HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Guide for
Class I Manufacturers on Compliance with European Communities (Medical Devices) Regulations, 1994

SUR-G0006-3
4 FEBRUARY 2021
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 Class I medical devices manufacturers, or the authorised representatives who place medical devices on the European market under the manufacturer's name, to meet the requirements of S.I. No. 252 of 1994 European Communities (Medical Devices) Regulations, 1994.

This document applies to all products that fall within the definition of a Class I medical device under the medical device regulations. Active implantable medical devices and *in-vitro* diagnostic medical devices are outside the scope of this document. The requirements for post-market vigilance or adverse event reporting are also outside the scope of this document.

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

Class I 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 14 June 1998.

This legislation, hereafter referred to as 'the Regulations' was amended in 2001, in 2002 and in 2009 by the following regulations which 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.

These are available from the Government Publications Sale Office, 52 St Stephen's Green, Dublin 2, and on the website of the Department of Health.

4 DEFINITIONS

Accessory - An article which whilst not being a device is intended specifically by its manufacturer to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device.

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 European Community instead of the manufacturer with regard 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 file/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 CLASS I 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,
- control of conception,

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

General medical devices are classified into four categories, ranging from low to high risk, depending on risk to the patient. Class I medical devices are devices that are considered low risk. Examples include tongue depressors, first aid bandages, crutches, etc.

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).

6 CE MARKING

All medical devices, with the exception of devices that are custom-made or intended for clinical investigation, placed on the market must bear the CE mark.

Details on affixing the CE mark are outlined in section 7.8 below.

7 PROCEDURE FOR AFFIXING A CE MARK TO CLASS I DEVICES

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. Reference should also be made to MEDDEV 2.1/1: Guidelines relating to the application of the Council Directive 90/385/EEC on active implantable medical devices and Council Directive 93/42/EEC on medical devices.

7.2 Confirm product as a Class I medical device

Confirm that the product is correctly classified as a Class I medical device. The application of the classification rules shall be governed by the intended purpose of the device, the duration of use, part of the body, whether it is active or not, whether it is invasive or non-invasive. If the device is not intended to be used solely or principally in a specific part of the body, it must be considered and classified on the basis of the most critical specified use. If several rules are applicable then the rule which results in the highest class applies.

For additional advice regarding device classification refer to MEDDEV 2.4/1- Guidelines for the Classification of Medical Devices and HPRA 'Guide to the classification of a medical device'.

7.3 Meet the essential requirements

Class I medical devices must meet the essential requirements detailed in schedule 1 of the Regulations, taking account of the intended purpose of the devices concerned.
It is necessary for the manufacturer of the device to review all of the essential requirements outlined in schedule 1 of the Regulations against their procedures and manufacturing processes.

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.

Where a relevant hazard exists, devices which are also machinery within the meaning of Article 2(a) of Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery shall also meet the essential health and safety requirements set out in Annex I to that Directive to the extent to which those essential health and safety requirements are more specific than the essential requirements set out in schedule 1 of the Regulations.

Where a device is intended by the manufacturer to be used in accordance with both the provisions on personal protective equipment in Council Directive 89/686/EEC and Directive 2007/47/EC, the relevant basic health and safety requirements of Directive 89/686/EEC shall also be fulfilled.

Appendix 2 of this guide, 'Essential requirements checklist for Class I medical device manufacturers' provides additional guidance on how conformity with the essential requirements can be demonstrated.

7.4 Prepare technical documentation

In accordance with the requirements of schedule 7 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 drawing up the EC declaration of conformity (refer to section 7.7 of this guide).

The manufacturer must make this documentation, including the declaration of conformity, available to the HPRA for inspection purposes for a period of at least five years after the last product has been manufactured.

Guidance on the format of the technical documentation can be found in the Recommendation NB-MED 2.5/1 - Technical Documentation.

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

7.4.1 Description

- "a general description of the product, including any variants planned and its intended use(s)"

Note: for example names, model number, sizes, intended use, indications for use, contraindications

7.4.2 Design

- "design drawings, methods of manufacture envisaged and diagrams of components, sub-assemblies, circuits, etc."

Note: specifications including, as applicable, appropriate drawings and/or master patterns, circuits, formulation, manufacturing methods, process validation data and any quality control procedures for the raw materials/components, intermediate products/sub-assemblies and final product.

7.4.3 Design explanation

- "the descriptions and explanations necessary to understand the above mentioned drawings and diagrams and the operations of the product"

7.4.4 Risk management

- "the results of the risk analysis and a list of the standards referred to in Article 5 of Directive 93/42/EEC as amended, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the Directive if the standards referred to in Article 5 of Directive 93/42/EEC have not been applied in full."

Note: to ensure that any risks associated with the use of the device 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 Class I 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.

7.4.5 Sterilisation method

- "in the case of products placed on the market in a sterile condition, description of the methods used and the validation report"

Note: this should also include the certificate of conformity issued by a Notified Body.

7.4.6 Design verification

- "the results of the design calculations and of the inspections carried out, etc.; if the device is to be connected to other device(s) in order to operate as intended, proof must be provided

that it conforms to the essential requirements when connected to any such device(s) having the characteristics specified by the manufacturer"

Note: 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. Information showing that a safe design has been established for a number of years and the product has been performing as intended during that time may satisfy this requirement.

7.4.7 Risk reduction

- "the solutions adopted as referred to in Schedule 1, Chapter I, Section 2 of the Regulations"

Note: 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.

7.4.8 Pre-Clinical Evaluation

- "the pre-clinical evaluation"

Note: pre-clinical evaluation may include, but is not limited to, bench testing, computational modelling, animal studies, etc.

7.4.9 Clinical Evaluation

- "the clinical evaluation in accordance with Schedule 10 of the Regulations"

Note: many Class I medical devices will not normally require a full clinical investigation/trial to establish data on performance and safety or side effects. For products which have been established a number of years and those which are modifications of such products, 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.

However, as a general rule, confirmation of conformity with the requirements concerning characteristics and performance of the device under the normal conditions of use including undesirable side effects should be based on clinical data.

Only in a minority of cases will a specifically designed clinical investigation be necessary in order to demonstrate device safety and performance as required by the Directive. Note that if a

clinical investigation is required to justify the use of a device, then the Competent Authority requires advance notification of the proposal.

Evaluation of clinical data must follow a defined and methodologically sound procedure based on:

- Either a critical evaluation of the relevant scientific literature currently available relating to the safety, performance, design characteristics and intended purpose of the device, where:
  - There is demonstration of equivalence of the device to the device to which the data relates, and
  - the data adequately demonstrate compliance with the relevant essential requirements;
- Or a critical evaluation of the results of all clinical investigations made,
- Or a critical evaluation of the combined clinical data provided in sections 1.1.1 and 1.1.2 of schedule 10 of the Regulations.

(Ref. schedule 10 of the Regulations)

Please refer to the HPRA 'Guide for Manufacturers on Clinical Investigations carried out in Ireland' for further information.

7.4.10 Labelling

- "the label and instructions for use"

Note: packaging specifications and copies of all labels and any instructions for use that are to be provided with the medical device.

7.4.11 Harmonised standards

- A list of relevant harmonised standards which have been applied in full or in part of the products should be supplied.
- Products manufactured according to harmonised standards benefit from the presumption of conformity to the related essential requirements. If relevant harmonised standards have not been applied in full, then additional data will be required detailing the solutions adopted to meet the relevant essential requirements.

7.5 Notified Body intervention

For Class I devices placed on the market in a sterile condition and/or Class I devices with a measuring function, the manufacturer must also observe one of the procedures referred to in schedule 2, 4, 5 or 6 of the Regulations.

This requires the intervention of a Notified Body that is limited to:

- in the case of products placed on the market in sterile condition; only the aspects of manufacture concerned with securing and maintaining sterile conditions,
- in the case of devices with a measuring function; only the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

In all other cases the intervention of a Notified Body is not required for Class I devices.

7.6 Prepare instructions for use and labelling

Each device must be accompanied by the information needed to use it safely and properly, taking account of the training and knowledge of the potential users and to identify the manufacturer. This information comprises the label and the data in the instructions for use. Refer to Appendix 2 of this guide for the essential requirements relating to instructions for use and labelling.

By way of derogation to the general principles no instructions for use are required for Class I devices if they can be used safely without such instruction. A justification for not providing instructions for use should be documented within the technical documentation.

National language requirements must be taken into account in relation to labelling and instructions for use. In Ireland, English must be used on all labelling and instructions for use. Competent Authorities in Member States where the device is to be placed on the market should be contacted in order to determine any language requirements for their particular market.

7.7 EC declaration of conformity

The EC declaration of conformity is the procedure whereby the manufacturer or his authorised representative (established in the European Community) who fulfils the obligations imposed by section 2 of schedule 7 of the Regulations ensures and declares that the products concerned meet the provisions of the Irish regulations and related directives that apply to them.

In the case of products placed on the market in a sterile condition and devices with a measuring function, the obligations imposed by schedule 7, section 5 of the Regulations must also be applied.

Where schedule 7 of the Regulations is applied in conjunction with the procedure referred to in schedule 2, 4, 5 or 6 (products placed on the market in a sterile condition and/or devices with a measuring function), the declaration of conformity referred to in the above-mentioned schedules form a single declaration.

The declaration of conformity should contain all information to identify the directives to which it is issued, as well as the manufacturer, the authorised representative, the Notified Body (if applicable) and the product and, where appropriate, a reference to harmonised standards or other relevant documents.

7.8 Affix CE mark

Article 6 of the Regulations states that the CE marking must be in a visible, legible and indelible form on:
- the device or its sterile pack, where practicable and appropriate, and
- the instructions for use, as well as
- any sales packaging.

In the case of devices placed on the market in a sterile condition and/or devices with a measuring function, the CE marking must be accompanied by the identification number of the relevant Notified Body responsible for implementation of the procedures set out in schedules 2, 4, 5 or 6 of the Regulations.

Note that Class I devices, with the exception of devices placed on the market in a sterile condition and devices with a measuring function, bear the CE mark without a Notified Body identification number as Notified Body intervention is not required.

It is prohibited to affix marks which are likely to mislead third parties with regards the meaning of the CE mark. Other additional marks may be fixed to the device, to the packaging or the instructions for use provided the visibility or legibility of the CE mark is not impaired.

The CE mark format should be in compliance with schedule 12 of the Regulations. Where the device is very small the minimum dimensions of the CE mark may be waived.

7.9 Manufacturing Records

Manufacturers should maintain records of 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).

Accurate and accessible records are a key factor in effective medical device management and are required by the medical devices legislation. Clear records should be kept from the outset of the device lifecycle, enabling the manufacturer to trace the individual components within the device and the particular batches of the device throughout their lifetime.

8 MANUFACTURER/AUTHORISED REPRESENTATIVE OBLIGATIONS

8.1 Registration of persons placing devices on the market

Article 14(1) of the Regulations requires Irish based manufacturers of Class I medical devices that 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 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 availability

The manufacturer, or his authorised representative established in the European Community, must make technical documentation and the declaration of conformity available to the HPRA for inspection purposes for a period ending at least five years after manufacture of the product. This includes making the documentation available by a manufacturer to his authorised representative. It also includes having the file available at the premises of the first importer into Europe if there is no designated authorised representative in Europe.

8.3 Record, evaluate and notify incidents

Any manufacturer of a medical device is obliged to ensure that they keep good records of the manufacturing of the medical device and have the ability to trace the device if a field safety corrective action or other activity is necessary. Schedule 7, section 4 of the Regulations makes the manufacturer or his authorised representative responsible for activating the vigilance system and informing the surveillance authority about incidents that invoke it. He shall notify the competent authorities of the following incidents immediately on learning of them:

(i) 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;

(ii) any technical or medical reason connected with the characteristics on the 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'
- HPRA 'Guide to field safety corrective actions for medical and i*n-vitro* diagnostic medical devices'
- HPRA 'Guide to incident reporting for general medical devices and active implantable medical devices'

8.4 Review experience from post-market surveillance

Schedule 7, section 4 of the Regulations requires the manufacturer to implement and keep updated a systematic procedure to review experience gained from devices in the post production phase including the provisions referred to in schedule 10, and to implement any appropriate means to apply any 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. 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
- Guidance Notes 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.
- Market Surveillance Operation Group (MSOG) – Guidance Notes for Manufacturers of Class I Medical Devices – 2007-09
- HPRA 'Guide to field safety corrective actions for medical devices and *in-vitro* diagnostic medical devices'
- HPRA 'Guide to the vigilance system for medical devices'
- HPRA 'Guide to incident reporting for general medical devices and active implantable medical devices'
- HPRA 'Guide for medical device manufacturers on auditing by the Health Products Regulatory Authority'
- HPRA 'Guide to the classification of a medical device'

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:

Medical Devices Department,
Health Products Regulatory Authority,
Kevin O'Malley House,
Earlsfort Centre,
Earlsfort Terrace,
Dublin 2
D02 XP77

Telephone: +353 1 676 4971
Fax: +353 1 676 7836
Email: devices@hpra.ie

The HPRA encourages communication with the medical device sector. Should you have specific queries please address them to the Medical Devices Department of the HPRA. Communication can be made by telephone, fax, email, or by post to the above address.

APPENDIX 1 CHECKLIST FOR CLASS 1 DEVICE MANUFACTURERS

DESCRIPTION	GUIDE REFERENCE	YES	NO	ADDITIONAL REFERENCES	S.I. 252, 994	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 Schedule 9	Article 1 Annex IX
Confirm product as a Class I device	Section 7.2				Article 2 Schedule 9	Article I Annex IX
Meet the essential requirements	Section 7.3			Appendix 2 of this guide	Article 5 Schedule 1	Article 3 Annex I
Prepare technical documentation	Section 7.4			NB-MED 2.5.1/ – Technical Documentation COEN guidance notes for manufacturers of Class I medical devices	Article 7 Schedule 1 Schedule 7 Schedule 10	Article 5 Article 11 Annex I Annex VII Annex X
Notified Body intervention	Section 7.5				Schedule 4 Schedule 5 Schedule 6	Annex IV Annex V Annex VI
Prepare instructions for use and labelling	Section 7.6				Schedule 1 Schedule 7	Annex I Annex VII
EC declaration of conformity	Section 7.7				Article 7 Schedule 7	Article 11 Annex VII
Affix CE Mark	Section 6 and Section 7.8				Article 6 Schedule 4 Schedule 5 Schedule 6 Schedule 12	Article 17 Annex IV Annex V Annex VI Annex XII
Manufacturing Records	Section 7.9				Article 7 Schedule 1 Schedule 7 Schedule 10	Article 11 Annex I Annex VII Annex X
Registration of persons placing devices on the market	Section 8.1			Guidance Note 2: Guide to the Registration of Persons	Article 14	Article 14

DESCRIPTION	GUIDE REFERENCE	YES	NO	ADDITIONAL REFERENCES	S.I. 252, 994	DIRECTIVE 93/42/ EEC
				Responsible for Placing Devices on the Market		
Record, evaluate and notify incidents	Section 8.3			MEDDEV 2.12-1Guidelines on a Medical Devices Vigilance System HPRA Guide to the vigilance system for medical devices	Schedule 7	Annex VII
Review experience from post-market surveillance	Section 8.4				Schedule 7	Annex VII
HPRA post-market Surveillance	Section 8.5				Article 22 Article 23	Article 22

* Reference to manufacturer's supporting documentation should be made.

** This is not a comprehensive list of references and should only be used as an example guide.

APPENDIX 2 ESSENTIAL REQUIREMENTS CHECKLIST FOR CLASS I MEDICAL DEVICE MANUFACTURERS

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. This shall include: - 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, experience, education and training and where applicable the medical and physical conditions of intended users (design for lay, professional, disabled or other users).				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
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. In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order: - eliminate or reduce risks as far as possible (inherently safe design and construction), - where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated, - inform users of the residual risks due to any shortcomings of the protection measures adopted.				To comply with this requirement, manufacturers should: - review the design brief of the product, - review published literature and experience of similar devices, - review the packaging of the device to harmonised standards, - review the labelling and instructions for use (if applicable), - review final release procedures.	
3. The devices must achieve the performances intended by the manufacturer and 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.				The manufacturer must have evidence that the device complies with his specified requirements. A design validation and test regime should reflect this.	
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				It should be demonstrated that the stresses that occur during the normal conditions of use intended by the	

ESSENTIAL PRINCIPLE	APPLICABLE TO THE DEVICE	METHOD OF CONFORMITY	IDENTITY OF SPECIFIC DOCUMENTS	GUIDANCE FOR THE MANUFACTURER OF THE DEVICE	RELEVANT HARMONISED STANDARDS
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.				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 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.	

ESSENTIAL PRINCIPLE	APPLICABLE TO THE DEVICE	METHOD OF CONFORMITY	IDENTITY OF SPECIFIC DOCUMENTS	GUIDANCE FOR THE MANUFACTURER OF THE DEVICE	RELEVANT HARMONISED STANDARDS
				If accessible, a review of complaints history should be used for established products.	
6. Any undesirable side-effect must constitute an acceptable risk when weighed against the performances intended. 6a. Demonstration of conformity with the essential requirements must include a clinical evaluation in accordance with Schedule 10.				For new or modified devices, the results of a risk analysis should be used to determine whether the side effects associated with the 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 For established products, the risk analysis should consist of experience in use. A clinical evaluation must be conducted in support of all devices.	EN ISO 14971 (Medical devices – Application of risk management to medical devices)
Requirements regarding design and construction					

ESSENTIAL PRINCIPLE	APPLICABLE TO THE DEVICE	METHOD OF CONFORMITY	IDENTITY OF SPECIFIC DOCUMENTS	GUIDANCE FOR THE MANUFACTURER OF THE DEVICE	RELEVANT HARMONISED STANDARDS
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: - the choice of materials used, particularly as regards toxicity and, where appropriate, flammability, - the compatibility between the materials used and biological tissues, cells and body fluids, taking account of the intended purpose of the device, - where appropriate, the results of biophysical or modelling research whose validity has been demonstrated beforehand.				It should be demonstrated that the materials chosen are appropriate given the intended use of the device. The risk of toxicity, and where appropriate, flammability and bio-incompatibility should be assessed and the product labelled accordingly. These tests should be included in the risk analysis. A biological safety evaluation should be made in accordance with relevant harmonised standards. 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				Any contaminants and residues in or on the device that could cause	EN 10993 series

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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.				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.	
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 2001/83/EC and which is liable to act upon the body with action ancillary to that of the device, the quality, safety and usefulness of the substance must be				This is not applicable to Class I manufacturers as Class I devices incorporating a medicinal substance automatically fall under a Class III categorisation and Rule	MEDDEV 2.4/1: Guidelines for the Classification of Medical Devices.

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verified by analogy with the methods specified in Annex I to Directive 2001/83/EC. For the substances referred to in the first paragraph, the notified body shall, having verified the usefulness of the substance as part of the medical device and taking account of the intended purpose of the device, seek a scientific opinion from one of the competent authorities designated by the Member States or the European Medicines Agency (EMA) acting particularly through its committee in accordance with Regulation (EC) No. 726/2004 on the quality and safety of the substance including the clinical benefit/risk profile of the incorporation of the substance into the device. When issuing its opinion, the competent authority or the EMA shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the notified body. Where a device incorporates, as an integral part, a human blood derivative, the notified body shall, having verified the usefulness of the substance as part of the medical device and taking into account the intended purpose of the device, seek a scientific opinion from the EMA,				13 of MEDDEV on classification.	

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acting particularly through its committee, on the quality and safety of the substance including the clinical benefit/risk profile of the incorporation of the human blood derivative into the device. When issuing its opinion, the EMA shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the notified body. Where changes are made to an ancillary substance incorporated in a device, in particular related to its manufacturing process, the notified body shall be informed of the changes and shall consult the relevant medicines competent authority (i.e. the one involved in the initial consultation), in order to confirm that the quality and safety of the ancillary substance are maintained. The competent authority shall take into account the data related to the usefulness of incorporation of the substance into the device as determined by the notified body, in order to ensure that the changes have no negative impact on the established benefit/risk profile of the addition of the substance in the medical device. When the relevant medicines competent authority (i.e. the one involved in the initial consultation) has obtained information on the ancillary substance, which could have an					

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impact on the established benefit/risk profile of the addition of the substance in the medical device, it shall provide the notified body with advice, whether this information has an impact on the established benefit/risk profile of the addition of the substance in the medical device or not. The notified body shall take the updated scientific opinion into account in reconsidering its assessment of the conformity assessment procedure.					
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. Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction, in accordance with Annex I to Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances. If parts of a device (or a device itself) intended to administer and/or remove medicines, body liquids or other substances to or from the body, or devices intended for transport and storage of such body fluids or substances, contain				Leaking includes leaching. Simulated use testing should be carried out. Assessment is normally carried out by appropriate bench testing.	

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phthalates which are classified as carcinogenic, mutagenic or toxic to reproduction, of category 1 or 2, in accordance with Annex I to Directive 67/548/EEC, these devices must be labelled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging as a device containing phthalates. If the intended use of such devices includes treatment of children or treatment of pregnant or nursing women, the manufacturer must provide a specific justification for the use of these substances with regard to compliance with the essential requirements, in particular of this paragraph, within the technical documentation and, within the instructions for use, information on residual risks for these patient groups and, if applicable, on appropriate precautionary measures.					
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.	

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8. Infection and microbial contamination					EN 11135 series (Sterilization of healthcare products) EN 10993 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 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.				The work done to meet the essential requirements 1-6 above should incorporate 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.	EN 11135 series EN 10993 series
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. Notified bodies shall				This requirement should be interpreted in the context of each particular	EN 22442 series (Medical devices utilising animal tissues and their derivatives)

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retain information on the geographical origin of the animals. 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 transmissible agents must be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process.				device given that Class I devices are non-invasive. 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 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.				Notified Body intervention is required for Class I devices that are labelled sterile.	
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 EN 11737 series

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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 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.				Bioburden checks, for 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.	

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9.2 Devices must be designed and manufactured in such a way as to remove or minimize as far as is possible: - the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features, - risks connected with reasonably foreseeable environmental conditions, such as magnetic fields, external electrical influences, electrostatic discharge, pressure, temperature or variations in pressure and acceleration, - the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given, - 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.					EN 60601 Series (Medical electrical equipment)
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 could cause combustion.					

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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.				The measuring function element of the device must be assessed by a Notified Body for Class I devices.	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.					
11. Protection against radiation					
11.1 General					
11.1.1. Devices shall be designed and manufactured in such a way that exposure 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					EN 60601 series

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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 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.					

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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
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					

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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				The majority of active medical devices will not be Class I, however refer to Rule 12 of MEDDEV 2.4/1 Guidelines for the Classification of Medical Devices for Class I examples.	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 should be adopted to eliminate or reduce as far as possible consequent risks. 12.1a For devices which incorporate software or which are medical software in themselves, the software must be validated according to the state of the art taking into account the principles of development lifecycle, risk management, validation and verification.					

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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 Devices must be designed and manufactured in 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.					EN 60601-1
12.7 Protection against mechanical and thermal risks					

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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 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					

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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 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. 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.					

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12.9 The function of the controls and indicators must be clearly specified on the devices. 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) 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 properly, taking account of the training and knowledge of the potential users, and to identify the manufacturer. This information comprises the details on the label and the data in the instructions for use. 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				If no instructions for use are included with Class I or IIa medical devices, the reasons for not including the instructions must be justified in the technical file.	

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packaging of each unit is not practicable, the information must be set out in the leaflet supplied with one or more devices. 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.					
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: (*a*) 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 the authorised representative where the manufacturer does not have a registered place of business in the Community;				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) EN 980 (Graphical symbols for use in the labelling of medical devices)

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(*b*) the details strictly necessary to identify the device and the contents of the packaging especially for the users; (*c*) where appropriate, the word 'STERILE'; (*d*) where appropriate, the batch code, preceded by the word 'LOT', or the serial number; (*e*) where appropriate, an indication of the date by which the device should be used, in safety, expressed as the year and month; (*f*) where appropriate, an indication that the device is for single use. A manufacturer's indication of single use must be consistent across the Community; (*g*) if the device is custom-made, the words 'custom-made device'; (*h*) if the device is intended for clinical investigations, the words 'exclusively for clinical investigations'; (*i*) any special storage and/or handling conditions;					

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(*j*) any special operating instructions; (*k*) any warnings and/or precautions to take; *(l)* year of manufacture for active devices other than those covered by (*e*). This indication may be included in the batch or serial number; (*m*) where applicable, method of sterilization; (*n*) in the case of a device within the meaning of Article 1(4a) of Directive 93/42/EEC as amended, an indication that the device contains a human blood derivative.					
13.4 If the intended purpose of the device is not obvious to the user, the manufacturer must 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:				The instructions for use must form part of the Technical file must be	EN 1041 (Information supplied by the manufacturer with medical devices)

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(*a*) the details referred to in Section 13.3, with the exception of (*d*) and (*e*); (*b*) the performances referred to in Section 3 and any undesirable side effects; (*c*) 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; (*d*) all the information needed to verify whether the device is properly installed and can operate 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; (*e*) where appropriate, information to avoid certain risks in connection with implantation of the device; (*f*) information regarding the risks of reciprocal interference posed by the presence of the				provided if requested by a competent authority.	EN 980 (Graphical symbols for use in the labelling of medical devices)

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device during specific investigations or treatment; (*g*) the necessary instructions in the event of damage to the sterile packaging and, where appropriate, details of appropriate methods of resterilization; (*h*) 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. Where devices are supplied with the intention that they be sterilized before use, the instructions for cleaning and sterilization must be such that, if correctly followed, the device will still comply with the requirements in Section I. If the device bears an indication that the device is for single use, information on known characteristics and technical factors known to the manufacturer that could pose a risk if the device were to be reused. If in accordance with Section 13.1 no instructions for use are needed, the information must be made available to the user upon request;				Point (o) is not applicable for Class I devices.	

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(i) details of any further treatment or handling needed before the device can be used (for example, sterilization, final assembly, etc.); (*j*) in the case of devices emitting radiation for medical purposes, details of the nature, type, intensity and distribution of this radiation. 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: (*k*) precautions to be taken in the event of changes in the performance of the device; (*l*) 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.; (*m*) adequate information regarding the medicinal product or products which the device in question is designed to administer, including					

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any limitations in the choice of substances to be delivered; (*n*) precautions to be taken against any special, unusual risks related to the disposal of the device; (*o*) medicinal substances, or human blood derivatives incorporated into the device as an integral part in accordance with Section 7.4; (*p*) degree of accuracy claimed for devices with a measuring function; (*q*) date of issue or the latest revision of the instructions for use.					