HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

# Guide for
# Custom-made Medical Device Manufacturers on Compliance with European Communities (Medical Devices) Regulations, 1994

**SUR-G0007-3**
**18 JUNE 2012**
This guide does not purport to be an interpretation of law and/or regulations and is for guidance purposes only.

## CONTENTS

## 1 INTRODUCTION

The purpose of this document is to provide guidance to enable manufacturers of custom-made medical devices to meet the requirements of S.I. No. 252 of 1994 European Communities (Medical Devices) Regulations, 1994.

This guide deals specifically with custom-made medical devices. Medical devices specifically made for a particular named patient, are classified under the Regulations as 'custom-made' medical devices.

## 2 BACKGROUND

The Health Products Regulatory Authority (HPRA) became the Competent Authority for general medical devices and active implantable medical devices on 1 October 2001. The Department of Health and Children previously held this role. 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 directives and consequent national regulations determine the role of the Competent Authority, which is to ensure that all medical devices sold on the Irish market meet the essential requirements of the legislation and in doing so do not compromise the health and safety of patients, users and where appropriate, any other persons.

## 3 LEGISLATION

Custom-made medical devices are regulated according to the following regulation:

- S.I. No. 252 of 1994 European Communities (Medical Devices) Regulations, 1994 which transposed Directive 93/42/EEC into Irish law and became mandatory on 14th June 1998.

This legislation, hereafter referred to as 'the Regulations' was amended in 2001, 2002 and 2009 by the following regulations and should be read in conjunction with the above:

- S.I. No. 444 of 2001 European Communities (Medical Devices) (Amendment) Regulations, 2001.

- S.I. No. 576 of 2002 European Communities (Medical Devices) (Amendment) Regulations, 2002.

- S.I. No. 110 of 2009 European Communities (Medical Devices) (Amendment) Regulations, 2009.

Manufacturers of custom-made medical devices are recommended to pay particular attention to S.I. 110 of 2009 which includes amendments to legislation in relation to custom-made medical devices.

Custom-made active implantable medical devices are regulated according to:

- S.I. No. 253 of 1994 European Communities (Active Implantable Medical Devices) Regulations, 1994 which transposed Directive 90/385/EEC into Irish law as amended by S.I. 109 of 2009.

These are available from the Government Publications Sale Office at Molesworth Street, Dublin 2 and on the website of the Department of Health and Children.

## 4 DEFINITIONS

**Authorised representative** - Any natural or legal person established in the Community who explicitly designated by the manufacturer, acts and may be addressed by authorities and bodies in the Community instead of the manufacturer with regards to the latter's obligations under the directive.

**Conformity assessment** - The process of demonstrating whether specified requirements relating to a product, process, service, system, person or body have been fulfilled.

**Manufacturer** - The natural or legal person with responsibility 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. The obligations of the Medical Device Directives to be met by manufacturers also apply to the natural or legal person who assembles, packages, processes, fully refurbishes and/or labels one or more ready-made products and/or assigns to them their intended purpose as a device with a view to their being placed on the market under his own name. This sub-paragraph does not apply to the person who, while not a manufacturer within the meaning of the first sub-paragraph, assembles or adapts devices already on the market to their intended purpose for an individual patient.

**Risk** - Combination of the probability of occurrence of harm and the severity of that harm

**Risk management** - The systematic application of management policies, procedures and practices to the tasks of analysing, evaluating, controlling and monitoring risk.

**Harmonised standards** - Technical specifications meeting the essential requirements of the directives, compliance with which will provide a presumption of conformity with the essential requirements.

**Notified Body** – A certification body with relevant expertise that is responsible for ensuring that the conformity assessment procedures are followed by the manufacturer as well as establishing that devices conform to the relevant essential requirements of the Directives and also to established standards in design and production.

**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 role of the Competent Authority is determined by the directives and consequent national regulations. The primary role of the Competent Authority is to ensure that all medical devices sold on the Irish market meet the essential requirements of the directives and in doing so do not compromise the health and safety of patients, users and where appropriate, any other persons.

**Placing on the market** - The first making available, whether 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, in the Community

**Putting into service** - Making a device ready for use in the State for the first time for its intended purpose

**Technical documentation** - Set of documentation prepared by the manufacturer and made available to the Competent Authority to assess compliance with the requirements of the directive.

## 5 CUSTOM-MADE DEVICES

According to Article 2 of the Regulations, a medical device is:

"any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and 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, or
- control of conception,

and 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."

Under the Regulations 'custom-made' means in relation to a device:

- that it is manufactured specifically in accordance with a written prescription of a registered medical practitioner or a professional user which gives, under his responsibility, specific characteristics as to its design; and that it is intended to be used only for a particular named patient; but does not include a mass-produced product which needs to be adapted to meet the specific requirements of the registered medical practitioner or professional user.

Appendix 1 of this guide provides guidance on the type of healthcare professionals who could be considered as professional users in relation to custom-made medical device manufacturing.

In the manufacturing cycle of a 'custom-made' medical device, it is considered that it is the prescriber who undertakes the design of the product and the manufacturer who manufactures it to a predefined specification. If manufacturing is carried out in accordance with a duly qualified medical practitioner's or professional user's written prescription for sole use of a particular patient, then the product is considered to be a 'custom-made medical device'.

Manufacturers of custom-made medical devices must meet the particular requirements of the regulations which relate to custom-made medical devices.

The requirements to be met by manufacturers of custom-made medical devices are not intended to interfere in any way with the professional and clinical responsibilities of the prescriber. The professional activities (e.g. preparation, impression-taking, prescribing, final fitting and any adaptation) carried out by the prescriber in the supply and fit of a custom-made medical device are outside the scope of the regulations and as such prescribers are not considered to be manufacturers.

Note that medical devices such as artificial teeth and contact lenses which are mass produced and then adapted to meet the specific requirements of the prescriber are not considered to be custom-made medical devices.
The manufacturers of such products would still have to meet the requirements of the regulations for general medical devices.

A manufacturer of a custom-made active implantable medical device, who places devices on the market under his own name, must meet the requirements of S.I. No. 253 of 1994, which transposes the Active Implantable Medical Devices Directive, 90/385/EEC (AIMD).

# 6 CE MARKING

Unlike other medical devices, manufacturers of custom-made medical devices do not have to place the CE mark on such devices. Article 6 of the Regulations allows for this exemption.

# 7 PLACING A CUSTOM-MADE MEDICAL DEVICE ON THE MARKET

## 7.1 Confirm product as a medical device

Confirm that the product comes within the definition of a medical device as defined in article 1 of the Regulations.

In cases where determination is difficult, please consult the HPRA or other relevant Competent Authority in Europe for classification advice.

## 7.2 Confirm product as a custom-made medical device

Confirm that the product is a custom-made medical device and is correctly classified.

Section 5 of this guide details what constitutes a custom-made medical device.

General medical devices are classified into four categories, ranging from low to high risk, depending on risk to the patient.

| CLASS | TYPE |
|---|---|
| I | Low risk |
| IIa | Medium risk |
| IIb | Higher risk |
| III | Highest risk |

Further details on device classification can be found in the HPRA *Guide to the Classification of a Medical Device*, schedule 9 of the Regulations, and also in the European Commission MEDDEV 2.4/1 - Guidelines for the Classification of Medical Devices (parts 1 and 2).

## 7.3 Meet the essential requirements

Custom-made devices must meet the essential requirements detailed in schedule I of the Regulations, taking account of the intended purpose of the devices concerned.
The manufacturer of a custom-made medical device should pay particular consideration to following essential requirements:

- Demonstration of conformity with the essential requirements must include a clinical evaluation in accordance with Schedule 10; (Ref. schedule I.I, point 6a of S.I. No. 110 of 2009)
- Handling and packaging of devices; (Ref. schedule I.I, point 5 of S.I. No. 252 of 1994)
- The choice of materials; (e.g. with regard to toxicity, when there is patient contact, CE-marked materials should be used or the manufacturer must guarantee the suitability of the materials by other means), (Ref. schedule I.II, point 7.1 of S.I. No. 252 of 1994),
- Cleanliness and cross infection control; (Ref. schedule I.II, point 11 of S.I. No. 252 of 1994),
- Protection against radiation; (Ref. schedule I.II, point 8 of S.I. No. 252 of 1994),
- Requirements for medical devices connected to or equipped with an energy source;
- Information to be supplied by the manufacturer. (Ref. schedule I.II, point 13 of S.I. No. 252 of 1994).

It is necessary for the manufacturer of the device to review all of the essential requirements outlined in schedule I of the Regulations against their procedures. The manufacturer must also review the essential requirements regarding the information that is to be supplied with the device and determine what is appropriate for his products.

Further guidance is provided in Appendix 4 of this Guide, 'Essential requirements checklist for custom-made medical devices'.

### 7.4 Prepare technical documentation

In accordance with the requirements of schedule 8 of the Regulations, the manufacturer or his authorised representative must hold technical documentation that demonstrates the conformity of their products with the provisions of the Irish regulations and related directives that apply to them. This technical documentation must be generated prior to generating the 'Statement Concerning Devices for Special Purposes' (refer to section 7.8 for further details) and kept available for review by the Competent Authority.

The technical documentation should be prepared following review of the essential requirements and other relevant requirements of the Irish regulations and related directives that apply.

Guidance on the format of the technical documentation can be found in the Recommendation NB-MED 2.5.1 - Technical Documentation.

As guidance, the technical documentation would be expected to include the following information:

### 7.4.1 Design

The technical documentation should summarise, reference or contain (as determined by the manufacturer) design verification and design validation data to the extent appropriate to the complexity and risk of the device.

Such documentation should typically include:

- declarations of conformity to the 'recognised' standards listed as applied by the manufacturer,
- summaries or reports of tests and evaluations based on other standards, manufacturer methods and tests, or alternative ways of demonstrating compliance, if harmonised standards are not applied.
- the results of qualification tests and design calculations relevant to the intended use of the product, including connections to other devices in order for it to operate as intended,
- the accessories, and other devices or equipment which are intended to be used in combination with the device,
- a general description of each of the functional parts/components of the device with labelled pictorial representations of the device (e.g. diagrams, photograph, drawing(s)), clearly indicating each part, including sufficient explanation to understand the drawings and diagrams,

### 7.4.2 Manufacturing

The following points should be considered:

- For custom-made devices, the documentation should include details of the manufacturing site(s) and sufficient detail to describe the design, manufacture and performances of the product, including the expected performances, so as to allow assessment of conformity with the requirements of Directive 93/42/EEC as amended. The manufacturer must take all the measures necessary to ensure that the manufacturing process produces products which are manufactured in accordance with the documentation;
- a documented review of the prescriber's requirements to ensure that adequate information has been supplied by the prescriber and to demonstrate an understanding of the manufacturing requirements for the design,
- the processing parameters must be defined together with the choice of materials used,
- CE-marked materials should be used where there is patient contact or the manufacturer must guarantee the suitability of materials by other means,
- manufacturing under controlled conditions e.g. following defined/documented processes, and have some method of demonstrating they are being followed (e.g. records/work instructions which can be used to show traceability),
- using suitably qualified personnel,
- where appropriate undertaking calibration and maintenance of equipment,

- considerations of cleanliness and infection control,
- defined handling activities and packaging, and
- a documented review of the final product against the prescribed initial requirements before it is placed on the market.

### 7.4.3 Product performance

The following points should be considered:

- the functional purpose of the device (intended use),
- the intended patient population(s) and medical condition(s) to be diagnosed and/or treated by the device (indications for use) and other considerations such as patient selection criteria,
- the reasonably-foreseeable medical conditions for which the device is not to be used (contraindications),
- other information as needed to provide a description of the device, e.g., for an implant, a description of the anatomical location of the device in the body, attachment mechanisms for the device, including diagrams or illustrations of the implant *in situ*, and
- comparisons to other devices used to establish conformity to the essential requirements. This could include, for example, information on previous designs of the same type of device or comparisons to other related devices.

### 7.4.4 Clinical data

The technical documentation should indicate how any applicable requirements for clinical evaluation of the device have been met (Ref. schedule I.II point 14 of the Regulations). Where applicable, this evaluation may take the form of a systematic review of existing bibliography, clinical experience with the same or similar devices.

Note that it is likely that a compilation and review of existing clinical experience would be sufficient to cover this requirement provided equivalence to existing medical devices can be shown. However, all manufacturers should review the intended use of the product and any medical claims that are being made to ensure that they have both adequate supporting test results and records of relevant experience.

### 7.4.5 Risk management

To ensure that any risks associated with the use of the custom-made devices are compatible with a high level of protection of health and safety and are acceptable when weighed against the benefits to the patient or user, the manufacturer should have risk management systems for identifying hazards associated with their custom-made medical devices, estimating and evaluating the associated risks, controlling these risks and monitoring the effectiveness of that control.

The risk management systems should be based upon international or other recognised standards, e.g. ISO 14971 and be appropriate to the complexity and risk of the device. Risk management systems may be designed for all elements of device life-cycle including design, production and post-production phases.

### 7.4.6 Instructions for use and labelling

As per point 13 of schedule I of the Regulations, each device must be accompanied by the information needed to use it safely and to identify the manufacturer, taking account of the training and knowledge of the potential users. This information comprises the label and the data in the instructions for use:

- the name or trade name and address of the manufacturer. For devices imported into the EU the name and address of an authorised representative based in the European Community are required in addition to the name and address of the manufacturer; (Ref. schedule I.II, point 13.3 (a) of the Regulations),
- the details strictly necessary for the professional to identify the device and the contents of the packaging; (e.g. patient name/description); (Ref. schedule I, point 13.3 (b) of the Regulations),
- the words 'custom-made' (Ref. schedule I, point 13.3 (g) of the Regulations),
- any special storage and/or handling conditions; (Ref. schedule I, point 13.3 (i) of the Regulations), and
- any warnings and/or precautions to take (Ref. schedule I, point 13.3 (k) of the Regulations).

## 7.5 Prepare technical documentation

Manufacturers of custom-made medical devices must follow the procedures set out in schedule 8 of the Regulations before placing such devices on the market.

This schedule requires that manufacturers of custom-made medical devices must draw up a statement for each custom-made device prior to placing it on the market. The statement must contain the following information:

- the name and address of the manufacturer,
- 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 patient name),
- the name of the medical practitioner or other authorised person who made the prescription and, where applicable, the name of the clinic concerned,

- the specific characteristics of the product as indicated by the prescription and
- a statement that the device conforms to the essential requirements set out in schedule I, and where applicable, indicating which essential requirements have not been fully met, together with the grounds,
- Article 5 of S.I. No. 110 of 2009 states that custom-made devices that fall into class IIa, IIb and III shall be accompanied by the statement referred to above. The statement must be available to the particular patient identified by name, an acronym or a numerical code.

# 8 MANUFACTURERS/AUTHORISED REPRESENTATIVE OBLIGATIONS

## 8.1 Registration of persons placing devices on the market

Article 14(1) of the Regulations requires Irish-based manufacturers of custom-made medical devices who place a device onto the Irish market in their own name:

- to inform the HPRA of their registered address, and
- to supply the HPRA with a description of the device which is sufficient to identify it.

In relation to manufacturers who do not have a registered place of business in the European Community, Article 14(3) of the Regulations requires the authorised representatives who have been designated by manufacturers to be their legal representatives in the European Union and who have a registered place of business in Ireland to inform the HPRA of:

- their registered place of business; and
- the type of device; and
- to furnish the HPRA with such evidence that the authorised representative has been appointed by the manufacturer to act on his behalf as his legal representative in the European Community, i.e. a letter of designation as the authorised representative from the manufacturer.

To register with the HPRA, please complete the application form for the Registration of persons responsible for placing medical devices on the market. For instructions on how to register, please see HPRA 'Guidance Note 2: Guide to the registration of persons responsible for placing devices on the market in accordance with Directive 93/42/EEC and S.I. No. 252 of 1994'. Alternatively, you may register online by completing an online registration form which can be found on the HPRA website at http://www.hpra.ie/registration.aspx.

The above documents can be found in the 'Publications and Forms' section of www.hpra.ie.

## 8.2 Technical documentation

According to schedule 8, point 4 of the Regulations, the manufacturer of a custom-made medical device must make the technical documentation, including the 'Statement Concerning

Devices for Special Purposes', available to the HPRA for inspection purposes for a period of at least five years after the last product has been manufactured or in the case of implantable devices, at least fifteen years after the last product has been manufactured. This includes making the technical documentation available by a manufacturer of a custom-made medical device to his authorised representative. It also includes having the technical documentation available at the premises of the first importer into Europe if there is no designated authorised representative in Europe.

### 8.3 List of custom-made devices

Article 15 of the Regulations states that the Competent Authority may require manufacturers of custom-made medical devices to submit a list of custom made medical devices, which have been put into service in the State. Therefore it is advisable that accurate records are kept in the event that this request is made by the HPRA.

### 8.4 Review experience gained from post-market surveillance and incident reporting

Custom-made device manufacturers are now required, under recent changes to the legislation, to review and document experience gained in the post-production phase and to set up a post-market vigilance system of reporting to authorities, as is already in place for other medical devices. Most custom-made device manufacturers already have in place a complaints handling system which, to comply with the new legislative requirements, will need to extend to cover reporting requirements to the HPRA.

According to paragraph 5 of Schedule 8 of S.I. No. 110 of 2009, the manufacturer must undertake to review and document experience gained in the post-production phase, including the provisions referred to in Schedule 10, and to implement appropriate means to apply any necessary corrective action. This undertaking must include an obligation for the manufacturer to notify the competent authorities of the following incidents immediately on learning of them and the relevant corrective actions:

- Any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labelling or the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his or her state of health;
- Any technical or medical reason connected with the characteristics or performance of a device for the reasons referred to in subparagraph (i) leading to systematic recall of devices of the same type by the manufacturer.

Additional information regarding the requirements of a vigilance system can be found in:
- MEDDEV 2.12-1 - Guidelines on a Medical Devices Vigilance System
- HPRA 'Guide to the vigilance system for medical devices'

Manufacturers must have in place processes and procedures to review experience gained from their custom-made medical devices on the market and to implement necessary corrective action, taking account of the nature and risks in relation to the product.

Such experience should be considered as an input to the risk management system.

### 8.5 HPRA post-market surveillance

As the Competent Authority for medical devices in Ireland, the HPRA may conduct post market surveillance in relation to products manufactured by Irish-based manufacturers and those placed on the Irish market. This post-market surveillance activity forms part of the review of manufacturers' compliance to the EU directives and related Irish regulations by the HPRA.

Post-market surveillance can take place by way of a review of manufacturer's technical documentation sent in to the HPRA and/or by audit at the manufacturer's premises. The aim of the post-market surveillance is to ensure that the medical device manufacturer is complying with the essential requirements and schedules of the medical device legislation and related statutory instruments (the Regulations).

For additional information in relation to HPRA medical device audits please refer to the HPRA *Guide for Medical Device Manufacturers on Auditing by the Health Products Regulatory Authority to the Medical Device Regulations*.

## 9 REFERENCES


- MEDDEV 2.4/1- Guidelines for the Classification of Medical Devices.
- NB-MED 2.5.1 - Technical Documentation
- MEDDEV 2.12-1 - Guidelines on a Medical Devices Vigilance System
- S.I. No. 252 of 1994 European Communities (Medical Devices) Regulations, 1994
- S.I. No. 253 of 1994 European Communities (Active Implantable Medical Devices) Regulations, 1994.
- S.I. No. 444 of 2001 European Communities (Medical Devices) (Amendment) Regulations, 2001
- S.I. No. 576 of 2002 European Communities (Medical Devices) (Amendment) Regulations, 1994
- S.I. No. 110 of 2009 European Communities (Medical Devices) (Amendment) Regulations, 2009
- Market Surveillance Operation Group (MSOG) - Guidance Note for Manufacturers of Custom-Made Medical Devices - 2007-09

- HPRA 'Guidance Note 2: Guidance note for the registration of persons responsible for placing devices on the market in accordance with Directive 93/42/EEC and S.I. No. 252 of 1994.
- HPRA 'Guide to the vigilance system for medical devices'

## 10 WHO TO CONTACT AT THE HPRA

This guide and associated documents can be found in the 'Publications and Forms' section of www.hpra.ie.

Alternatively, they can be obtained from the HPRA directly as follows:

Human Products Monitoring Department
Health Products Regulatory Authority,
Kevin O'Malley House,
Earlsfort Centre,
Earlsfort Terrace,
Dublin 2.

Telephone: +353 1 676 4971
Fax: +353 1 676 7836
E-mail: devices@hpra.ie

The HPRA encourages communication with the medical device sector. Should you have specific queries please address them to the Human Products Monitoring Department of the HPRA.

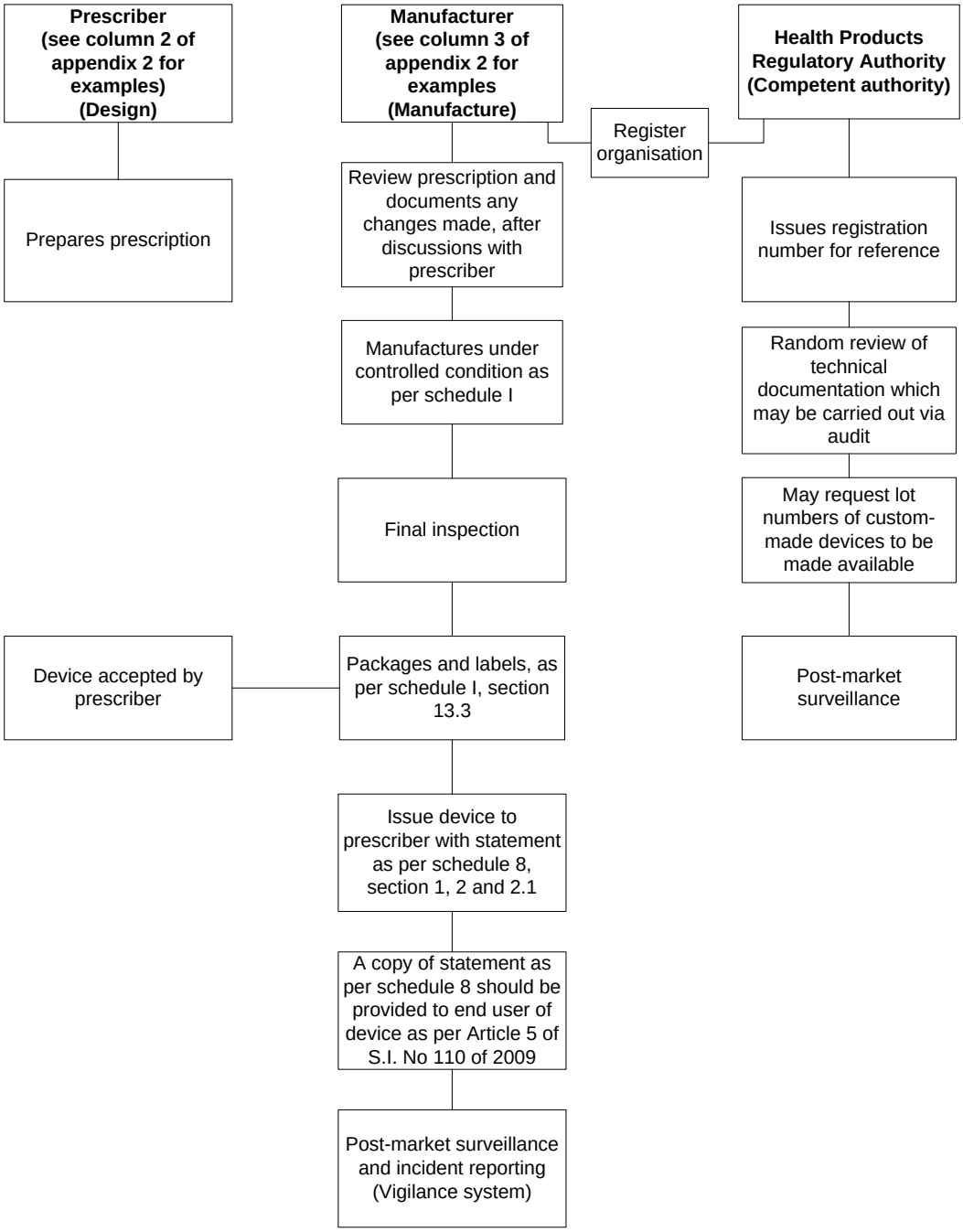
Communication can be made by telephone, fax, e-mail, or by post to the above address.

## APPENDIX I EXAMPLES OF CUSTOM-MADE DEVICES AND DEVICE MANUFACTURERS

The table below shows examples of device types, which might fall into the category of custom-made medical devices although some of the device types listed below will also be available as mass-produced, rather than custom-made medical devices.

| DEVICE TYPE | PRESCRIBER | MANUFACTURER | COMMENT |
|---|---|---|---|
| Dental appliances | Dentist | Dental laboratories | See this guide specifically for manufacturers of custom-made dental devices. |
| 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, Audiology Technician or Hearing Aid Dispenser/Audiologist | Insert Maker | Patient specific |
| In-the-Ear Aids | Medical Consultant, Audiology Technician or Hearing Aid Dispenser/Audiologist | Aid Manufacturer | Patient specific |
| Orthopaedic Footwear | Orthotist or Shoe fitter | Shoemaker | Patient specific |
| Joint Replacement Implants (designed for a specific individual) | Orthopaedic Surgeon | Implant Manufacturer | Patient specific |
| Prosthetics and Orthotics | Rehabilitation Consultant, Orthopaedic Consultant, Prosthetists or Orthotists | Prosthetic and Orthotic Service Companies and Manufacturers | Patient specific |

## APPENDIX 2 FIGURE I REQUIREMENTS OF S.I. NO. 252 OF 1994



## APPENDIX 3 CHECKLIST FOR CUSTOM-MADE DEVICE MANUFACTURERS

| DESCRIPTION | GUIDELINE REFERENCE | YES | NO | ADDITIONAL REFERENCES | SI NO. 252, 1994 | DIRECTIVE 93/42/EEC |
|---|---|---|---|---|---|---|
| Confirm product as a medical device | Section 7.1 | | | MEDDEV 2.4/1 - Guidelines for the Classification of medical devices | Article 2<br>Schedule 9 | Article 1<br>Annex IX |
| Confirm product as a custom-made medical device | Section 7.2 | | | | Article 2<br>Schedule 9 | Article I<br>Annex IX |
| Meet the essential requirements | Section 7.3 | | | Appendix 4 of this guide | Article 5<br>Schedule I | Article 3<br>Annex I |
| Prepare technical documentation, | Section 7.4 | | | MEDDEV 2.5.1 - Technical Documentation<br>COEN Guidance note for manufacturers of custom-made medical devices (2007-09) | Article 15<br>Schedule I<br>Schedule 8 | Article 11<br>Annex I<br>Annex VIII |
| Maintain manufacturing records to demonstrate that manufacturing is carried out according to documentation. | | | | | Schedule 8, 3.1 | Annex VII, 3.1 |
| Statement concerning devices for special purposes | Section 7.5 | | | | Article 5<br>Schedule 8 | Article 11<br>Annex VIII |
| Registration of persons placing devices on the market | Section 8.1 | | | HPRA Guidance Note 2: Guide to the Registration of Persons responsible for placing Medical Devices on the Market | Article 14 | Article 14 |

| DESCRIPTION | GUIDELINE REFERENCE | YES | NO | ADDITIONAL REFERENCES | SI NO. 252, 1994 | DIRECTIVE 93/42/EEC |
|---|---|---|---|---|---|---|
| Post-market surveillance and incident reporting (vigilance system) | Section 8.4 | | | HPRA Guide to Vigilance System for Medical Devices | Schedule 8 | Annex VIII |

## APPENDIX 4 ESSENTIAL REQUIREMENTS CHECKLIST FOR CUSTOM-MADE MEDICAL DEVICES

| ESSENTIAL PRINCIPLE | APPLICABLE TO THE DEVICE | METHOD OF CONFORMITY | IDENTITY OF SPECIFIC DOCUMENTS | GUIDANCE FOR THE MANUFACTURER OF THE DEVICE | RELEVANT HARMONISED STANDARDS |
|---|---|---|---|---|---|
| **General requirements** | | | | | |
| 1. The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their intended use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.<br><br>This shall include:<br>reducing, as far as possible, the risk of use error due to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and consideration of the technical knowledge, | | | | This requirement requires the device to be safe when used as intended by the manufacturer. A risk assessment according to the relevant harmonised standard should be performed. | EN ISO 14971 (Medical devices – Application of risk management to medical devices) |

| ESSENTIAL PRINCIPLE | APPLICABLE TO THE DEVICE | METHOD OF CONFORMITY | IDENTITY OF SPECIFIC DOCUMENTS | GUIDANCE FOR THE MANUFACTURER OF THE DEVICE | RELEVANT HARMONISED STANDARDS |
|---|---|---|---|---|---|
| experience, education and training and where applicable the medical and physical conditions of intended users (design for lay, professional, disabled or other users). | | | | | |
| 2. The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art.<br>In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order:<br>eliminate or reduce risks as far as possible (inherently safe design and construction),<br>where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated,<br>inform users of the residual risks due to any shortcomings of the protection measures adopted. | | | | To comply with this requirement, manufacturers should:<br>- review the design brief of the product<br>- review published literature and experience of similar devices<br>- review the packaging of the device to harmonised standards.<br>- review the labelling and instructions for use( if applicable)<br>- review final release procedures. | |
| 3. The devices must achieve the performances intended by the manufacturer and | | | | The manufacturer must have evidence that the | |

| ESSENTIAL PRINCIPLE | APPLICABLE TO THE DEVICE | METHOD OF CONFORMITY | IDENTITY OF SPECIFIC DOCUMENTS | GUIDANCE FOR THE MANUFACTURER OF THE DEVICE | RELEVANT HARMONISED STANDARDS |
|---|---|---|---|---|---|
| be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions referred to in Article 1(2)(a) of Directive 93/42/EEC as amended, as specified by the manufacturer. | | | | device complies with the specified requirements. | |
| 4. The characteristics and performances referred to in Sections 1, 2 and 3 must not be adversely affected to such a degree that the clinical conditions and safety of the patients and, where applicable, of other persons are compromised during the lifetime of the device as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use. | | | | It should be demonstrated that the stresses that occur during the normal conditions of use intended by the manufacturer during the expected lifetime of the device are identified. Possible adverse effects must be considered and assessed. Assessments are normally done by appropriate bench testing, simulated shelf life testing and clinical evaluation if applicable. If accessible, a review of complaints history should | |

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| | | | | be used for established products. | |
| 5. The devices must be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage taking account of the instructions and information provided by the manufacturer. | | | | It should be demonstrated that the stresses that can occur during the transport and storage of the device, in accordance with the instructions and information, are identified and have been addressed in the design, manufacturing and packaging of the device.<br>If accessible, a review of complaints history should be used for established products. | |
| 6. Any undesirable side effects must constitute an acceptable risk when weighed against the performances intended. | | | | For new or modified devices, the results of a risk analysis should be used to determine whether the side effects associated with the | EN ISO 14971 (Medical devices - Application of risk management to medical devices) |

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| | | | | intended use of the product are acceptable when evaluated against the benefits of the device to the user. This should be based upon harmonised standards.<br>For established products, the risk analysis should consist of experience in use. | |
| **Requirements regarding design and construction** | | | | | |
| 7. Chemical, physical and biological properties | | | | | EN 10993 series (Biological evaluation of medical devices) |
| 7.1 The devices must be designed and manufactured in such a way as to guarantee the characteristics and performances referred to in Section I on the 'General requirements'. Particular attention must be paid to:<br>the choice of materials used, particularly as regards toxicity and, where appropriate, | | | | It should be demonstrated that the materials chosen are appropriate given the intended use of the device. The risk of toxicity, flammability and bioincompatibility should | |

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| flammability,<br>the compatibility between the materials used and biological tissues, cells and body fluids, taking account of the intended purpose of the device. | | | | be assessed and the product labelled accordingly. These tests should be included in the risk analysis.<br>A biological safety evaluation should be made in accordance with relevant harmonised standards.<br>Historic data on materials used in similar products should also be reviewed. | |
| 7.2 The devices must be designed, manufactured and packed in such a way as to minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to the patients, taking account of the intended purpose of the product. Particular attention must be paid to the tissues exposed and to the duration and frequency of exposure. | | | | Any contaminants and residues in or on the device that could cause significant adverse effects should be identified and potential risks to patients or others exposed to the product should be considered and reduced as far as practicable. | EN 10993 series |

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| 7.3 The devices must be designed and manufactured in such a way that they can be used safely with the materials, substances and gases with which they enter into contact during their normal use or during routine procedures; if the devices are intended to administer medicinal products they must be designed and manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and restrictions governing these products and that their performance is maintained in accordance with the intended use. | | | | Interactions with materials, substances and gases in normal use must be tested. Assessments are normally done by appropriate bench testing. | |
| 7.4 Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product as defined in Article 1 of Directive 65/65/EEC and which is liable to act upon the body with action ancillary to that of the device, the safety, quality and usefulness of the substance must be verified, taking account of the intended purpose of the device, by analogy with the appropriate methods specified in Directive 75/318/EEC. | | | | Refer to: MEDDEV 2.4/1: Guidelines for the Classification of Medical Devices. | MEDDEV 2.4/1: Guidelines for the Classification of Medical Devices. |

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| 7.5 The devices must be designed and manufactured in such a way as to reduce to a minimum the risks posed by substances leaking from the device. | | | | Leaking includes leaching. Simulated use testing should be carried out. Assessment is normally carried out by appropriate bench testing. | |
| 7.6 Devices must be designed and manufactured in such a way as to reduce, as much as possible, risks posed by the unintentional ingress of substances into the device taking into account the device and the nature of the environment in which it is intended to be used. | | | | This would normally be addressed by appropriate bench testing, biological safety testing and, if applicable, clinical evaluation. | |
| 8. Infection and microbial contamination | | | | | EN 11135 series (Sterilization of healthcare products)<br>EN 10993<br>EN 11737 series (Sterilization of medical devices) |
| 8.1 The devices and manufacturing processes must be designed in such a way as to eliminate or reduce as far as possible the risk of infection to | | | | The work done to meet the essential requirements 1-6 above should incorporate | EN 11135 series<br>EN 10993 series |

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| the patient, user and third parties. The design must allow easy handling and, where necessary, minimize contamination of the device by the patient or vice versa during use. | | | | most of the information needed to satisfy this requirement. Sterilisation validation and bioburden data are particularly relevant. Single use devices should be reviewed in detail and single use sterile devices, as far as practicable, should facilitate an aseptic presentation for use. | |
| 8.2 Tissues of animal origin must originate from animals that have been subjected to veterinary controls and surveillance adapted to the intended use of the tissues.<br>Notified bodies shall retain information on the geographical origin of the animals.<br>Processing, preservation, testing and handling of tissues, cells and substances of animal origin must be carried out so as to provide optimal security. In particular safety with regard to viruses and other | | | | This requirement should be interpreted in the context of each particular device. Where appropriate, certificates of origin from suppliers of materials of animal origin that could be associated with a substantial degree of risk of infection or adverse | EN 22442 series (Medical devices utilising animal tissues and their derivatives) |

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| transferable agents must be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process. | | | | reaction should be requested. Handling and processing procedures should be reviewed in relation to these materials. | |
| 8.3 Devices delivered in a sterile state must be designed, manufactured and packed in a non-reusable pack and/or according to appropriate procedures to ensure that they are sterile when placed on the market and remain sterile, under the storage and transport conditions laid down, until the protective packaging is damaged or opened. | | | | | |
| 8.4 Devices delivered in a sterile state must have been manufactured and sterilized by an appropriate, validated method. | | | | The Harmonised Standards should be applied. | EN 11135 series<br>EN 11737 series |
| 8.5 Devices intended to be sterilized must be manufactured in appropriately controlled (e.g. environmental) conditions. | | | | Bioburden checks, for example, may be used to control the level of microbial contamination prior to sterilization. | |
| 8.6 Packaging systems for non-sterile devices | | | | Bioburden checks, for | |

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| must keep the product without deterioration at the level of cleanliness stipulated and, if the devices are to be sterilized prior to use, minimize the risk of microbial contamination; the packaging system must be suitable taking account of the method of sterilization indicated by the manufacturer. | | | | example, may be used to control the level of microbial contamination prior to sterilization. | |
| 8.7 The packaging and/or label of the device must distinguish between identical or similar products sold in both sterile and non-sterile condition. | | | | All sterile products must be labelled 'STERILE'. | EN 980 (Graphical symbols for use in the labelling of medical devices) |
| 9. Construction and environmental properties | | | | | |
| 9.1 If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system must be safe and must not impair the specified performances of the devices. Any restrictions on use must be indicated on the label or in the instructions for use. | | | | Simulated use of the performance of the combination should be carried out by way of bench testing | |
| 9.2 Devices must be designed and manufactured in such a way as to remove or minimize as far as is possible: | | | | | EN 60601 Series (Medical electrical equipment) |

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| the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features,<br>risks connected with reasonably foreseeable environmental conditions, such as magnetic fields, external electrical influences, electrostatic discharge, pressure, temperature or variations in pressure and acceleration,<br>the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given,<br>risks arising where maintenance or calibration are not possible (as with implants), from ageing of materials used or loss of accuracy of any measuring or control mechanism. | | | | | |
| 9.3 Devices must be designed and manufactured in such a way as to minimize the risks of fire or explosion during normal use and in single fault condition. Particular attention must be paid to devices whose intended use includes exposure to flammable substances or to substances which | | | | | |

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| could cause combustion. | | | | | |
| 10. Devices with a measuring function | | | | | EN 60601 Series (Medical electrical equipment) |
| 10.1 Devices with a measuring function must be designed and manufactured in such a way as to provide sufficient accuracy and stability within appropriate limits of accuracy and taking account of the intended purpose of the device. The limits of accuracy must be indicated by the manufacturer. | | | | | EN 60601 part 2 |
| 10.2 The measurement, monitoring and display scale must be designed in line with ergonomic principles, taking account of the intended purpose of the device. | | | | | EN 60601 series |
| 10.3 The measurements made by devices with a measuring function must be expressed in legal units conforming to the provisions of Council Directive 80/181/EEC (1). | | | | | |
| 11. Protection against radiation | | | | | |
| 11.1 General | | | | | |
| 11.1.1. Devices shall be designed and manufactured in such a way that exposure | | | | | EN 60601 series |

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| of patients, users and other persons to radiation shall be reduced as far as possible compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes. | | | | | |
| 11.2 Intended radiation | | | | | |
| 11.2.1 Where devices are designed to emit hazardous levels of radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent in the emission, it must be possible for the user to control the emissions. Such devices shall be designed and manufactured to ensure reproducibility and tolerance of relevant variable parameters. | | | | | EN 60601-1 |
| 11.2.2 Where devices are intended to emit potentially hazardous, visible and/or invisible radiation, they must be fitted, where practicable, with visual displays and/or audible warnings of such emissions. | | | | | |
| 11.3. Unintended radiation | | | | | EN 60601-1 and the |

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| | | | | | relevant part 2s |
| 11.3.1 Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as possible | | | | | |
| 11.4 Instructions | | | | | |
| 11.4.1 The operating instructions for devices emitting radiation must give detailed information as to the nature of the emitted radiation, means of protecting the patient and the user and on ways of avoiding misuse and of eliminating the risks inherent in installation. | | | | | EN 60601-1 and the relevant part 2s |
| 11.5 Ionizing radiation | | | | | |
| 11.5.1 Devices intended to emit ionizing radiation must be designed and manufactured in such a way as to ensure that, where practicable, the quantity, geometry and quality of radiation emitted can be varied and controlled taking into account the intended use. | | | | | EN 60601-1 and the relevant part 2s |

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| 11.5.2 Devices emitting ionizing radiation intended for diagnostic radiology shall be designed and manufactured in such a way as to achieve appropriate image and/or output quality for the intended medical purpose whilst minimizing radiation exposure of the patient and user. | | | | | |
| 11.5.3 Devices emitting ionizing radiation, intended for therapeutic radiology shall be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam type and energy and where appropriate the quality of radiation. | | | | | |
| 12. Requirements for medical devices connected to or equipped with an energy source | | | | | EN 60601 series (Medical electrical equipment) |
| 12.1 Devices incorporating electronic programmable systems must be designed to ensure the repeatability, reliability and performance of these systems according to the intended use. In the event of a single fault condition (in the system) appropriate means | | | | | |

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| should be adopted to eliminate or reduce as far as possible consequent risks. | | | | | |
| 12.2 Devices where the safety of the patients depends on an internal power supply must be equipped with a means of determining the state of the power supply. | | | | | EN 60601 part 2 |
| 12.3 Devices where the safety of the patients depends on an external power supply must include an alarm system to signal any power failure. | | | | | EN 60601 part 2 |
| 12.4 Devices intended to monitor one or more clinical parameters of a patient must be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health. | | | | | EN 60601 part 2 |
| 12.5 Devices must be designed and manufactured in such a way as to minimize the risks of creating electromagnetic fields which could impair the operation of other devices or equipment in the usual environment. | | | | | EN 60601-1 |
| 12.6 Protection against electrical risks<br>Devices must be designed and manufactured in | | | | | EN 60601-1 |

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| such a way as to avoid, as far as possible, the risk of accidental electric shocks during normal use and in single fault condition, provided the devices are installed correctly. | | | | | |
| 12.7 Protection against mechanical and thermal risks | | | | | |
| 12.7.1 Devices must be designed and manufactured in such a way as to protect the patient and user against mechanical risks connected with, for example, resistance, stability and moving parts. | | | | | |
| 12.7.2 Devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance. | | | | | |
| 12.7.3 Devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising | | | | | |

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| from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance. | | | | | |
| 12.7.4 Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user has to handle must be designed and constructed in such a way as to minimize all possible risks. | | | | | |
| 12.7.5 Accessible parts of the devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings must not attain potentially dangerous temperatures under normal use. | | | | | |
| 12.8 Protection against the risks posed to the patient by energy supplies or substances | | | | | |
| 12.8.1 Devices for supplying the patient with energy or substances must be designed and constructed in such a way | | | | | |

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| that the flow-rate can be set and maintained accurately enough to guarantee the safety of the patient and of the user. | | | | | |
| 12.8.2. Devices must be fitted with the means of preventing and/or indicating any inadequacies in the flow-rate, which could pose a danger.<br>Devices must incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy from an energy and/or substance source. | | | | | |
| 12.9. The function of the controls and indicators must be clearly specified on the devices.<br>Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information must be understandable to the user and, as appropriate, the patient. | | | | | |
| 13. Information supplied by the manufacturer | | | | | EN 1041 (Information supplied by the manufacturer with medical devices) |

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| | | | | | EN 980 (Graphical symbols for use in the labelling of medical devices) |
| 13.1. Each device must be accompanied by the information needed to use it safely and to identify the manufacturer, taking account of the training and knowledge of the potential users.<br>This information comprises the details on the label and the data in the instructions for use.<br>As far as practicable and appropriate, the information needed to use the device safely must be set out on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging. If individual packaging of each unit is not practicable, the information must be set out in the leaflet supplied with one or more devices.<br>Instructions for use must be included in the packaging for every device. By way of exception, no such instructions for use are needed for devices in Class I or IIa if they can be used safely without any such instructions. | | | | | |

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| 13.2. Where appropriate, this information should take the form of symbols. Any symbol or identification colour used must conform to the harmonized standards. In areas for which no standards exist, the symbols and colours must be described in the documentation supplied with the device. | | | | | EN 980 (Graphical symbols for use in the labelling of medical devices) |
| 13.3. The label must bear the following particulars:<br>the name or trade name and address of the manufacturer. For devices imported into the Community, in view of their distribution in the Community, the label, or the outer packaging, or instructions for use, shall contain in addition the name and address of either the person responsible referred to in Article 14(2) or of the authorized representative of the manufacturer established within the Community or of the importer established within the Community, as appropriate;<br>the details strictly necessary for the user to identify the device and the contents of the | | | | The label must form part of the Technical documentation and must be provided if requested by a Competent Authority. | EN 1041 (Information supplied by the manufacturer with medical devices)<br>EN 980 (Graphical symbols for use in the labelling of medical devices) |

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| packaging;<br>where appropriate, the word 'STERILE';<br>where appropriate, the batch code, preceded by the word 'LOT', or the serial number;<br>where appropriate, an indication of the date by which the device should be used, in safety, expressed as the year and month;<br>where appropriate, an indication that the device is for single use;<br>if the device is custom-made, the words 'custom-made device';<br>if the device is intended for clinical investigations, the words 'exclusively for clinical investigations';<br>any special storage and/or handling conditions;<br>any special operating instructions;<br>any warnings and/or precautions to take;<br>year of manufacture for active devices other than those covered by (e). This indication may be included in the batch or serial number;<br>- where applicable, method of sterilization. | | | | | |
| 13.4 If the intended purpose of the device is not obvious to the user, the manufacturer must | | | | | |

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| clearly state it on the label and in the instructions for use. | | | | | |
| 13.5 Wherever reasonable and practicable, the devices and detachable components must be identified, where appropriate in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices and detachable components. | | | | | |
| 13.6 Where appropriate, the instructions for use must contain the following particulars:<br>the details referred to in Section 13.3, with the exception of (d) and (e);<br>the performances referred to in Section 3 and any undesirable side-effects;<br>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 in order to obtain a safe combination;<br>all the information needed to verify whether the device is properly installed and can operate | | | | The instructions for use must form part of the Technical Documentation and must be provided if requested by a Competent Authority. | EN 1041 (Information supplied by the manufacturer with medical devices)<br>EN 980 (Graphical symbols for use in the labelling of medical devices) |

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| correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the devices operate properly and safely at all times;<br>where appropriate, information to avoid certain risks in connection with implantation of the device;<br>information regarding the risks of reciprocal interference posed by the presence of the device during specific investigations or treatment;<br>the necessary instructions in the event of damage to the sterile packaging and, where appropriate, details of appropriate methods of resterilization;<br>if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of sterilization of the device to be resterilized, and any restriction on the number of reuses.<br>Where devices are supplied with the intention that they be sterilized before use, the instructions for cleaning and sterilization must be such that, if | | | | | |

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| correctly followed, the device will still comply with the requirements in Section I;<br>details of any further treatment or handling needed before the device can be used (for example, sterilization, final assembly, etc.);<br>in the case of devices emitting radiation for medical purposes, details of the nature, type, intensity and distribution of this radiation.<br>The instructions for use must also include details allowing the medical staff to brief the patient on any contra-indications and any precautions to be taken. These details should cover in particular:<br>precautions to be taken in the event of changes in the performance of the device;<br>precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources, etc.;<br>adequate information regarding the medicinal product or products which the device in question | | | | | |

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| is designed to administer, including any limitations in the choice of substances to be delivered;<br>precautions to be taken against any special, unusual risks related to the disposal of the device;<br>medicinal substances incorporated into the device as an integral part in accordance with Section 7.4;<br>degree of accuracy claimed for devices with a measuring function. | | | | | |
| 14. Where conformity with the essential requirements must be based on clinical data, as in Section I(6), such data must be established in accordance with Annex X. | | | | It is likely that a compilation and review of existing clinical experience would be sufficient to cover this requirement provided equivalence to existing medical devices can be shown. | EN 14155 parts 1 & 2 (Clinical investigation of medical devices for human subjects) |