical practitioner as, or is undergoing training intended to lead to qualifications, a specialist'.

Examples of professional users:
Ophthalmologist, optometrist, orbital prosthetist, ocularist, audiology technicians, orthotist, dentist, hearing aid dispenser, orthopaedic shoe fitter.

A written prescription may take the form of 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.

Note 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).

Examples

The table below gives examples of products that might be considered as custom-made. This is for guidance only and must not be considered as an exhaustive list:

Device	Prescriber	Manufacturer	Comment
Dental appliances	Dentist	Dental laboratories	
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 (designed for a	Orthopaedic surgeon	Implant manufacturer	No two implants alike but some parts the same. Basic

Device	Prescriber	Manufacturer	Comment
specific individual)			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 the NHS	See MHRA's Guidance for manufacturers of prosthetic and orthotic devices.

Conformity assessment requirements

Manufacturers of custom-made devices must follow the requirements specified in the relevant Annexes of the Directives which apply to them. 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 of the directives. The manufacturer should consider whether the following are relevant.

- chemical, physical and biological properties of the device
- infection and microbial contamination
- construction and environmental properties
- protection against radiation
- requirements for medical devices connected to or equipped with an energy source;
- information supplied by the manufacturer, including labels.

As a minimum requirement the labels on a custom-made device must include:

- 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 their products.

CE marking

The Directives stipulate that custom-made devices and custom-made active implantable medical devices are not required to be CE marked when they are first placed on the market and/or put into service. However, they must meet the relevant provisions of the Directives that apply to them. In addition, manufacturers of custom-made devices do not require the intervention of a notified body.

Statement concerning custom-made devices

The manufacturer of a custom-made device must comply with the relevant Annex 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.

If the custom-made device in question would have been classified as either a class IIa, class II(b) or class III device, within the definition of a medical device or is an active implantable medical device then that device must be accompanied by the statement referred to in the relevant Annex to the Directive. It should be noted that the statement does not need to be provided with a custom-made device which has been classified as class I.

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

- data allowing identification of the device in question, i.e. description, serial number, order number, generic name
- 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)
- the name of the qualified person, medical practitioner or other authorised person who made out the prescription and, where applicable, their place of work
- 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
- 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
- the name and address of the manufacturer.

Additionally, the manufacturer must:

- 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. The documentation for all active implantable medical devices shall be kept for a period of at least 15 years from the date of manufacture of the

last product. For all other medical devices the period is at least five years and in the case of implantable devices at least 15 years

- make the statement available to the named patient for whom the device has been manufactured.

Legislative changes for statements concerning custom-made device

Through an amendment to Article 2.3 of Directive 2007/47/EC a requirement was introduced that the 'statement' detailed in Article 11.6 and Annex VIII of Directive 93/42/EC and Article 9(2) and Annex 6 of Directive 90/85 should be available to the named patient for whom the device has been manufactured. Previously, responsibility rested purely with the manufacturer of the custom-made device to provide a copy of the statement to the prescriber of the device. The amendment extends this duty by requiring that the statement is available to the patient. Whilst the technical document issued with the device should indicate if the manufacturer operates from more than one site, this need not be included in the statement.

We have examples of how each sector of custom-made medical devices has dealt with this requirement.

The Regulations, implementing Directive 2007/47/EC into UK law, simply require that patients are made aware that they can request a statement and that it should be made available on request. It does not go into detail about how this will be achieved. This was left to member states to determine as a matter of implementation policy according to national systems for making custom-made devices available to patients.

During the period of negotiations the MHRA invited all stakeholder representatives affected by the changes to attend discussions. This was then followed up by visits to manufacturers across the custom-made field during the consultation period to explore any practical problems which might arise.
The MHRA then held discussions with representatives from the different fields of custom-made devices to gain an appreciation of the different ways each of these sectors of the industry would be able to implement the changes.

Post-market surveillance, corrective action and vigilance procedure

Manufacturers of custom-made devices are required to review and document experience gained in the post-production phase and to set up a post-market vigilance system of reporting to authorities.

Specifically, manufacturers need to report any incidents resulting from the constituents or design of the device if they pose a serious risk to public health, or the manufacturer initiates a field safety corrective action (e.g. a recall).

Note: Ordinary return of devices to manufacturers for adjustment or fitting would not need to be reported.

More detailed guidance on vigilance is available in the vigilance and adverse incidents section.

Registration

A manufacturer of custom-made devices or their authorised representative must register with the competent authority of the member state in which they have registered the business. Registration will include a description of the devices concerned and the business address. This requirement applies to both general medical devices and active implantable medical devices. More detailed guidance on registration is available in the registration of medical devices section.