



## VELFERÐARRÁÐUNEYTIÐ

*Ministry of Welfare*

### **REGULATION on Medical Devices, No. 934/2010.**

#### CHAPTER 1

#### **Scope and Definitions.**

##### Article 1

##### *Scope.*

This Regulation covers the production, sales, marketing, use and maintenance of medical devices and their parts, and the health authority surveillance of such devices. The Regulation applies equally to the devices and their parts. Medical devices and parts are in this Regulation called devices.

When a device is intended to administer a medicinal product in the understanding of Article 5 of the Medicinal Products Act, No. 93/1994, as amended, then such a device shall be covered by this Regulation, with the reservation of the provisions of the Medicinal Products Act, No. 93/1994, with respect to medicinal products.

Where a device according to paragraph 3 is placed on the market in such a manner that the device and the medicinal product constitute one integrated manufactured product, which shall only be used in this combination and is disposable, then the provisions of the Medicinal Products Act, No. 93/1994, shall apply to that product. The relevant basic requirements in Annex I in accompanying document 1 to this Regulation shall apply to the safety and to the attributes of the device with respect to its functionality.

Where part of a device is a substance that when used on its own could be considered a medicinal product in the understanding of the Medicinal Products Act, No. 93/1994, and could have other effects on the body and those that the device has, then the device shall be assessed and its use authorised on the basis of this Regulation.

If a medical device which contains as a constituent part, a substance that can be judged, if used on its own, to constitute substance of a medicinal product or products, which is produced from human blood or blood plasma in the understanding of the Medicinal Products Act, No. 93/1994, and that substance, which hereafter is called „derivative from human blood“, can have other effects on the human body than one could expect from the device itself, then such a device shall be assessed in accordance with this Regulation.

Where the manufacturer intends the device to be used in accordance with the provisions of personal protection equipment in Regulation No. 501/1994, on the type of personal protection equipment, and in accordance with this Regulation, then the device shall also fulfil the provisions of the relevant basic requirements for health protection and safety in Regulation No. 501/1994, on the type of personal protection equipment.

This Regulation is a specialised regulation in the understanding of Regulation No. 270/2008, on electromagnetic compatibility.

This Regulation does not apply to:

- a) Devices for in vitro diagnostic devices, as they are covered by the Regulation on for in vitro diagnostic devices.
- b) Surgically implanted devices, as they are covered by the Regulation on active surgically implanted medical devices.

- c) Medicinal products covered by the Medicinal Products Act, No. 93/1994, as amended. In deciding whether a product is covered by this act or this Regulation, the basic functionality of the product shall first and foremost be taken into account.
- d) Cosmetics, as they are covered by Regulation No. 748/2003, on cosmetics.
- e) Human blood, human blood products, human plasma or blood cells of human origin or devices which incorporate at the time of placing on the market such blood products, plasma or cells, with the exception of the devices specified in paragraph 6 of Article 2.
- f) Transplants or tissues or cells of human origin or products incorporating or derived from tissues or cells of human origin, with the exception of the devices specified in paragraph 6 of Article 2.
- g) Transplants or tissues or cells of animal origin, unless a device is manufactured utilizing animal tissue which is rendered non-viable or nonviable products derived from animal tissue.
- h) Use and maintenance of x-ray diagnosis or treatment devices or the use of radioactive materials, as they are covered by Act No. 44/2002, on Radiation Protection.
- i) Devices specified in paragraph 1 of Article 25 where they are not intended to come into contact with the human body or are only intended to come into contact with undamaged skin.

## Article 2

### *Definitions.*

In this Regulation the meanings of the following concepts are as follows:

- 1) *Medical device*: Any instrument, equipment, appliance, software, substance or other article, whether it is used alone or in combination, including the software that a manufacturer intends specifically for use in diagnosis and/or treatment and which is necessary for proper use of the device, and intended by the manufacturer for use for humans in order to:
  - diagnose, prevent, investigate, treat or alleviate an illness,
  - diagnose, monitor, treat or repair damage to the body, handicap and/or limited capacity,
  - investigate, change or replace the functionality of the anatomy or physiological activity,
  - control pregnancy,
 that does not perform its main function in or on the human body by pharmacological, immunological or metabolic means, but may support its function with such means.
- 2) *Accessories*: An accessory is not a medical device, but is intended by the manufacturer intends for specialised use with a medical device in order for it to be used in the manner the manufacturer intends.
- 3) *A medical device for diagnosis (in vitro)*: A medical device that is a reactant, a product of a reactant, calibrator, control material, kit, instrument, apparatus, equipment or system, whether it is used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information:
  - concerning a physiological or pathological state, or
  - concerning a congenital abnormality, or
  - to determine the safety and compatibility with potential recipients, or
  - to monitor therapeutic measures.
 Specimen receptacles are considered to be in vitro diagnostic medical devices, whether vacuum-type or not, and that are specifically intended by their manufacturers for the primary containment and preservation of specimens derived from the human body for the purpose of in vitro diagnostic examination.  
 Products for general laboratory use are not in vitro diagnostic medical devices unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for in vitro diagnostic examination.
- 4) *Custom-made devices*: A device that is custom-made according to a written prescription from a doctor who has the required education and competence and that on his/her responsibility is designed with special attributes and that is only intended for one specific patient.  
 In addition to this, any individual can issue such a prescription should he/she have the authority to do so based on his/her vocational training and competence.

A mass-produced device that has to be adapted to specific requirements of a doctor or of another professional is not considered to be a custom-made device.

- 5) *A device intended for clinical investigation*: A device intended to be used by a doctor, suitably educated and competent, for testing, as is specified in item 2.1 of Annex X in accompanying document 1 to this Regulation in a clinically adequate environment.  
For the performing of clinical investigation, all other persons that have the authority to perform tests on the basis of their vocational training and competence are considered the equivalent of an educated and competent doctor.
- 6) *Kit*: A prepared package of items, which are usually all sterilised and which are packaged for specific operations. Individual items in the package can be from more than one manufacturer.
- 7) *Manufacturer*: A natural or legal person that bears responsibility for the design, manufacture, packing and labelling of a device before it is placed on the market in his/her name, whether he/she performs these actions himself/herself or where a third party does so on his/her behalf.  
The obligations of this Directive 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/her own name. This paragraph does not apply to persons who package or refurbish devices that are on the market for specific use for specific patients, and that are not manufacturers in the understanding of paragraph 1 of this item.
- 8) *Intended use*: The use for which the device is intended according to the information provided by the manufacturer on labels, in instructions and/or promotional material about the product.
- 9) *The user*: The person that needs medical devices because of illness, handicap or impaired capacity, that works with medical devices or has supervision of them and/or maintains them.
- 10) *Marketing*: To offer a device in the first instance, in return for payment or without charge, except for a device for clinical investigation, with the intention of distributing and/or using it on markets within the EEA, whether it is new or completely refurbished.
- 11) *To take into use*: When a device has become accessible to end users and is ready for the first time for intended use on the EEA market.
- 12) *Recognised representative*: A natural or legal person based in the EEA who is specially authorised by the manufacturer and who represents him/her where parties based in the EEA can communicate with him/her instead of with the manufacturer regarding the obligations of the latter according to this Regulation.
- 13) *Authorised parties*: Parties that are authorised to perform tasks regarding those methods specified in Article 11.
- 14) *Legally competent authorities*: In Iceland, the Medical Director of Health, *cf.* Article 10 of Act No. 16/2001, on Medical Devices.
- 15) *Sterilisation*: Sterilisation, where all micro-organisms have been removed or killed on and/or in a defined area or part.
- 16) *Responsible party*: The party who is responsible for marketing medical devices in this country. The responsible party can be a manufacturer or importer. The responsible party bears certain obligations in excess of those borne by other sellers.
- 17) *CE-Conformity marking*: Marking to confirm that the product fulfils all specified basic requirements in regulations and harmonised standards in the EEA.
- 18) *Surveillance*: Surveillance of the safety of medical devices is the responsibility of the Medical Director of Health, *cf.* Article 10 of the Act on Medical Devices, No. 16/2001, as amended. Among other things surveillance means surveillance of the market, i.e. surveillance to determine whether the medical devices marketed in Iceland fulfil safety requirements and requirements for labelling, *cf.* Article 8, and on the other hand surveillance to determine whether maintenance is performed on the medical devices, *cf.* Article 17, and surveillance of the use of medical devices, *cf.* Article 16. The Medical Director of Health is authorised to delegate specific surveillance tasks to other parties.
- 19) *Harmonised standard*: A standard that has been written with reference to the basic requirements of the European Committee for Standardisation (CEN) or of European Committee for Electro-technical Standardisation (CENELEC) on behalf of the EEA.

- 20) *Declaration of conformity*: A declaration by a manufacturer of his/her responsibility for a product conforming to standards or other documented requirements.
- 21) *Cell*: The smallest structural unit of a living form that can live independently and can renew itself in a suitable environment.
- 22) *Tissue*: An aggregate of cells and/or extra-cellular constituents.
- 23) *Derivative*: A substance derived from animal tissue with a manufacturing process, such as collagen, gelatine or monoclonal antibodies.
- 24) *Non-viable*: Non-viable means having no potential for metabolism multiplication.
- 25) *Transmissible agents*: Transmissible agents means unclassified pathogenic entities, prions and such entities as bovine spongiform encephalopathies agents and scrapie agents.
- 26) *Reduction and elimination or removal*: A process by which the number of transmissible agents is reduced, eliminated or removed in order to prevent infection or pathogenic reaction.
- 27) *Inactivation*: A process by which the ability to cause infection or pathogenic reaction by transmissible agents is reduced.
- 28) *Source country*: The country in which the animal was born, has been reared and/or has been slaughtered.
- 29) *Starting materials*: Raw materials or any other product of animal origin out of which, or with the help of which, the devices referred to in paragraph 1 of Article 25 are produced.
- 30) *Hip, knee and shoulder joint replacement*: An implantable part of the total system of replacement of a joint that is intended to create the capability of movement similar to that of natural hip, knee and shoulder joints. Additional parts, i.e. screws, wedges, plates and tools are not included here.
- 31) *Clinical data*: Information on safety and/or operation that is collected with use of a device  
Clinical data is collected:
- from clinical tests of the device in question or
  - from clinical tests or other observations, that are described in scientific papers, on a similar device where it is possible to demonstrate that that device is equivalent to the device in question or
  - from published and/or unpublished reports on other clinical experience, either on the device in question or on a similar device where it is possible to demonstrate that the device is equivalent to the device in question here.
- 32) *Subcategories of devices*: A group of devices with common intended usage or that are based on the same technology.
- 33) *General category of devices*: A group of devices with the same or similar intended use or that are based on common technology which makes it possible to categorise them in a general manner but which does not reflect specialised attributes.
- 34) *Disposable devices*: A device that is only intended to be used once and for one patient.
- See further definitions in Annex IX in accompanying document 1 to this Regulation on the criteria for categorising medical devices.

## CHAPTER II

### **Marketing, market surveillance, use and basic requirements.**

#### Article 3

##### *Marketing and use.*

It is only authorised to market medical devices and/or put them into service if they fulfil the requirements prescribed in this Regulation and on condition that they are delivered in a proper manner, correctly installed, used in the intended manner and maintained such that they work as intended and where requirements for safety are fulfilled.

#### Article 4

##### *Basic requirements.*

The devices must fulfil basic requirements as prescribed in Annex I in accompanying document 1 to this Regulation that apply to them, having taken into account their intended use.

Devices that are produced with or from tissue of animal origin, *cf.* paragraph 1 of Article 25, shall also fulfil basic requirements as prescribed in Annex I in accompanying document 1 to this Regulation

and that applied to them, having taking into account their intended use and the requirements prescribed in Annex XIII in accompanying document 1 to this Regulation.

If a relevant risk exists then devices that are also machines in the understanding of Article 2 of Regulation No. 1005/2009, on machines and technical equipment, shall also fulfil basic requirements for health and safety as prescribed in Annex I of that Regulation to the extent that these basic requirements for health and safety are more specialised than the basic requirements prescribed in Annex I in accompanying document 1 to this Regulation.

#### Article 5

##### *Free movement and devices for specialised use.*

It is only authorised to market devices and to put them into service if they carry the CE marking as prescribed in Article 23 that indicates that conformity assessment in accordance with the provisions of Article 11 has been performed.

It is authorised that devices intended for clinical investigation be made available to doctors or to those who have authority for such tests if they fulfil the conditions of Article 21 and of Annex VIII in accompanying document 1 to this Regulation.

It is authorised to place on the market custom-made devices and put them into service if they fulfil the conditions prescribed in Article 11 and in Annex VIII in a company document 1 to this Regulation. Devices in categories IIa, IIb and III shall carry a declaration prescribed in Annex VIII in accompanying document 1 to this Regulation but shall be accessible to specific patients specified in the declaration and identified by name, by initials or by a number code.

Devices according to paragraphs 2 and 3 shall not carry the CE marking.

At trade fairs, exhibitions, at demonstrations and at related events it is authorised to show devices that do not fulfil the conditions of this Regulation on condition that is clearly shown on a prominent sign that it is not possible to market the devices nor to put them into service before they have fulfilled the requirements of the Regulation.

When devices are also covered by other laws and regulations based on directives from the European Union regarding other issues where it is also prescribed that the CE marking should be used, the mark means that the devices also fulfil those laws and regulations.

Should such laws or regulations on the other hand allow the manufacturer to choose during the period of adjustment an arrangement that he/she asks be applied, then the CE marking means that the devices only fulfil the provisions of the regulations applied by the manufacturer. In such circumstances information must be provided about specific aspects of such an arrangement in documents, notifications or instructions that are included with the devices.

#### Article 6

##### *Reference to standards.*

The basic requirements in Article 4 shall be considered fulfilled for devices that are in accordance with the appropriate Icelandic standards that have been adopted on the basis of harmonised European standards and been endorsed by Iceland Standards, *cf.* Act No. 36/2003. Reference to standards is also considered a reference to chapters in the European drugs registry, particularly on chapters about surgical sutures and interaction between medicinal substances and substances in devices that contain medicinal substances, *cf.* Article 6 of the Medicinal Products Act, No. 93/1994, as amended.

#### Article 7

##### *Safety provisions.*

Should it come to light that devices specified in paragraphs 1 and 3 of Article 5 and that have been installed, maintained and used in the proper and intended manner, may threaten the health and/or safety of patients, of users or other parties, then the Medical Director of Health shall take all appropriate temporary measures to take such devices off the market or to ban them from being placed on the market or placed in use. The Medical Director of Health shall inform the EFTA Surveillance Authority of all such measures, specified the reasons for his/her decision and in particular whether nonconformity is a result of:

- a) A failure to fulfil the basic requirements prescribed by Article 4.

- b) The standards prescribed in Article 6 have not been applied properly, where it is maintained that the standards have been applied.
- c) The standards themselves are faulty.

The Medical Director of Health shall always ensure that the handling of cases is always in accordance with laws governing public administration. The right to appeal decisions by the Medical Director of Health shall be governed by the provisions of the Administrative Procedure Act.

If a device that is not in compliance with the requirements as a CE marking then the Medical Director of Health shall take appropriate measures according to Articles 10 and 13 of the Act on Medical Devices, No. 16/2001, against whatever party has applied the marking and he/she shall report this to the EFTA Surveillance Authority. The treatment of cases by the Medical Director of Health shall be according to Article 13 of Act No. 16/2001, on Medical Devices, *cf.* Chapters IV and V of Act No. 134/1995, on the Safety of Products and on Official Market Surveillance.

## Article 8

### *Market surveillance.*

Market surveillance involves monitoring to ensure that medical devices that are marketed in Iceland are in accordance with laws and regulations and that they fulfil safety requirements and requirements for labelling. Market surveillance shall aim to ensure that medical devices do not create risk.

The Medical Director of Health is responsible for market surveillance and is authorised to delegate to the parties certain tasks in this surveillance, *cf.* Article 10 of the Act on Medical Devices, No. 16/2001.

Surveillance parties can request necessary information for the surveillance, take samples and make those comments and performance tests that are considered necessary to avoid damage being caused by medical devices, *cf.* paragraph 2 of Article 33.

Employees of the Directorate of Health and those parties that the Medical Director of Health may make an agreement with for market surveillance are bound by confidentiality on matters that come to light in their investigations of medical devices that are covered by commercial confidentiality. Confidentiality still applies after termination of employment.

The implementation of market surveillance, its frequency and scope, is further prescribed in a regulation on surveillance by the Medical Director of Health of medical devices.

## CHAPTER III

### **Categorisation of devices, obligation to inform and assessment of conformity.**

## Article 9

### *Categorisation.*

Devices shall be categorised into category I, category IIa, category IIb and category III, according to risk associated with their use. The categorisation shall be made in accordance with Annex IX in accompanying document 1 to this Regulation.

Despite the provisions of Annex XI in accompanying document 1 to this Regulation the categorisation shall:

- a) Categorise implants that are used to enlarge or reconstruct breasts as category III.
- b) Categorise hip, knee and shoulder joint replacements, *cf.* item 30 of paragraph 1 of Article 2, as category III.

Should a dispute arise between the manufacturer and the party in question who has been authorised, that can be attributed to rules for categorisation, then the matter will be referred to legally competent authorities who have jurisdiction over the authorised party.

## Article 10

### *Information on instances that occur after the marketing of medical devices.*

Information that emerges in accordance with the provisions of this Regulation, on the instances below, regarding devices in category I, category IIa, category IIb or category III shall be registered and assessed by the Medical Director of Health, *cf.* Article 11 of Act No. 16/2001. This means information about:

- a) Whatever fault or changing attributes and/or operation of a device to the worse and whatever mistake in labelling or in instructions for use that may cause or may have caused the death of a patient or user or have caused his/her health to deteriorate significantly.
- b) Whatever reason, technical and medical relating to the attributes or operation of devices, for the reasons stated in item a, that leads to the manufacturer systematically withdrawing devices of the same type.

Those that manufacture, sell, own or use devices, e.g. doctors, other health employees or health institutions, are bound to report to the Medical Director of Health according to Article 11 of the Act on Medical Devices, No. 16/2001, all instances specified in paragraph 1. The Medical Director of Health shall next ensure that the manufacturer of the device in question or his/her recognised representative be also authorised about the event.

When the Medical Director of Health has performed an assessment, if possible along with the manufacturer or his/her recognised representative, then he/she shall, with the reservations of Article 7, inform the EFTA Surveillance Authority and other member states of the EEA without delay about the measures that have been taken or that are planned to prevent an event as specified in paragraph 1, happening again, including information on events in question.

## Article 11

### *Rules on conformity assessment.*

In the case of other devices in category III, than those that are custom-made or intended for clinical trials then the manufacturer shall, when attaching the CE marking, either:

- a) follow the method for EU conformity declaration as specified in Annex II in accompanying document 1 to this Regulation (full quality assurance) or
- b) follow the method for EU quality testing as specified in Annex III in accompanying document 1 to this Regulation (full quality assurance) along with:
  - i. the method for EU validation as specified in Annex IV in accompanying document 1 to this Regulation (full quality assurance) or
  - ii. the method for EU conformity declaration as specified in Annex V in the same accompanying document (quality assurance in production).

In the case of devices in category IIa other than those that are custom-made or that are intended for clinical trials then the manufacturer shall follow the method for EU conformity declaration as specified in Annex VII in accompanying document 1 to this Regulation when he/she attaches the CE marking, along with:

- a) the method for EU validation as specified in Annex IV in accompanying document 1 to this Regulation (full quality assurance) or
- b) the method for EU conformity declaration as specified in Annex V in the same accompanying document (quality assurance in production) or
- c) the method for EU conformity declaration as specified in Annex VI in the same accompanying document (quality assurance of a product).

Instead of the methods in paragraph 2 the manufacturer is also authorised to use the methods specified in item a of paragraph 4 below.

In the case of other devices in category IIb, than those that are custom-made or intended for clinical trials then the manufacturer shall when attaching the CE marking, either:

- a) follow the methods for EU conformity declaration as specified in Annex II in accompanying document 1 to this Regulation (full quality assurance in production) and in this instance item 4 of Annex II in the same accompanying document applies, or
- b) follow the method for EU quality testing as specified in Annex III in accompanying document 1 to this Regulation along with:
  - i. the method for EU validation as specified in Annex IV in accompanying document 1 to this Regulation or
  - ii. the method for EU conformity declaration as specified in Annex V in the same accompanying document (quality assurance in production) or
  - iii. the method for EU conformity declaration as specified in Annex VI in the same accompanying document (quality assurance of a product).

In the case of devices in category I other than those that are custom-made or that are intended for clinical trials then the manufacturer shall follow the method for EU conformity declaration as specified in Annex VII in accompanying document 1 to this Regulation when he/she attaches the CE marking, which is required before the device is marketed.

In the case of a custom-made device, the manufacturer must use the method prescribed in Annex VIII in accompanying document 1 to this Regulation and make the declaration that is prescribed in that Annex before he/she puts each device on the market. The manufacturer in Iceland shall inform the Medical Director of Health of such devices that are placed in use in Iceland.

In conformity assessment of a device the manufacturer and/or the authorised party shall take into account the results of assessments and validation that have been made at the production stage in accordance with this Regulation, as appropriate.

The manufacturer can delegate his/her recognised representative to commence the measures prescribed for in Appendices III, IV, VII and VIII in accompanying document 1 to this Regulation.

When the authorised party is involved in conformity assessment, the manufacturer or his/her recognised representative can approach an authorised party of their own choice in the case of tasks that the authorised party must perform.

The authorised party may, having provided satisfactory arguments, demand all information and data needed to confirm and maintain conformity accreditation with reference to the method that was chosen.

Decisions that authorised parties make in accordance with Appendices to, III, V and VI in accompanying document 1 to this Regulation shall be in force for a maximum of five years and they may be extended for a maximum of a further five years following an application presented during that time and that is agreed in a contract that both parties sign.

Documents and communications by letter related to those methods prescribed in paragraphs 1–6, shall be in the language agreed on in the EEA member agreement and that the authorised party agrees to.

Despite the provisions of paragraphs 1–6, the Medical Director of Health may authorise, having received a request supported by adequate arguments, that individual devices that have not been tested according to the methods specified in paragraphs 1–6 be placed on the market in this country if their use is of benefit to the protection of health.

## Article 12

### *Special rules on system and operation packs and rules on sterilisation.*

Despite the provisions of Article 11, this Article applies to device systems and operation packs.

A natural person or a legal person that prepares a package of CE marking devices in accordance with their intended use and with the use specified by the manufacturer, for the purpose of putting them on the market as a device system or operation pack, shall provide a declaration that:

- a) he/she has validated the reciprocal compatibility of the devices in accordance with the manufacturer's instructions and that his/her actions are in accordance with these instructions and
- b) that he/she has packaged the device system or operation pack and has provided the necessary information for users, including necessary instructions from the manufacturers and
- c) that all operations receive appropriate internal auditing and scrutiny.

When conditions according to paragraph 2 are not fulfilled, for example when a device system or operation pack contains devices that do not carry the CE marking or where the combination of devices is not compatible with the original intended use, then the device systems and the operation pack should be treated as distinct devices that must receive appropriate treatment according to Article 11.

Individuals or legal entities that sterilise, with marketing in mind, system or operation packs as specified in paragraphs 2 and 3 or other CE marked medical devices that manufacturers have designed to be sterilised prior to use, then one of the methods specified in Annex II or V in accompanying document 1 to this Regulation shall be selected. The implementation of the provisions of the above named Annexes and the participation of the authorised party shall be limited to the parts of the method that are directed at achieving sterilisation until the sterilised package has been opened or has been damaged. The individual shall make a declaration where it is stated that sterilisation has taken place in accordance with the manufacturer's instructions.



The products referred to in paragraphs 2–4 shall not themselves be marked with another CE marking. They shall include information in accordance with item 13 of Annex I in accompanying document 1 to this Regulation, including information from the manufacturers of the devices that were aggregated.

The statements referred to in paragraphs 2 and 4 above shall be kept available for legally competent authorities for a period of five years.

### Article 13

#### *Decisions on categorisation, provisions for exceptions.*

It is authorised to send a request supported by arguments to the Medical Director of Health that he/she take necessary measures, if it is considered that the implementation of the rules for categorisation in Annex IX in accompanying document 1 to this Regulation requires a decision on the categorisation of a specific device or type of device or that a specific device or category of devices should be put in another category, despite the provisions of Annex IX in the same accompanying document or that the compatibility of a device or category of devices should be determined, despite the provisions of Article 11, by applying only one of the specified methods, chosen from the methods specified in Article 11.

The Medical Director of Health shall provide a suitably argued request to the EFTA Surveillance Authority that the authority takes necessary action in the following circumstances:

- a) if the Medical Director of Health considers that the use of the categorisation rules in Annex IX in accompanying document 1 to this Regulation requires a decision on the categorisation of a specific device or category of devices;
- b) if the Medical Director of Health considers it appropriate to put a specific device or category of devices in another risk category, despite the provisions of Annex IX in accompanying document 1 to this Regulation;
- c) if the Medical Director of Health considers from the method specified in Article 11 it to be necessary to clarify compatibility of a device or category of devices, despite the provisions of Article 11, by only applying one of the specified methods in Article 11;
- d) if the Medical Director of Health considers it necessary to make a decision on whether a specific product or category of products falls under one of the definitions in items a–e in paragraph 1 of Article 2.

The EFTA Surveillance Authority shall notify the member states of the European Economic Area about the measures that have been taken.

## CHAPTER IV

### **Use and maintenance of medical devices. Surveillance of use and maintenance.**

#### Article 14

##### *User instructions.*

All medical devices shall carry user instructions that contain the necessary information from the manufacturer for their safe use, *cf.* item 13 of Annex I in accompanying document 1 to this Regulation. Instructions necessary for using the device in a safe manner shall as far as possible be on the device itself and/or on its packaging. Medical devices that are intended for public use shall carry user instructions in Icelandic.

#### Article 15

##### *Responsibility of the owner.*

The owner of a medical device is responsible for the proper use of the device and for the competence of the user. In addition to this the owner shall ensure that the treatment and storage of the device is adequate and maintenance and repair service and quality control are implemented by the competent parties such that the safety of patients and users is assured, *cf.* Article 17.

#### Article 16

##### *Use of medical devices and surveillance of their use.*

Medical devices shall be used in accordance with their intended use and with the instructions of the manufacturer. Users should know the main aspects of how the device works and have received

minimum training in handling and using the device so that it can be used effectively and so that patients, users and others are not at risk from the device.

The Medical Director of Health is responsible for monitoring that the use of medical devices is in accordance with the intended use of the device and with laws and regulations governing medical devices. The Medical Director of Health or his/her representative are authorised to scrutinise how medical devices are used and may demand information on user training and a certificate to validate their competence, *cf.* paragraph 2 of Article 33. The owner of a medical device shall notify the Medical Director of Health according to a more detailed rules from the Medical Director of Health about the medical devices that are used under his/her authority. The Medical Director of Health shall maintain a register of medical devices and he/she is authorised to set more detailed rules on the implementation of the obligation to notify and can limit this obligation two specific risk categories of medical devices.

Employees of the directorate of health and those parties with whom the Medical Director of Health may make an agreement for market surveillance are bound by confidentiality on matters that come to light in their investigations of medical devices that are covered by commercial confidentiality. Confidentiality still applies after termination of employment.

#### Article 17

##### *Maintenance of medical devices and surveillance of maintenance.*

An owner of medical devices is obliged to implement regular quality and safety monitoring and maintenance on the medical devices that he/she uses, in accordance with instructions from the manufacturer and according to the best professional knowledge at any given time. Such regular monitoring and all maintenance of a device shall only be entrusted to a recognised professional who must have the necessary professional knowledge or have received recognised training from the manufacturer of the device, to enable him/her to carry out the maintenance. A log shall be maintained on such monitoring and on ad hoc maintenance to devices.

The Medical Director of Health is responsible for monitoring that the implementation of maintenance and repairs of medical devices is in accordance with the manufacturers' instructions and with the best professional knowledge at any given time. Information on monitoring and maintenance shall be available to the Medical Director of Health or to other parties with whom he/she has made an agreement on the monitoring, *cf.* Article 10 of the Act on Medical Devices, No. 16/2001. The monitoring party can demand necessary information from the owner or from the party performing the maintenance and he/she can perform the investigations and tests necessary to verify the safety of the product, *cf.* paragraph 2 of Article 33.

Employees of the Directorate of Health and those parties that the Medical Director of Health may make an agreement with for market surveillance are bound by confidentiality on matters that come to light in their investigations of medical devices and which are covered by commercial confidentiality. Confidentiality still applies after termination of employment.

### CHAPTER V

#### **Registration of information.**

##### Article 18

##### *Registration of those responsible for marketing devices.*

A manufacturer who has a registered place of work in this country and who places a device on the market in his/her own name in accordance with the methods in paragraphs 5 and 6 of Article 11, and other natural persons or legal entities that conduct the activities specified in Article 12, shall notify the Medical Director of Health of the address of their registered place of work along with a description of the device in question.

The Medical Director of Health can demand to receive for all medical devices in categories IIa, IIb and in category III, information on documentation that makes it possible to identify the devices and on labelling and user instructions if the devices are placed in use in this country.

If a manufacturer who places a device on the market under his/her own name does not have a registered place of work in a member state of the European Economic Area then he/she shall nominate a recognised representative in the European Economic Area. With regards to devices specified in

paragraph 1, the recognised representative with a registered place of work in the European Economic Area who shall inform the Medical Director of Health about the items specified in paragraphs 1 and 2.

The Medical Director of Health shall, should it be requested, provide other member states of the European Economic Area and the EFTA Surveillance Authority information provided to him/her by the manufacturer or his/her recognised representative about the items specified in paragraph 1.

#### Article 19

##### *Cooperation on registration in the European Economic Area.*

Documentation demanded according to this Regulation shall be kept in a European database to which the Medical Director of Health has access, so that he/she can perform his/her duties according to these rules on the basis of good information.

The database shall contain:

- a) Data on the registration of manufacturers and recognised representatives and on devices in accordance with Article 18, with the exception of data concerning custom-made devices.
- b) Data regarding certificates that are issued, changed, extended, temporarily revoked, withdrawn or denied according to the method recommended in Appendices II–VII in accompanying document 1 to this Regulation.
- c) Data has been collected in accordance to the vigilance procedure specified in Article 10.
- d) Data regarding clinical tests specified in Article 21.
- e) Other data that is required or that the Medical Director of Health has gathered on the basis of this Regulation.

For registration in the European database the Medical Director of Health shall, in accordance with Article 8 of the Act on Medical Devices, No. 16/2001, register all information about manufacturers of medical devices that are based in this country or that are responsible for marketing medical devices in this country. The Medical Director of Health shall maintain a register for the same purpose of notifications in accordance with Article 11, *cf.* paragraph 2 of Article 5 of the same Act.

Data shall be forwarded in a standard format. The Medical Director of Health sets more detailed rules for the collection of such data.

#### Article 20

##### *Special measures to monitor health.*

Should the Medical Director of Health consider it necessary to ban or take a specific product or category of products off the market, to limit or to impose special conditions on its marketing or use, in order to protect health and safety and/or ensure that requirements for public health are met, he/she is then authorised to take all necessary and justified temporary measures. The Medical Director of Health shall inform the EFTA Surveillance Authority and other member states of the European Economic Area about such measures and provide arguments for the decision.

The EFTA Surveillance Authority assesses whether the measures taken by the Medical Director of Health are justified and issues an opinion. In making its opinion the EFTA Surveillance Authority shall, to the extent possible, consult with stakeholders and member states of the European Economic Area and shall inform other member states of the European Economic Area and stakeholders who were consulted about the conclusions of the opinion.

### CHAPTER VI

#### **Clinical tests.**

##### Article 21

##### *Clinical tests.*

In the case of a device intended for clinical tests, the manufacturer or his/her recognised representative based on the European Economic Area shall use the method specified in Annex VIII in accompanying document 1 to this Regulation. The manufacturer or his/her recognised representative, *cf.* sentence 1, shall notify the Medical Director of Health of the intention to conduct such tests in this country, *cf.* Article 9 of Act No. 16/2001, on Medical Devices, and other legally competent authorities in the member states of the European Economic Area where tests are to be conducted, with the declaration specified in item 2.2 in Annex VIII in accompanying document 1 to this Regulation.

In the case of a device in category III, implant and invasive devices for long-term use in category IIa or b, the manufacturer is authorised to commence the clinical investigation in question 60 days from the notification unless the Medical Director of Health or another legally competent authority has within this time informed him/her that a decision to the contrary was taken in the light of public health or a general rule.

The Medical Director of Health or another legally competent authority can however authorise manufacturers to commence the clinical tests in question before the 60 day period has expired, given that the ethics committee in question has returned a positive opinion on the testing schedule in question, including the committee's scrutiny of the clinical investigation schedule.

In the case of devices other than those specified in paragraphs 2 and 3 the Medical Director of Health or another legally competent authority can authorise manufacturers to commence the clinical tests in question immediately after the date of notification, given that the ethics committee in question has returned a positive opinion on the testing schedule in question, including the committee's scrutiny of the clinical investigation schedule.

Clinical tests according to paragraph 1 shall be conducted in accordance with the provisions of Annex 10 in accompanying document 1 to this Regulation.

The Medical Director of Health shall, if necessary, take the appropriate measures to ensure public health and general rules. Should the Medical Director of Health stop or deny clinical investigation then he/she shall inform other member states of the European Economic Area and the EFTA surveillance authority about his/her decision and the reasons for the decision. Should the Medical Director of Health have requested significant changes or temporary postponement of clinical investigation then he/she shall inform the appropriate member states of the European Economic Area about these measures and the reasons for the measures that were taken.

The manufacturer or his/her recognised representative shall inform the Medical Director of Health and the legally competent authorities of member states of the European Economic Area in question about the conclusion of clinical investigation, with arguments should it have been concluded early. In the case of clinical investigation that has been concluded early, a notification to this effect shall be sent to all member states of the European Economic Area and to the EFTA Surveillance Authority. The manufacturer or his/her recognised representative shall have the report specified in item 2.3.7 in Annex X in accompanying document 1 to this Regulation, available for the Medical Director of Health and for other legally competent authorities in the European Economic Area.

The provisions of paragraph 1, 2 and 3 do not apply when clinical investigation is conducted with devices where the CE marking is in accordance with Article 11 unless the objective of the tests is to use the devices for another purpose than is specified in the device's conformity assessment. The provisions of Annex X in accompanying document 1 to this Regulation apply as before.

## CHAPTER VII

### **Authorised parties and CE marking.**

#### Article 22

##### *Authorised parties.*

The board for technical accreditation of the Icelandic patent office is responsible for, according to the law on technical accreditation etc., assessing those parties that apply to handle conformity assessment according to this Regulation and they shall fulfil the conditions prescribed in Annex XI in accompanying document 1 to this Regulation. Parties that fulfil the assessment conditions specified in the harmonised standards in question are also considered to have fulfilled the conditions in Annex XI in the same accompanying document. The Medical Director of Health sends a notification about the parties that have been recognised in the manner described above, to the EFTA Surveillance Authority and to other member states of the European Economic Area, specifying the specific tasks that have been assigned to these parties.

A register of authorised parties along with the identity number they have been allocated and the tasks assigned to them are published in the Official Journal of the European Union.

Should an authorised party no longer fulfil the conditions prescribed in Annex XI in an accompanying document 1 to this Regulation then the board for technical accreditation of the Icelandic patents office will withdraw his/her accreditation according to paragraph 1 and will inform

the Medical Director of Health of this decision. The Medical Director of Health informs the EFTA Surveillance Authority and other member states of the European Economic Area.

The authorised party and the manufacturer or his/her recognised representative shall agree on time limits for the completion of assessment and verification measures specified in Appendices II–VI in accompanying document 1 to this Regulation.

The authorised party shall inform the Medical Director of Health about all certificates issued, changed, extended, temporarily withdrawn, revoked or denied and shall inform other authorised parties covered by the scope of this Regulation about certificates that are temporarily withdrawn, revoked or denied should this be requested regarding issued certificates. The authorised party shall also provide, if requested, or additional appropriate information.

This should the authorised party reach the conclusion that the manufacturer does not fulfil the appropriate provisions of this Regulation or that it had not been justifiable to issue a certificate, he/she shall, keeping in mind the principle of proportionality, cancel the certificate or revoke it or impose limitations on it unless the manufacturer ensures with appropriate measures that requirements will be met. Should a certificate be withdrawn, temporarily revoked or limitations be imposed on the certificate or if the intervention of a legally competent authority prove necessary, the authorised party shall inform the Medical Director of Health. The Medical Director of Health shall notify the above to the EFTA Surveillance Authority and to other member states.

The authorised party shall, if this is requested, provide all appropriate information and documents including bookkeeping documents needed by the board for technical accreditation of the Icelandic patents office to verify in accordance with the requirements of Annex XI in accompanying document 1 to this Regulation.

#### Article 23 *CE marking.*

Devices that are considered to meet basic requirements specified in Article 4, with the exception of those devices that are custom-made or that their intended for clinical tests, shall carry the CE conformity mark when they are marketed.

CE conformity marking, *cf.* Annex XII in accompanying document 1 to this Regulation, shall be visible, legible and non-erasable from the devices or from their sterilised packaging as appropriate and it shall also be on the devices' user instructions. The CE marking shall be on the sales packaging, if any.

The CE conformity mark shall include the identity number of the party that is responsible for applying the methods specified in Appendices 2, 4, 5 and 6 in accompanying document 1 to this Regulation.

It is unauthorised to include marks or lettering that are likely to mislead a third-party regarding the meaning or appearance of the CE conformity marking. It is authorised to put other labels on the device, on packaging or on the instruction brochure with the device on condition that the CE conformity marking will neither be less visible nor less legible as a result.

#### Article 24 *CE marking wrongly fixed to a product.*

Should the Medical Director of Health discover that a device has been wrongly marked with the CE marking or if it is lacking, *cf.* Article 23, then the manufacturer or his/her recognised representative are obliged to ensure that the device will be changed such that it fulfil the provisions of this Regulation regarding the CE marking.

Should the product in question not be changed in accordance with the requirements then the Medical Director of Health shall take all necessary measures to limit or ban the marketing of the device or shall ensure that it will be withdrawn from the market.

The provisions of paragraphs 1 and 2 apply also when goods that are not covered by this Regulation have wrongly been marked with the CE marking, where the methods of this Regulation have been applied.

The provisions of paragraph 1 do not limit the application of measures provided for in Article 7.

## CHAPTER VIII

### **Devices that are produced with or from tissue of animal origin.**

#### Article 25

##### *Scope of application for medical devices manufactured with or from tissue of animal origin.*

This chapter prescribes the requirements that devices that are manufactured with or from animal tissue, which has been made non-viable, or from non-viable products from tissue of animal origin, need to fulfil to prevent the danger of spongiform encephalopathies being transmitted to patients or others with normal use of the medical devices.

Animal tissue covered by this chapter is tissue originating from cattle, sheep and goats and also from deer, elk, mink and cats.

Collagen, gelatine and tallow used in the manufacture of medical devices shall at least meet the requirements for human consumption, *cf.* Act No. 93/1995, on Foodstuffs, as amended, and Act No. 96/1997, on the Raising and Health of Slaughter Animals, Slaughtering, Processing, Health Inspection and Quality Grading of Slaughter Products, as amended.

#### Article 26

##### *Preparation for an application for conformity assessment for a medical device produced with or from tissue of animal origin.*

Before an application for conformity assessment according to paragraph 1 of Article 11 is submitted, the manufacturer of the medical devices in question in paragraph 1 of Article 25, shall implement the risk analysis and risk management system prescribed in Annex XIII in accompanying document 1 to this Regulation.

#### Article 27

##### *Validation tests by authorised parties of medical devices produced with or from tissue of animal origin.*

The board for technical accreditation of the Icelandic Patent Office shall verify that the parties that are authorised according to Article 22 have the newest knowledge of medical devices specified in paragraph 1 of Article 25 to be able to assess whether the devices fulfil the provisions of this Regulation and the requirements prescribed in Annex XIII in accompanying document 1 to this Regulation.

If necessary, on the basis of the validation, that the board for technical accreditation of the Icelandic Patent Office change the tasks of the authorised party then the patent office shall inform the Medical Director of Health of this decision. The Medical Director of Health shall inform the EFTA Surveillance Authority and other member states of the European Economic Area about the decision.

#### Article 28

##### *Conformity assessment for medical devices manufactured with or from tissue of animal origin.*

Rules on conformity assessment, *cf.* Article 11, for medical devices covered by paragraph 1 of Article 25, shall constitute assessment of whether basic requirements are met, *cf.* Article 4, and the requirements prescribed in Annex XIII in accompanying document 1 to this Regulation.

In addition to the requirements according to paragraph 1, the authorised parties shall when assessing the risk analysis and risk management system of the manufacturer, pay particular attention to the following:

- a) The information provided by the manufacturer.
- b) Arguments for using animal tissue or derivatives of animal tissue.
- c) Conclusions of research on destruction and/or making non-viable or the results of search for references.
- d) The manufacturer's monitoring of the source of raw materials, fully manufactured products and subcontractors.
- e) The necessity for scrutiny of matters that relate to origin, including stocks from third parties.

During the process of assessment of risk analysis and risk management the domestic authorised parties shall according to the rules on conformity assessment, take into consideration the competence

certificate for transmissible spongiform encephalopathy issued by the European Directorate for the Quality of Medicines hereafter called „certificate for transmissible spongiform encephalopathy“ for starting materials, if available.

Domestic authorised parties shall, through the mediation of the Medical Director of Health, seek the opinion of legally competent authorities in the European Economic Area on their assessment and conclusions regarding the risk analysis and risk management system of the manufacturer of the medical device with regards to tissue or derivatives that are to be used in a medical device, except in the case of a medical device from source material which has received certification for transmissible spongiform encephalopathy as is stated in paragraph 3.

Before domestic authorised parties issue an EU certificate on design surveillance or an EU manufacturer testing certificate they shall pay appropriate attention to all comments that have been received within 12 weeks from the date that the opinion according to paragraph 4 was sought.

#### Article 29

##### *Marketing of medical devices either produced with or from tissue of animal origin.*

The Medical Director of Health shall take all necessary measures to ensure that medical devices specified in paragraph 1 of Article 25 are only placed on the market and placed in use if they are in accordance with the provisions of this Regulation and with the requirements prescribed in Annex XIII in accompanying document 1 to this Regulation.

### CHAPTER IX

#### **Various provisions.**

#### Article 30

##### *Decisions on denial or limitation.*

All decisions made on the basis of this Regulation on:

- a) denial or limitation of marketing or use of a device or the implementation of clinical investigation or
- b) the withdrawal of devices from the market,

shall be supported with detailed arguments and notified to the party in question without delay. He/she shall at the same time be notified of the measures he/she can take according to the law in force and/or regulations and the notice he/she has to do this.

Before a decision is made according to paragraph 1 the manufacturer or his/her recognised representative shall have the opportunity to present their views unless this is not possible because of the urgent nature of the measures.

#### Article 31

##### *Confidentiality.*

With the reservation of the provisions of laws in force and of practices regarding confidentiality of health information, all parties involved in the implementation of this Regulation are obliged to treat all information they receive in their work as confidential.

Obligations according to paragraph 1 have no any effect on the duties of the Medical Director of Health, of authorised parties nor of other legally competent authorities in the European Economic Area to exchange information and issue warnings nor on the duties of the parties in question to provide information to the courts.

The following information shall not be treated as confidential, *cf.* paragraph 1:

- a) information on the registration of parties that are responsible for pudding devices on the market in accordance with Article 19;
- b) information to users that the manufacturer, recognised representative or distributor send out in connection with a measure according to paragraph 3 of Article 10;
- c) information that appears on certificates that are issued, changed, extended, revoked or temporarily withdrawn.

Article 32  
*Cooperation.*

The Medical Director of Health shall take part in cooperation between legally competent authorities in the member states of the European Economic Area and with the EFTA Surveillance Authority and shall exchange the information with them that is necessary for the implementation of this Regulation in a uniform manner. The Medical Director of Health shall also take part in cooperation and in the dissemination of experience between legally competent authorities that they are the responsibility for market surveillance for the purpose of harmonising and ensuring uniformity in the implementation of this Regulation.

Article 33  
*Surveillance, treatment of cases and legal options.*

The Medical Director of Health is responsible for monitoring the implementation of this Regulation the monitoring of the Medical Director of Health is according to Article 10 of Act No. 16/2001, on Medical Devices.

Surveillance parties can request information for the surveillance, take samples and make those comments and perform the tests that are considered necessary to avoid damage being caused by medical devices. Manufacturers, importers, sellers, owners and users of medical devices shall provide the assistance and information requested in each instance.

Treatment of cases and legal options of the Medical Director of Health shall be, as appropriate, according to Chapters IV and V of Act No. 134/1995, on Product Safety and Official Market Control, as amended, and according to the Administrative Procedure Act.

Article 34  
*Legal recourse and sanctions.*

Legal issues arising in respect of violations of this Act shall be subject to rules on public prosecution, *cf.* paragraph 2 of Article 13 of the Act on Medical Devices, No. 16/2001.

Article 35  
*Right to appeal.*

The right to appeal is according to the provisions of the Administrative Procedure Act, No. 37/1993.

Article 36  
*Coming into force and legal authority.*

This Regulation which is set according to Article 14 of Act No. 16/2001, on Medical Devices, as amended, is in accordance with the provisions of Directive No. 93/42/EEC on the harmonisation of the laws of member countries on medical devices as amended with Directives No. 98/79/EEC, 2000/70/EEC, 2001/104/EEC, 2003/12/EEC and 2007/47/EEC. This Regulation is also in accordance with the provisions of Directive 2003/32/EEC on detailed specifications as regards the requirements laid down in Council Directive 93/42/EEC with respect to medical devices manufactured utilising tissues of animal origin, Directive 2005/50/EEC amending the classification of knee, hip and shoulder joint replacement implants within the framework of the Council Directive 93/42/EEC on medical devices.

This Regulation comes into force immediately. From the same time Regulation No. 368/1994, on the coming into force of the European Union directive on medical devices, Regulation No. 892/2004, on Medical Devices and Regulation No. 435/2006, on (1.) amendments to Regulation No. 892/2004, on Medical Devices, cease to have force.

**Temporary provisions**

Hip, knee and shoulder joint replacement, *cf.* item 30 of paragraph 1 of Article 2, which have received conformity assessment according to item a of paragraph 4 of Article 11 before 1 September 2007, may be marketed and placed in use up to 1 September 2009.

Hip, knee and shoulder joint replacement, *cf.* item 30 of paragraph 1 of Article 2, which have received conformity assessment according to item b of paragraph 4 of Article 11, i.e. according to the



method of the EU conformity declaration which is specified in Annex VI (quality assurance of product) in accompanying document 1 to this Regulation before 1 September 2007, may be marketed until 1 September 2010 and be placed in use after that date.

Holders of an EC design-examination certificate or an EC type examination certificate, that were issued before 1 April 2004 for medical devices specified in paragraph 1 of Article 25 shall apply for an EC additional certificate for design examination or EC additional certificate for type examination as confirmation that requirements are met that are prescribed in Annex XIII in accompanying document 1 with this Regulation.

Devices covered by paragraph 1 of Article 25 and that have received EC certification for design-examination or EC type examination certification issued before 1 April 2004 and that have been marketed and taken into use before 30 September 2004 are recognised in this country.

The provisions of Article 19 of the Regulation shall be implemented no later than 5 September 2012.

*Ministry of Health, 18 November 2010.*

**Guðbjartur Hannesson.**

Guðríður Þorsteinsdóttir.

### **Accompanying Document 1**

#### **ANNEX I Essential requirements.**

##### **I. 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).

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:

- a) Eliminate or reduce risks as far as possible (inherently safe design and construction).
- b) Where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated.
- c) Inform users of the residual risks due to any shortcomings of the protection measures adopted.

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 item a of paragraph 1 of Article 2 of the Regulation, as specified by the manufacturer.

4. The characteristics and performances referred to in items 1, 2 and 3 above 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.

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.

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 Annex X.

## II. REQUIREMENTS REGARDING DESIGN AND CONSTRUCTION

### 7. **Chemical, physical and biological properties.**

7.1. The devices must be designed and manufactured in such a way as to guarantee the characteristics and performances referred to in Part I, „General requirements“. Particular attention must be paid to:

- a) The choice of materials used, particularly as regards toxicity and, where appropriate, flammability.
- b) The compatibility between the materials used and biological tissues, cells and body fluids, taking account of the intended purpose of the device.
- c) Where appropriate, the results of biophysical or modelling research whose validity has been demonstrated beforehand.

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.

7.3. The devices must be designed, manufactured and packed 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.

7.4. Where an active medical device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product as defined in Article 5 of the Medicinal Products Act, No. 93/1994, 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 verified by analogy with the methods specified in Annex I to Directive 2001/83/EC.

For the substances referred to in paragraph 1, 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 EEA Member States or by the European Medicines Agency (EMA), acting particularly through its committee in accordance with Regulation (EC) No. 726/2004/EC, 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, 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 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 the transport and storage of such body fluids or substances, contain 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 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 section, 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.

## **8. Infection and microbial contamination.**

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.

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 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 through the implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process.

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.

8.5. Devices intended to be sterilized must be manufactured in appropriately controlled (e.g. environmental) conditions.

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.

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.

## **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.

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, and their 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.

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.

## 10. **Devices with a measuring function.**

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.

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.

10.3. Measurements made with devices with a measuring function must be expressed in legal units conforming to the provisions of the Measurements, Measurement Standards and Official Weighters Act, No. 91/2006.

## 11. **Protection against radiation.**

### 11.1. *General.*

11.1.1. Devices must be designed and manufactured in such a way as to reduce as far as possible the exposure of patients, users and other persons to radiation, taking account of 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.

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.*

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.

### 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.

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.**

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.

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.

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.

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.

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.

12.6. *Protection against electrical risks.*

12.6.1. 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.

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 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 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 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.

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.**

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 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 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.

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 European Economic Area, in view of their distribution within the area, the label, the outer packaging, or the instructions for use shall contain in addition the name and address of the authorised representative in cases where the manufacturer does not have a registered place of business within the European Economic Area.
- 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 European Economic Area.
- 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.
- 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 item (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 paragraph 6 of Article 2 of the Regulation, 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:

- a) The details referred to in Section 13.3, with the exception of item (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 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 re-sterilized, 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 Part 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 re-used. If in accordance with Section 13.1 no instructions for use are needed, the information must be made available to the user upon request.
- 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 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.

## ANNEX II

### **EC declaration of conformity. (Full quality assurance system).**

1. The manufacturer must ensure application of the quality system approved for the design, manufacture and final inspection of the products concerned, as specified in Section 3, and is subject to audit as laid down in Sections 3.3 and 4 and to surveillance as specified in Section 5.

2. The EC declaration of conformity is the procedure whereby a manufacturer who fulfils the obligations imposed by Section 1 ensures and declares that the products concerned meet the relevant provisions of this Regulation.

The manufacturer must affix the CE marking in accordance with Article 23 of the Regulation and draw up a written declaration of conformity. This declaration must cover one or more medical devices manufactured, clearly identified by means of product name, product code or other unambiguous reference, and must be kept by the manufacturer.

### 3. Quality system.

3.1. The manufacturer must lodge an application for assessment of his/her quality system with a notified body.

The application must include:

- The name and address of the manufacturer and any additional manufacturing site covered by the quality system.
- All the relevant information on the product or product category covered by the procedure.
- A written declaration that no application has been lodged with any other notified body for the same product-related quality system.
- The documentation on the quality system.
- An undertaking by the manufacturer to fulfil the obligations imposed by the quality system approved.
- An undertaking by the manufacturer to keep the approved quality system adequate and efficacious.
- An undertaking by the manufacturer to institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase, including the provisions referred to in Annex X, 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:
  - i. Any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in 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/her state of health.
  - ii. Any technical or medical reason connected with the characteristics or performance of a device leading for the reasons referred to in item (i) to systematic recall of devices of the same type by the manufacturer.

3.2. The application of the quality system must ensure that the products conform to the provisions of this Regulation which apply to them at every stage, from design to final inspection. All the elements, requirements and provisions adopted by the manufacturer for his/her quality system must be documented in a systematic and orderly manner in the form of written policies and procedures such as quality programmes, quality plans, quality manuals and quality records.

It shall include in particular the corresponding documentation, data and records arising from the procedures referred to in item (c).

It shall include in particular an adequate description of:

- a) The manufacturer's quality objectives.
- b) The organization of the business, in particular:
  - the organizational structures, the responsibilities of the managerial staff and their organizational authority where quality of design and manufacture of the products is concerned,
  - the methods of monitoring the efficient operation of the quality system and in particular its ability to achieve the desired quality of design and of product, including control of products which fail to conform,
  - where the design, manufacture and/or final inspection and testing of the products, or elements thereof, is carried out by a third party, the methods of monitoring the efficient operation of the quality system and in particular the type and extent of control applied to the third party.
- c) The procedures for monitoring and verifying the design of the products, including the corresponding documentation, in particular:
  - a general description of the product, including any variants planned, and its intended use(s),
  - the design specifications, including the standards which will be applied and the results of the risk analysis, and also a description of the solutions adopted to fulfil the essential requirements which apply to the products if the standards referred to in Article 6 are not applied in full,
  - the techniques used to control and verify the design and the processes and systematic measures which will be used when the products are being designed,



- 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,
  - a statement indicating whether or not the device incorporates, as an integral part, a substance or a human blood derivative referred to in Section 7.4 of Annex I and the data on the tests conducted in this connection required to assess the safety, quality and usefulness of that substance or human blood derivative, taking account of the intended purpose of the device,
  - a statement indicating whether or not the device is manufactured utilising tissues of animal origin as referred to in Commission Directive 2003/32/EC,
  - the solutions adopted as referred to in section 2 of Chapter 1 of Annex I,
  - the pre-clinical evaluation,
  - the clinical evaluation referred to in Annex X,
  - the draft label and, where appropriate, instructions for use.
- d) The inspection and quality assurance techniques at the manufacturing stage and in particular:
- the processes and procedures which will be used, particularly as regards sterilization, purchasing and the relevant documents,
  - the product identification procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture;
- e) The appropriate tests and trials which will be carried out before, during and after manufacture, the frequency with which they will take place, and the test equipment used; it must be possible to trace back the calibration of the test equipment adequately.

3.3. The notified body must audit the quality system to determine whether it meets the requirements referred to in Section 3.2. It must presume that quality systems which implement the relevant harmonized standards conform to these requirements.

The assessment team must include at least one member with past experience of assessments of the technology concerned. The assessment procedure must include an assessment, on a representative basis, of the documentation of the design of the product(s) concerned, an inspection on the manufacturer's premises and, in duly substantiated cases, on the premises of the manufacturer's suppliers and/or subcontractors to inspect the manufacturing processes.

The decision is notified to the manufacturer. It must contain the conclusions of the inspection and a reasoned assessment.

3.4. The manufacturer must inform the notified body which approved the quality system of any plan for substantial changes to the quality system or the product-range covered. The notified body must assess the changes proposed and verify whether after these changes the quality system still meets the requirements referred to in Section 3.2. It must notify the manufacturer of its decision. This decision must contain the conclusions of the inspection and a reasoned assessment.

#### **4. Examination of the design of the product.**

4.1. In addition to the obligations imposed by Section 3, the manufacturer must lodge with the notified body an application for examination of the design dossier relating to the product which he/she plans to manufacture and which falls into the category referred to in Section 3.1.

4.2. The application must describe the design, manufacture and performances of the product in question. It must include the documents needed to assess whether the product conforms to the requirements of this Regulation, as referred to in item (c) in Section 3.2.

4.3. The notified body must examine the application and, if the product conforms to the relevant provisions of this Regulation, issue the applicant with an EC design-examination certificate. The notified body may require the application to be completed by further tests or proof to allow assessment of conformity with the requirements of the Regulation. The certificate must contain the conclusions of the examination, the conditions of validity, the data needed for identification of the approved design and, where appropriate, a description of the intended purpose of the product.

In the case of devices referred to in paragraph 2 of Section 7.4 of Annex I, the notified body shall, as regards the aspects referred to in that paragraph, consult one of the competent authorities designated by the Member States in accordance with Directive 2001/83/EC or the EMEA before taking a decision. The opinion of the competent national authority or the EMEA must be drawn up within 210

days after receipt of valid documentation. The scientific opinion of the competent national authority or the EMEA must be included in the documentation concerning the device. The notified body will give due consideration to the views expressed in this consultation when making its decision. It will convey its final decision to the competent body concerned.

In the case of devices referred to in paragraph 3 of Section 7.4 of Annex I, the scientific opinion of the EMEA must be included in the documentation concerning the device. The opinion of the EMEA must be drawn up within 210 days after receipt of valid documentation. The notified body will give due consideration to the opinion of the EMEA when making its decision. The notified body may not deliver the certificate if the EMEA's scientific opinion is unfavourable. It will convey its final decision to the EMEA.

In the case of devices manufactured utilising tissues of animal origin as referred to in Directive 2003/32/EC, the notified body must follow the procedures referred to in that Directive.

4.4. Changes to the approved design must receive further approval from the notified body which issued the EC design-examination certificate wherever the changes could affect conformity with the essential requirements of this Regulation or with the conditions prescribed for use of the product. The applicant shall inform the notified body which issued the EC design examination certificate of any such changes made to the approved design. This additional approval must take the form of a supplement to the EC design-examination certificate.

## **5. Surveillance.**

5.1. The aim of surveillance is to ensure that the manufacturer duly fulfils the obligations imposed by the approved quality system.

5.2. The manufacturer must authorize the notified body to carry out all the necessary inspections and supply it with all relevant information, in particular:

- The documentation on the quality system.
- The data stipulated in the part of the quality system relating to design, such as the results of analyses, calculations, tests, the solutions adopted as referred to in Section 2 of Chapter I of Annex I, pre-clinical and clinical evaluation, post-market clinical follow-up plan and the results of the post-market clinical follow-up, if applicable, etc.
- The data stipulated in the part of the quality system relating to manufacture, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.

5.3. The notified body must periodically carry out appropriate inspections and assessments to make sure that the manufacturer applies the approved quality system and must supply the manufacturer with an assessment report.

5.4. In addition, the notified body may pay unannounced visits to the manufacturer. At the time of such visits, the notified body may, where necessary, carry out or ask for tests in order to check that the quality system is working properly. It must provide the manufacturer with an inspection report and, if a test has been carried out, with a test report.

## **6. Administrative provisions.**

6.1. The manufacturer or his/her authorised representative must, for a period ending at least five years, and in the case of implantable devices at least 15 years, after the last product has been manufactured, keep at the disposal of the national authorities:

- The declaration of conformity.
- The documentation referred to in indent 4 of paragraph 2 of Section 3.1, and in particular the documentation, data and records referred to in paragraph 2 of Section 3.2.
- The changes referred to in Section 3.4.
- The documentation referred to in Section 4.2.
- The decisions and reports from the notified body as referred to in Sections 3.3, 4.3, 4.4, 5.3 and 5.4.

## **7. Application to devices in Classes IIa and IIb.**

7.1. In line with paragraphs 2 and 4 of Article 11, this Annex may apply to products in Classes IIa and IIb. Section 4, however, does not apply.

7.2. For devices in Class IIa the notified body shall assess, as part of the assessment described in Section 3.3, the technical documentation as described in item (c) of Section 3.2 for at least one representative sample for each device subcategory for compliance with the provisions of this Regulation.

7.3. For devices in Class IIb the notified body shall assess, as part of the assessment described in Section 3.3, the technical documentation as described in item (c) of Section 3.2 for at least one representative sample for each generic device group for compliance with the provisions of this Regulation.

7.4. In choosing representative sample(s), the notified body shall take into account the novelty of the technology, similarities in design, technology, manufacturing and sterilisation methods, the intended use and the results of any previous relevant assessments (e.g. with regard to physical, chemical or biological properties) that have been carried out in accordance with this Regulation. The notified body shall document and keep available to the competent authority its rationale for the sample(s) taken.

7.5. Further samples shall be assessed by the notified body as part of the surveillance assessment referred to in Section 5.

## **8. Application to the devices referred to in paragraph 6 of Article 2 of the Regulation.**

Upon completing the manufacture of each batch of devices referred to in paragraph 6 of Article 2 of the Regulation, the manufacturer shall inform the notified body of the release of the batch of devices and send to it the official certificate concerning the release of the batch of human blood derivative used in the device, issued by a State laboratory or a laboratory designated for that purpose by a Member State in accordance with paragraph 2 of Article 114 of Directive 2001/83/EBE on the Community code relating to medicinal products for human use.

### **ANNEX III EC type-examination.**

1. EC type-examination is the procedure whereby a notified body ascertains and certifies that a representative sample of the production covered fulfils the relevant provisions of this Regulation.

2. The application must include:

- The name and address of the manufacturer and the name and address of the authorized representative if the application is lodged by the representative.
- The documentation described in Section 3 needed to assess the conformity of the representative sample of the production in question, hereinafter referred to as the ‘type’, with the requirements of this Regulation. The applicant must make a ‘type’ available to the notified body. The notified body may request other samples as necessary.
- A written declaration that no application has been lodged with any other notified body for the same type.

3. The documentation must allow an understanding of the design, the manufacture and the performances of the product and must contain the following items in particular:

- a general description of the type, including any variants planned, and its intended use(s),
- design drawings, methods of manufacture envisaged, in particular as regards sterilisation, and diagrams of components, sub-assemblies, circuits, etc.,
- the descriptions and explanations necessary to understand the abovementioned drawings and diagrams and the operation of the product,
- a list of the standards referred to in Article 6, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements if the standards referred to in Article 6 have not been applied in full,
- the results of the design calculations, risk analysis, investigations, technical tests, etc. carried out,
- a statement indicating whether or not the device incorporates, as an integral part, a substance or human blood derivative referred to in Section 7.4 of Annex I, and the data on the tests conducted in this connection which are required to assess the safety, quality and usefulness of

that substance or human blood derivative, taking account of the intended purpose of the device,

- a statement indicating whether or not the device is manufactured utilising tissues of animal origin as referred to in Directive 2003/32/EC,
- the solutions adopted as referred to in Section 2 of Chapter I of Annex I,
- the pre-clinical evaluation,
- the clinical evaluation referred to in Annex X,
- the draft label and, where appropriate, instructions for use.

4. The notified body must:

4.1. Examine and assess the documentation and verify that the type has been manufactured in conformity with that documentation; it must also record the items designed in conformity with the applicable provisions of the standards referred to in Article 6 of the Regulation, as well as the items not designed on the basis of the relevant provisions of the abovementioned standards;

4.2. Carry out or arrange for the appropriate inspections and the tests necessary to verify whether the solutions adopted by the manufacturer meet the essential requirements of this Regulation if the standards referred to in Article 6 have not been applied; 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;

4.3. Carry out or arrange for the appropriate inspections and the tests necessary to verify whether, if the manufacturer has chosen to apply the relevant standards, these have actually been applied;

4.4. Agree with the applicant on the place where the necessary inspections and tests will be carried out.

5. If the type conforms to the provisions of this Regulation, the notified body issues the applicant with an EC type-examination certificate. The certificate must contain the name and address of the manufacturer, the conclusions of the inspection, the conditions of validity and the data needed for identification of the type approved. The relevant parts of the documentation must be annexed to the certificate and a copy kept by the notified body.

In the case of devices referred to in paragraph 2 of Section 7.4 of Annex I, the notified body shall, as regards the aspects referred to in that paragraph, consult one of the authorities designated by the Member States in accordance with Directive 2001/83/EC or the EMEA before taking a decision. The opinion of the competent national authority or the EMEA must be drawn up within 210 days after receipt of valid documentation. The scientific opinion of the competent national authority or the EMEA must be included in the documentation concerning the device. The notified body will give due consideration to the views expressed in this consultation when making its decision. It will convey its final decision to the competent body concerned.

In the case of devices referred to in paragraph 3 of Section 7.4 of Annex I, the scientific opinion of the EMEA must be included in the documentation concerning the device. The opinion of the EMEA must be drawn up within 210 days after receipt of valid documentation. The notified body will give due consideration to the opinion of the EMEA when making its decision. The notified body may not deliver the certificate if the EMEA's scientific opinion is unfavourable. It will convey its final decision to the EMEA.

In the case of devices manufactured utilising tissues of animal origin as referred to in Directive 2003/32/EC, the notified body must follow the procedures referred to in that Directive.

6. The applicant must inform the notified body which issued the EC type-examination certificate of any significant change made to the approved product.

Changes to the approved product must receive further approval from the notified body which issued the EC type-examination certificate wherever the changes may affect conformity with the essential requirements or with the conditions prescribed for use of the product. This new approval must, where appropriate, take the form of a supplement to the initial EC type-examination certificate.

**7. Administrative provisions.**

7.2. Other notified bodies may obtain a copy of the EC type-examination certificates and/or the supplements thereto. The Annexes to the certificates must be made available to other notified bodies on reasoned application, after the manufacturer has been informed.

7.3. The manufacturer or his/her authorised representative must keep with the technical documentation copies of EC type-examination certificates and their additions for a period ending at least five years after the last device has been manufactured. In the case of implantable devices, the period shall be at least 15 years after the last product has been manufactured.

#### ANNEX IV **EC verification.**

1. EC verification is the procedure whereby the manufacturer or his/her authorized representative ensures and declares that the products which have been subject to the procedure set out in Section 4 conform to the type described in the EC typeexamination certificate and meet the relevant requirements of this Regulation.

2. The manufacturer must take all the measures necessary to ensure that the manufacturing process produces products which conform to the type described in the EC type-examination certificate and to the relevant requirements of the Regulation. Before the start of manufacture, the manufacturer must prepare documents defining the manufacturing process, in particular as regards sterilization where necessary, together with all the routine, pre-established provisions to be implemented to ensure homogeneous production and, where appropriate, conformity of the products with the type described in the EC typeexamination certificate and with the relevant requirements of this Regulation. The manufacturer must affix the CE marking in accordance with Article 23 of the Regulation and draw up a declaration of conformity.

In addition, for products placed on the market in sterile condition, and only for those aspects of the manufacturing process designed to secure and maintain sterility, the manufacturer must apply the provisions of Sections 3 and 4 of Annex V.

3. The manufacturer must undertake to institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase, including the provisions referred to in Annex X, 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:

- 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/her state of health.
- ii. Any technical or medical reason connected with the characteristics or performance of a device leading for the reasons referred to in item (i) to systematic recall of devices of the same type by the manufacturer.

4. The notified body must carry out the appropriate examinations and tests in order to verify the conformity of the product with the requirements of the Regulation, either by examining and testing every product as specified in Section 5 or by examining and testing products on a statistical basis as specified in Section 6, as the manufacturer decides.

The aforementioned checks do not apply to those aspects of the manufacturing process designed to secure sterility.

#### **5. Verification by examination and testing of every product.**

5.1. Every product is examined individually and the appropriate tests defined in the relevant standard(s) referred to in Article 6, or equivalent tests, must be carried out in order to verify, where appropriate, the conformity of the products with the type described in the EC type-examination certificate and with the relevant requirements of the Regulation.

5.2. The notified body must affix or have affixed its identification number to each approved product and must draw up a written certificate of conformity relating to the tests carried out.

## **6. Statistical verification.**

6.1. The manufacturer must present the manufactured products in the form of homogeneous batches.

6.2. A random sample is taken from each batch. The products which make up the sample are examined individually and the appropriate tests defined in the relevant standard(s) referred to in Article 6 of the Regulation, or equivalent tests, must be carried out to verify, where appropriate, the conformity of the products with the type described in the EC type-examination certificate and with the relevant requirements of the Regulation in order to determine whether to accept or reject the batch.

6.3. Statistical control of products will be based on attributes and/or variables, entailing sampling schemes with operational characteristics which ensure a high level of safety and performance according to the state of the art. The sampling schemes will be established by the harmonised standards referred to in Article 6, taking account of the specific nature of the product categories in question.

6.4. If the batch is accepted, the notified body affixes or has affixed its identification number to each product and draws up a written certificate of conformity relating to the tests carried out. All products in the batch may be put on the market except any in the sample which failed to conform.

If a batch is rejected, the competent notified body must take appropriate measures to prevent the batch from being placed on the market. In the event of frequent rejection of batches, the notified body may suspend the statistical verification.

The manufacturer may, on the responsibility of the notified body, affix the notified body's identification number during the manufacturing process.

## **7. Administrative provisions.**

7.1. The manufacturer or his/her authorised representative must, for a period ending at least five years, and in the case of implantable devices at least 15 years, after the last product has been manufactured, make available to the national authorities:

- The declaration of conformity.
- The documentation referred to in Section 2.
- The certificates referred to in Sections 5.2 and 6.4.
- Where appropriate, the type-examination certificate referred to in Annex III.

## **8. Application to devices in Class IIa.**

In line with paragraph 2 of Article 11, this Annex may apply to products in Class IIa, subject to the following:

8.1. In derogation from Sections 1 and 2, by virtue of the declaration of conformity the manufacturer ensures and declares that the products in Class IIa are manufactured in conformity with the technical documentation referred to in Section 3 of Annex VII and meet the relevant requirements of this Regulation.

8.2. In derogation from Sections 1, 2, 5 and 6, the verifications conducted by the notified body are intended to confirm the conformity of the products in Class IIa with the technical documentation referred to in Section 3 of Annex VII.

## **9. Application to the devices referred to in paragraph 6 of Article 2 of the Regulation.**

In the case of section 5, upon completing the manufacture of each batch of devices referred to in paragraph 6 of Article 2, and in the case of verification under section 6, the manufacturer shall inform the notified body of the release of this batch of devices and send to it the official certificate concerning the release of the batch of human blood derivative used in the device, issued by a State laboratory or a laboratory designated for that purpose by a Member State in accordance with paragraph 2 of Article 114 of Directive 2001/83/EC on the Community code relating to medicinal products for human use.

### ANNEX V

#### **EC declaration of conformity. (Production quality assurance).**

1. The manufacturer must ensure application of the quality system approved for the manufacture of the products concerned and carry out the final inspection, as specified in Section 3. He/she is subject to the surveillance referred to in Section 4.

2. The EC declaration of conformity is the part of the procedure whereby the manufacturer who fulfils the obligations imposed by Section 1 ensures and declares that the products concerned conform to the type described in the EC type-examination certificate and meet the relevant provisions of this Regulation.

The manufacturer must affix the CE marking in accordance with Article 23 and draw up a written declaration of conformity. This declaration must cover one or more medical devices manufactured, clearly identified by means of product name, product code or other unambiguous reference, and must be kept by the manufacturer.

### 3. **Quality system.**

3.1. The manufacturer must lodge an application for assessment of his/her quality system with a notified body.

The application must include:

- The name and address of the manufacturer.
- All the relevant information on the product or product category covered by the procedure.
- A written declaration that no application has been lodged with any other notified body for the same products.
- The documentation on the quality system.
- An undertaking to fulfil the obligations imposed by the quality system approved.
- An undertaking to maintain the practicability and effectiveness of the approved quality system.
- Where appropriate, the technical documentation on the types approved and a copy of the EC type-examination certificates.
- An undertaking by the manufacturer to institute and keep up to date a systematic procedure to review experience gained from devices in the postproduction phase, including the provisions referred to in Annex X, 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:
  - 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/her state of health;
  - ii. any technical or medical reason connected with the characteristics or performance of a device for the reasons referred to in item (i) leading to a systematic recall of devices of the same type by the manufacturer.

3.2. The application of the quality system must ensure that the products conform to the type described in the EC type-examination certificate.

All the elements, requirements and provisions adopted by the manufacturer for his quality system must be documented in a systematic and orderly manner in the form of written policy statements and procedures. This quality system documentation must permit uniform interpretation of the quality policy and procedures such as quality programmes, plans, manuals and records.

It must include in particular an adequate description of:

- a) The manufacturer's quality objectives.
- b) The organization of the business, in particular:
  - The organizational structures, the responsibilities of the managerial staff and their organizational authority where manufacture of the products is concerned.
  - The methods of monitoring the efficient operation of the quality system and in particular its ability to achieve the desired quality of product, including control of products which fail to conform.
  - Where the manufacture and/or final inspection and testing of the products, or elements thereof, are carried out by a third party, the methods of monitoring the efficient operation

of the quality system and in particular the type and extent of control applied to the third party.

- c) The inspection and quality assurance techniques at the manufacturing stage, in particular:
  - The processes and procedures which will be used, particularly as regards sterilization, purchasing and the relevant documents.
  - The product identification procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture.
- d) The appropriate tests and trials to be carried out before, during and after manufacture, the frequency with which they will take place, and the test equipment used; it must be possible adequately to trace back the calibration of the test equipment.

3.3. The notified body must audit the quality system to determine whether it meets the requirements referred to in Section 3.2. It must presume that quality systems which implement the relevant harmonized standards conform to these requirements.

The assessment team must include at least one member with past experience of assessments of the technology concerned. The assessment procedure must include an inspection on the manufacturer's premises and, in duly substantiated cases, on the premises of the manufacturer's suppliers and/or subcontractors to inspect the manufacturing processes.

The decision must be notified to the manufacturer after the final inspection. It must contain the conclusions of the inspection and a reasoned assessment.

3.4. The manufacturer must inform the notified body which approved the quality system of any plan for substantial changes to the quality system.

The notified body must assess the changes proposed and verify whether after these changes the quality system still meets the requirements referred to in Section 3.2.

After the abovementioned information has been received the decision is notified to the manufacturer. It must contain the conclusions of the inspection and a reasoned assessment.

#### **4. Surveillance.**

4.1. The aim of surveillance is to ensure that the manufacturer duly fulfils the obligations imposed by the approved quality system.

4.2. The manufacturer authorizes the notified body to carry out all the necessary inspections and must supply it with all relevant information, in particular:

- The documentation on the quality system.
- The technical documentation.
- The data stipulated in the part of the quality system relating to manufacture, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.

4.3. The notified body must periodically carry out appropriate inspections and assessments to make sure that the manufacturer applies the approved quality system and supply the manufacturer with an assessment report.

4.4. In addition, the notified body may pay unannounced visits to the manufacturer. At the time of such visits, the notified body may, where necessary, carry out or ask for tests in order to check that the quality system is working properly. It must provide the manufacturer with an inspection report and, if a test has been carried out, with a test report.

#### **5. Administrative provisions.**

5.1. The manufacturer or his authorised representative must, for a period ending at least five years, and in the case of implantable devices at least 15 years, after the last product has been manufactured, make available to the national authorities:

- The declaration of conformity.
- The documentation referred to in indent 4 of paragraph 2 of Section 3.1.
- The changes referred to in Section 3.4.
- The documentation referred to in indent 7 of paragraph 2 of Section 3.1.
- The decisions and reports from the notified body as referred to in Sections 4.3 and 4.4.
- Where appropriate, the type-examination certificate referred to in Annex III.

#### **6. Application to devices in Class IIa.**



In line with paragraph 2 of Article 11, this Annex may apply to products in Class IIa, subject to the following:

6.1. By way of derogation from Sections 2, 3.1 and 3.2, by virtue of the declaration of conformity the manufacturer ensures and declares that the products in Class IIa are manufactured in conformity with the technical documentation referred to in Section 3 of Annex VII and meet the relevant requirements of this Regulation.

6.2. For devices in Class IIa the notified body shall assess, as part of the assessment described in Section 3.3, the technical documentation as described in Section 3 of Annex VII for at least one representative sample for each device subcategory for compliance with the provisions of this Regulation.

6.3. In choosing representative sample(s), the notified body shall take into account the novelty of the technology, similarities in design, technology, manufacturing and sterilisation methods, the intended use and the results of any previous relevant assessments (e.g. with regard to physical, chemical or biological properties) that have been carried out in accordance with this Regulation. The notified body shall document and keep available to the competent authority its rationale for the sample(s) taken.

6.4. Further samples shall be assessed by the notified body as part of the surveillance assessment referred to in Section 4.3.

### **7. Application to the devices referred to in paragraph 6 of Article 2 of the Regulation.**

Upon completing the manufacture of each batch of devices referred to in paragraph 6 of Article 2 of the Regulation, the manufacturer shall inform the notified body of the release of the batch of devices and send to it the official certificate concerning the release of the batch of human blood derivative used in the device, issued by a State laboratory or a laboratory designated for that purpose by a Member State in accordance with paragraph 2 of Article 114 of Directive 2001/83/EC on the Community code relating to medicinal products for human use.

## **ANNEX VI** **EC declaration of conformity.** **(Product quality assurance).**

1. The manufacturer must ensure application of the quality system approved for the final inspection and testing of the product, as specified in Section 3, and must be subject to the surveillance referred to in Section 4.

In addition, for products placed on the market in sterile condition, and only for those aspects of the manufacturing process designed to secure and maintain sterility, the manufacturer must apply the provisions of Sections 3 and 4 of Annex V.

2. The EC declaration of conformity is the part of the procedure whereby the manufacturer who fulfils the obligations imposed by Section 1 ensures and declares that the products concerned conform to the type described in the EC type-examination certificate and meet the relevant provisions of this Regulation.

The manufacturer affixes the CE marking in accordance with Article 23 and draws up a written declaration of conformity. This declaration must cover one or more medical devices manufactured, clearly identified by means of product name, product code or other unambiguous reference, and be kept by the manufacturer. The CE marking must be accompanied by the identification number of the notified body which performs the tasks referred to in this Annex.

### **3. Quality system.**

3.1. The manufacturer lodges an application for assessment of his quality system with a notified body.

The application must include:

- The name and address of the manufacturer.
- All the relevant information on the product or product category covered by the procedure.
- A written declaration specifying that no application has been lodged with any other notified body for the same products.

- The documentation on the quality system.
- An undertaking by the manufacturer to fulfil the obligations imposed by the quality system approved.
- An undertaking by the manufacturer to keep the approved quality system adequate and efficacious.
- Where appropriate, the technical documentation on the types approved and a copy of the EC type-examination certificates.
- An undertaking by the manufacturer to institute and keep up to date a systematic procedure to review experience gained from devices in the postproduction phase, including the provisions referred to in Annex X, 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:
  - 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 state of health.
  - ii. Any technical or medical reason connected with the characteristics or the performance of a device for the reasons referred to in item (i) leading to a systematic recall of devices of the same type by the manufacturer.

3.2. Under the quality system, each product or a representative sample of each batch is examined and the appropriate tests defined in the relevant standard(s) referred to in Article 6 of the Regulation, or equivalent tests, are carried out to ensure that the products conform to the type described in the EC type-examination certificate and fulfil the relevant provisions of this Regulation. All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner in the form of written measures, procedures and instructions. This quality system documentation must permit uniform interpretation of the quality programmes, quality plans, quality manuals and quality records.

It must include in particular an adequate description of:

- The quality objectives and the organizational structure, responsibilities and powers of the managerial staff with regard to product quality.
- The examinations and tests that will be carried out after manufacture. It must be possible to trace back the calibration of the test equipment adequately.
- The methods of monitoring the efficient operation of the quality system.
- The quality records, such as reports concerning inspections, tests, calibration and the qualifications of the staff concerned, etc.
- Where the final inspection and testing of the products, or elements thereof, are carried out by a third party, the methods of monitoring the efficient operation of the quality system and in particular the type and extent of control applied to the third party.

The aforementioned checks do not apply to those aspects of the manufacturing process designed to secure sterility.

3.3. The notified body audits the quality system to determine whether it meets the requirements referred to in section 3.2. It must presume that quality systems which implement the relevant harmonized standards conform to these requirements.

The assessment team must include at least one member with past experience of assessments of the technology concerned. The assessment procedure must include an inspection on the manufacturer's premises and, in duly substantiated cases, on the premises of the manufacturer's suppliers to inspect the manufacturing processes.

The decision must be notified to the manufacturer. It must contain the conclusions of the inspection and a reasoned assessment.

3.4. The manufacturer must inform the notified body which approved the quality system of any plan for substantial changes to the quality system.

The notified body must assess the changes proposed and verify whether after these changes the quality system will still meet the requirements referred to in Section 3.2.

After receiving the abovementioned information it must notify the manufacturer of its decision. This decision must contain the conclusions of the inspection and a reasoned assessment.

#### **4. Surveillance.**

4.1. The aim of surveillance is to ensure that the manufacturer duly fulfils the obligations imposed by the approved quality system.

4.2. The manufacturer must allow the notified body access for inspection purposes to the inspection, testing and storage locations and supply it with all relevant information, in particular:

- The documentation on the quality system.
- The technical documentation.
- The quality records, such as inspection reports, test data, calibration data, qualification reports of the staff concerned, etc.

4.3. The notified body must periodically carry out appropriate inspections and assessments to make sure that the manufacturer applies the quality system and must supply the manufacturer with an assessment report.

4.4. In addition, the notified body may pay unannounced visits to the manufacturer. At the time of such visits, the notified body may, where necessary, carry out or ask for tests in order to check that the quality system is working properly and that the production conforms to the relevant requirements of this Regulation. To this end, an adequate sample of the final products, taken on site by the notified body, must be examined and the appropriate tests defined in the relevant standard(s) referred to in Article 6 of the Regulation, or equivalent tests, must be carried out. Where one or more of the samples fails to conform, the notified body must take the appropriate measures.

It must provide the manufacturer with an inspection report and, if a test has been carried out, with a test report.

#### **5. Administrative provisions.**

5.1. The manufacturer or his authorised representative must, for a period ending at least five years, and in the case of implantable devices at least 15 years, after the last product has been manufactured, make available to the national authorities:

- The declaration of conformity.
- The documentation referred to in indent 7 of Section 3.1.
- The changes referred to in Section 3.4.
- The decisions and reports from the notified body as referred to in the final indent of Section 3.4 and in Sections 4.3 and 4.4.
- Where appropriate, the certificate of conformity referred to in Annex III.

#### **6. Application to devices in Class IIa.**

In line with paragraph 2 of Article 11, this Annex may apply to products in Class IIa, subject to the following:

6.1. By way of derogation from Sections 2, 3.1 and 3.2, by virtue of the declaration of conformity the manufacturer ensures and declares that the products in Class IIa are manufactured in conformity with the technical documentation referred to in Section 3 of Annex VII and meet the relevant requirements of this Regulation.

6.2. For devices in Class IIa the notified body shall assess, as part of the assessment described in Section 3.3, the technical documentation as described in Section 3 of Annex VII for at least one representative sample for each device subcategory for compliance with the provisions of this Regulation.

6.3. In choosing representative sample(s), the notified body shall take into account the novelty of the technology, similarities in design, technology, manufacturing and sterilisation methods, the intended use and the results of any previous relevant assessments (e.g. with regard to physical, chemical or biological properties) that have been carried out in accordance with this Regulation. The notified body shall document and keep available to the competent authority its rationale for the sample(s) taken.

6.4. Further samples shall be assessed by the notified body as part of the surveillance assessment referred to in Section 4.3.

### **ANNEX VII EC declaration of conformity.**

1. The EC declaration of conformity is the procedure whereby the manufacturer or his authorised representative who fulfils the obligations imposed by Section 2 and, in the case of products placed on the market in a sterile condition and devices with a measuring function, the obligations imposed by Section 5, ensures and declares that the products concerned meet the relevant provisions of this Regulation.

2. The manufacturer must prepare the technical documentation described in Section 3. The manufacturer or his authorised representative must make this documentation, including the declaration of conformity, available to the national authorities for inspection purposes for a period ending at least five years after the last product has been manufactured. In the case of implantable devices, the period shall be at least 15 years after the last product has been manufactured.

3. The technical documentation must allow assessment of the conformity of the product with the requirements of the Regulation. It must include in particular:

- A general description of the product, including any variants planned and its intended use(s).
- Design drawings, methods of manufacture envisaged and diagrams of components, sub-assemblies, circuits, etc.
- The descriptions and explanations necessary to understand the abovementioned drawings and diagrams and the operations of the product.
- The results of the risk analysis and a list of the standards referred to in Article 6, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the Regulation if the standards referred to in Article 6 have not been applied in full.
- In the case of products placed on the market in a sterile condition, description of the methods used and the validation report.
- 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.
- The solutions adopted as referred to in Section 2 of Chapter I of Annex I.
- The pre-clinical evaluation.
- The clinical evaluation in accordance with Annex X.
- The label and instructions for use.

4. The manufacturer shall institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase, including the provisions referred to in Annex X, and to implement appropriate means to apply any necessary corrective actions, taking account of the nature and risks in relation to the product. He/she 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/her state of health.
- ii. Any technical or medical reason connected with the characteristics or the performance of a device for the reasons referred to in item (i) leading to systematic recall of devices of the same type by the manufacturer.

5. With products placed on the market in sterile condition and Class I devices with a measuring function, the manufacturer must observe not only the provisions laid down in this Annex but also one of the procedures referred to in Annex II, IV, V or VI. The application of the abovementioned Annexes and the intervention by the notified body 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.

Section 6.1 of this Annex is applicable.

## **6. Application to devices in Class IIa.**

In line with paragraph 2 of Article 11, this Annex may apply to products in Class IIa, subject to the following derogation:

6.1. Where this Annex is applied in conjunction with the procedure referred to in Annex IV, V or VI, the declaration of conformity referred to in the abovementioned Annexes forms a single declaration. As regards the declaration based on this Annex, the manufacturer must ensure and declare that the product design meets the relevant provisions of this Regulation.

### **ANNEX VIII**

#### **Statement concerning devices for special purposes.**

1. For custom-made devices or for devices intended for clinical investigations, the manufacturer or his authorized representative must draw up the statement containing the information stipulated in Section 2.

2. The statement must contain the following information:

2.1. For custom-made devices:

- The name and address of the manufacturer.
- Data allowing the identification of the device in question.
- A statement that the device is intended for exclusive use by a particular patient, together with the name of the patient.
- The name of the medical practitioner or other authorized person who made out the prescription and, where applicable, the name of the clinic concerned.
- The specific characteristics of the product as indicated by the prescription.
- A statement that the device in question conforms to the essential requirements set out in Annex I and, where applicable, indicating which essential requirements have not been fully met, together with the grounds.

2.2. For devices intended for the clinical investigations covered by Annex X:

- Data allowing the identification of the device in question.
- The clinical investigation plan.
- The investigator's brochure.
- A confirmation of insurance of subjects.
- The documents used to obtain informed consent.
- A statement indicating whether or not the device incorporates, as an integral part, a substance or human blood derivative referred to in Section 7.4 of Annex I.
- A statement indicating whether or not the device is manufactured utilising tissues of animal origin as referred to in Directive 2003/32/EC.
- The opinion of the Science Ethics Committee pursuant to paragraph 2 of Article 9 of the Act on Medical Devices, No. 16/2001, and details of the aspects covered by its opinion.
- The name of the medical practitioner or other authorized person and of the institution responsible for the investigations.
- The place, starting date and scheduled duration of the investigations.
- A statement that the device in question conforms to the essential requirements apart from the aspects covered by the investigations, and that, with regard to these aspects, every precaution has been taken to protect the health and safety of the patient.

3. The manufacturer must also undertake to keep available for the competent national authorities:

3.1. For custom-made devices, documentation indicating manufacturing site(s) and allowing an understanding of the design, manufacture and performances of the product, including the expected performances, so as to allow assessment of conformity with the requirements of this Regulation.

The manufacturer must take all the measures necessary to ensure that the manufacturing process produces products which are manufactured in accordance with the documentation mentioned in paragraph 1.

3.2. For devices intended for clinical investigations, the documentation must contain:

- a general description of the product and its intended use,
- design drawings, methods of manufacture envisaged, in particular as regards sterilisation, and diagrams of components, sub-assemblies, circuits, etc.,
- the descriptions and explanations necessary to understand the abovementioned drawings and diagrams and the operation of the product,
- the results of the risk analysis and a list of the standards referred to in Article 6, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of this Regulation if the standards referred to in Article 6 have not been applied,
- if the device incorporates, as an integral part, a substance or human blood derivative referred to in Section 7.4 of Annex I, the data on the tests conducted in this connection which are required to assess the safety, quality and usefulness of that substance or human blood derivative, taking account of the intended purpose of the device,
- if the device is manufactured utilising tissues of animal origin as referred to in Directive 2003/32/EC, the risk management measures in this connection which have been applied to reduce the risk of infection,
- the results of the design calculations, and of the inspections and technical tests carried out, etc. The manufacturer must take all the measures necessary to ensure that the manufacturing process produces products which are manufactured in accordance with the documentation referred to in paragraph 1 of this Section. The manufacturer must authorise the assessment, or audit where necessary, of the effectiveness of these measures.

4. The information contained in the declarations concerned by this Annex shall be kept for a period of time of at least five years. In the case of implantable devices the period shall be at least 15 years.

5. For custom-made devices, the manufacturer must undertake to review and document experience gained in the post-production phase, including the provisions referred to in Annex X, 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 of the relevant corrective actions:

- 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 state of health;
- ii. any technical or medical reason connected with the characteristics or performance of a device for the reasons referred to in item (i) leading to systematic recall of devices of the same type by the manufacturer.

## ANNEX IX Classification criteria.

### I. DEFINITIONS

#### 1. Definitions for the classification rules.

- 1.1. Duration:
 

Transient:	Normally intended for continuous use for less than 60 minutes.
Short term:	Normally intended for continuous use for not more than 30 days.
Long term:	Normally intended for continuous use for more than 30 days.
- 1.2. Invasive device:
 

Invasive device:	A device which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body.
Body orifice:	Any natural opening in the body, as well as the external surface of the eyeball, or any permanent artificial opening, such as a stoma.
Surgically invasive device:	An invasive device which penetrates inside the body through the surface of the body, with the aid or in the context of a surgical operation.

For the purposes of this Regulation devices other than those referred to in the previous paragraph and which produce penetration other than through an established body orifice, shall be treated as surgically invasive devices.

Implantable device: Any device which is intended:

- to be totally introduced into the human body or,
- to replace an epithelial surface or the surface of the eye

by surgical intervention, which is intended to remain in place after the procedure.

Any device intended to be partially introduced into the human body through surgical intervention and intended to remain in place after the procedure for at least 30 days is also considered an implantable device.

1.3. Reusable surgical instrument:

Instrument intended for surgical use by cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar procedures, without connection to any active medical device and which can be reused after appropriate procedures have been carried out.

1.4. Active medical device:

Any medical device the operation of which depends on a source of electrical energy or any source of power other than that directly generated by the human body or gravity and which acts by converting this energy. Medical devices intended to transmit energy, substances or other elements between an active medical device and the patient, without any significant change, are not considered to be active medical devices. Stand-alone software is considered to be an active medical device.

1.5. Active therapeutical device:

Any active medical device, whether used alone or in combination with other medical devices, to support, modify, replace or restore biological functions or structures with a view to treatment or alleviation of an illness, injury or handicap.

1.6. Active device for diagnosis:

Any active medical device, whether used alone or in combination with other medical devices, to supply information for detecting, diagnosing, monitoring or treating physiological conditions, states of health, illnesses or congenital deformities.

1.7. Central circulatory system:

For the purposes of this Regulation, „central circulatory system“ means the following vessels: arteriae pulmonales, aorta ascendens, arcus aorta, aorta descendens to the bifurcatio aortae, arteriae coronariae, arteria carotis communis, arteria carotis externa, arteria carotis interna, arteriae cerebrales, truncus brachiocephalicus, venae cordis, venae pulmonales, vena cava superior, vena cava inferior.

1.8. Central nervous system:

For the purposes of this Regulation, „central nervous system“ means brain, meninges and spinal cord.

## II. IMPLEMENTING RULES

### 2. Implementing rules.

2.1. The application of the classification rules shall be governed by the intended purpose of the devices.

2.2. If the device is intended to be used in combination with another device, the classification rules shall apply separately to each of the devices. Accessories are classified in their own right separately from the device with which they are used.

2.3. Software which drives a device or influences the use of a device falls automatically in the same class.

2.4. 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.

2.5. If several rules apply to the same device, based on the performance specified for the device by the manufacturer, the strictest rules resulting in the higher classification shall apply.

2.6. In calculating the duration referred to in Section 1.1 of Chapter I, continuous use means „an uninterrupted actual use of the device for the intended purpose“. However, where usage of a device is discontinued in order for the device to be replaced immediately by the same or an identical device, this shall be considered an extension of the continuous use of the device.

## III. CLASSIFICATION

## **1. Non-invasive devices.**

### **1.1. Rule 1.**

All non-invasive devices are in Class I, unless one of the rules set out hereinafter applies.

### **1.2. Rule 2.**

All non-invasive devices intended for channelling or storing blood, body liquids or tissues, or liquids or gases for the purpose of eventual infusion, administration or introduction into the body, are in Class IIa:

- If they may be connected to an active medical device in Class IIa or a higher class.
- If they are intended for use for storing or channelling blood or other body liquids or for storing organs, parts of organs or body tissues.

In all other cases they are in Class I.

### **1.3. Rule 3.**

All non-invasive devices intended for modifying the biological or chemical composition of blood, other body liquids or other liquids intended for infusion into the body are in Class IIb, unless the treatment consists of filtration, centrifugation or exchanges of gas, heat, in which case they are in Class IIa.

### **1.4. Rule 4.**

All non-invasive devices which come into contact with injured skin:

- Are in Class I if they are intended to be used as a mechanical barrier, for compression or for the absorption of exudates.
- Are in Class IIb if they are intended to be used principally with wounds which have breached the dermis and can only heal by secondary intent.
- Are in Class IIa in all other cases, including devices principally intended to manage the micro-environment of a wound.

## **2. Invasive devices.**

### **2.1. Rule 5.**

All invasive devices with respect to body orifices, other than surgically invasive devices and which are not intended for connection to an active medical device or which are intended for connection to an active medical device in Class I:

- Are in Class I if they are intended for transient use.
- Are in Class IIa if they are intended for short-term use, except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum, or in a nasal cavity, in which case they are in Class I.
- Are in Class IIb if they are intended for long-term use, except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum, or in a nasal cavity, and are not liable to be absorbed by the mucous membrane, in which case they are in Class IIa.

All invasive devices with respect to body orifices, other than surgically invasive devices, intended for connection to an active medical device in Class IIa or a higher class, are in Class IIa.

### **2.2. Rule 6.**

All surgically invasive devices intended for transient use are in Class IIa unless they are:

- Intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class III.
- reusable surgical instruments, in which case they are in Class I.
- Intended specifically for use in direct contact with the central nervous system, in which case they are in Class III.
- Intended to supply energy in the form of ionising radiation, in which case they are in Class IIb.
- Intended to have a biological effect or to be wholly or mainly absorbed, in which case they are in Class IIb.
- Intended to administer medicines by means of a delivery system, if this is done in a manner that is potentially hazardous taking account of the mode of application, in which case they are in Class IIb.

### **2.3. Rule 7.**

All surgically invasive devices intended for short-term use are in Class IIa unless they are intended:



- Either specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class III.
- Or specifically for use in direct contact with the central nervous system, in which case they are in Class III.
- Or to supply energy in the form of ionizing radiation, in which case they are in Class IIb.
- Or to have a biological effect or to be wholly or mainly absorbed, in which case they are in Class III.
- Or to undergo chemical change in the body, except if the devices are placed in the teeth, or to administer medicines, in which case they are in Class IIb.

#### 2.4. Rule 8.

All implantable devices and long-term surgically invasive devices are in Class IIb unless they are intended:

- To be placed in the teeth, in which case they are in Class IIa.
- To be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in Class III.
- To have a biological effect or to be wholly or mainly absorbed, in which case they are in Class III.
- Or to undergo chemical change in the body, except if the devices are placed in the teeth, or to administer medicines, in which case they are in Class III.

### 3. Additional rules applicable to active devices.

#### 3.1. Rule 9.

All active therapeutic devices intended to administer or exchange energy are in Class IIa unless their characteristics are such that they may administer or exchange energy to or from the human body in a potentially hazardous way, taking account of the nature, the density and site of application of the energy, in which case they are in Class IIb.

All active devices intended to control or monitor the performance of active therapeutic devices in Class IIb, or intended directly to influence the performance of such devices, are in Class IIb.

#### 3.2. Rule 10.

Active devices intended for diagnosis are in Class IIa:

- If they are intended to supply energy which will be absorbed by the human body, except for devices used to illuminate the patient's body in the visible spectrum.
- If they are intended to image in vivo distribution of radiopharmaceuticals.
- If they are intended to allow direct diagnosis or monitoring of vital physiological processes, unless they are specifically intended for monitoring of vital physiological parameters, where the nature of variations is such that it could result in immediate danger to the patient, for instance variations in cardiac performance, respiration, or activity of CNS, in which case they are in Class IIb.

Active devices intended to emit ionizing radiation and intended for diagnostic and therapeutic interventional radiology, including devices which control or monitor such devices, or which directly influence their performance, are in Class IIb.

#### Rule 11.

All active devices intended to administer and/or remove medicines, body liquids or other substances to or from the body are in Class IIa, unless this is done in a manner:

- That is potentially hazardous, taking account of the nature of the substances involved, of the part of the body concerned and of the mode of application, in which case they are in Class IIb.

#### 3.3. Rule 12.

All other active devices are in Class I.

### 4. Special rules.

#### 4.1. Rule 13.

All devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, in the meaning of Directive 2001/83/EC, and which is liable to act on the human body with action ancillary to that of the devices, are in Class III.

All devices incorporating, as an integral part, a human blood derivative are in Class III.

4.2. Rule 14.

All devices used for contraception or the prevention of the transmission of sexually transmitted diseases are in Class IIb, unless they are implantable or long term invasive devices, in which case they are in Class III.

4.3. Rule 15.

All devices intended specifically to be used for disinfecting, cleaning, rinsing or, when appropriate, hydrating contact lenses are in Class IIb.

All devices intended specifically to be used for disinfecting medical devices are in Class IIa unless they are specifically to be used for disinfecting invasive devices, in which case they are in Class IIb.

This rule does not apply to products that are intended to clean medical devices other than contact lenses by means of physical action.

4.4. Rule 16.

Devices specifically intended for recording of X-ray diagnostic images are in Class IIa.

4.5. Rule 17.

All devices manufactured utilizing animal tissues or derivatives rendered nonviable are Class III except where such devices are intended to come into contact with intact skin only.

5. Rule 18.

By derogation from other rules, blood bags are in Class IIb.

## ANNEX X

### Clinical evaluation.

#### 1. General provisions.

1.1. As a general rule, confirmation of conformity with the requirements concerning the characteristics and performances referred to in Sections 1 and 3 of Annex I, under the normal conditions of use of the device, and the evaluation of the sideeffects and of the acceptability of the benefit/risk ratio referred to in Section 6 of Annex I, must be based on clinical data. The evaluation of this data, hereinafter referred to as „clinical evaluation“, where appropriate taking account of any relevant harmonised standards, must follow a defined and methodologically sound procedure based on:

1.1.1. 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,

1.1.2. or a critical evaluation of the results of all clinical investigations made,

1.1.3. or a critical evaluation of the combined clinical data provided in sections 1.1.1 and 1.1.2.

1.1a. In the case of implantable devices and devices in Class III, clinical investigations shall be performed unless it is duly justified to rely on existing clinical data.

1.1b. The clinical evaluation and its outcome shall be documented. This documentation shall be included and/or fully referenced in the technical documentation of the device.

1.1c. The clinical evaluation and its documentation must be actively updated with data obtained from the post-market surveillance. Where post-market clinical follow-up as part of the post-market surveillance plan for the device is not deemed necessary, this must be duly justified and documented.

1.1d. Where demonstration of conformity with essential requirements based on clinical data is not deemed appropriate, adequate justification for any such exclusion has to be given based on risk management output and under consideration of the specifics of the device/body interaction, the clinical performances intended and the claims of the manufacturer. Adequacy of demonstration of conformity with the essential requirements by performance evaluation, bench testing and pre-clinical evaluation alone has to be duly substantiated.

1.2. All the data must remain confidential in accordance with the provisions of Article 31 of the Regulation.

#### 2. Clinical investigations.

## 2.1. Objectives.

The objectives of clinical investigations are:

- to verify that, under normal conditions of use, the performance of the devices conform to those referred to in Section 3 of Annex I, and
- to determine any undesirable side-effects, under normal conditions of use, and assess whether they constitute risks when weighed against the intended performance of the device.

## 2.2. Ethical considerations.

Clinical investigations must be carried out in accordance with the Helsinki Declaration adopted by the 18th World Medical Assembly in Helsinki, Finland, in 1964, as last amended by the World Medical Assembly. It is mandatory that all measures relating to the protection of human subjects are carried out in the spirit of the Helsinki Declaration. This includes every step in the clinical investigation from first consideration of the need and justification of the study to publication of the results.

## 2.3. Methods.

2.3.1. Clinical investigations must be performed on the basis of an appropriate plan of investigation reflecting the latest scientific and technical knowledge and defined in such a way as to confirm or refute the manufacturer's claims for the device; these investigations must include an adequate number of observations to guarantee the scientific validity of the conclusions.

2.3.2. The procedures used to perform the investigations must be appropriate to the device under examination.

2.3.3. Clinical investigations must be performed in circumstances similar to the normal conditions of use of the device.

2.3.4. All the appropriate features, including those involving the safety and performances of the device and its effect on patients, must be examined.

2.3.5. All serious adverse events must be fully recorded and immediately notified to all competent authorities of the Member States in which the clinical investigation is being performed.

2.3.6. The investigations must be performed under the responsibility of a medical practitioner or another authorized qualified person in an appropriate environment.

The medical practitioner or other authorized person must have access to the technical and clinical data regarding the device.

2.3.7. The results of the clinical investigations shall be the subject of a written report. The report, signed by the medical practitioner or other authorized person responsible, must contain a critical evaluation of all the data collected during the clinical investigation.

## ANNEX XI

### **Criteria to be met for the designation of notified bodies.**

1. The notified body, its Director and the assessment and verification staff shall not be the designer, manufacturer, supplier, installer or user of the devices which they inspect, nor the authorized representative of any of these persons. They may not be directly involved in the design, construction, marketing or maintenance of the devices, nor represent the parties engaged in these activities. This in no way precludes the possibility of exchanges of technical information between the manufacturer and the body.

2. The notified body and its staff must carry out the assessment and verification operations with the highest degree of professional integrity and the requisite competence in the field of medical devices and must be free from all pressures and inducements, particularly financial, which might influence their judgment or the results of the inspection, especially from persons or groups of persons with an interest in the results of the verifications.

Should the notified body subcontract specific tasks connected with the establishment and verification of the facts, it must first ensure that the subcontractor meets the provisions of the Regulation and, in particular, of this Annex. The notified body shall keep at the disposal of the national authorities the relevant documents assessing the subcontractor's qualifications and the work carried out by the subcontractor under this Regulation.

3. The notified body must be able to carry out all the tasks assigned to such bodies by one of Annexes II–VI and for which it has been notified, whether these tasks are carried out by the body itself or on its responsibility. In particular, it must have the necessary staff and possess the facilities needed to perform properly the technical and administrative tasks entailed in assessment and verification. This presupposes the availability of sufficient scientific staff within the organisation who possess experience and knowledge sufficient to assess the medical functionality and performance of devices for which it has been notified, having regard to the requirements of this Regulation and, in particular, those set out in Annex I. It must also have access to the equipment necessary for the verifications required.

4. The notified body must have:

- Sound vocational training covering all the assessment and verification operations for which the body has been designated.
- Satisfactory knowledge of the rules on the inspections which it carries out and adequate experience of such inspections.
- The ability required to draw up the certificates, records and reports to demonstrate that the inspections have been carried out.

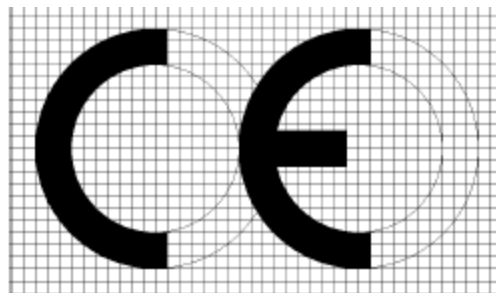
5. The impartiality of the notified body must be guaranteed. Its remuneration must not depend on the number of inspections carried out, nor on the results of the inspections.

6. The body must take out civil liability insurance, unless liability is assumed by the State under domestic legislation or the State itself carries out the inspections directly.

7. Under the provisions of this Regulation and other relevant provisions of national law, the staff of the notified body are bound to observe professional secrecy with regard to all information gained in the course of their duties, except vis-à-vis higher-level competent authorities.

## ANNEX XII CE marking of conformity.

The CE conformity marking shall consist of the initials „CE“ taking the following form:



- If the marking is reduced or enlarged, the proportions given in the above graduated drawing must be respected.
- The various components of the CE marking must have substantially the same vertical dimension, which may not be less than 5 mm.
- This minimum dimension may be waived for small-scale devices.

## ANNEX XIII Risk analysis and risk management scheme for medical devices manufactured utilising tissues of animal origin.

### I. RISK ANALYSIS AND RISK MANAGEMENT

1.1. Justification for the use of animal tissues or derivatives.

The manufacturer must justify, on the basis of his overall risk analysis and risk management strategy for a specific medical device, the decision to use animal tissues or derivatives referred to in Article 25 (specifying animal species and tissues), taking into account the expected clinical benefit, potential residual risk and suitable alternatives.

#### 1.2. Assessment procedure.

In order to ensure a high level of protection for patients or users, the manufacturer of devices utilising animal tissues or derivatives referred to in section 1.1 must implement an appropriate and well documented risk analysis and risk management strategy addressing all relevant aspects relating to TSE. He/she must identify the hazards associated with those tissues or derivatives, establish documentation on measures taken to minimise the risk of transmission and demonstrate the acceptability of the residual risk associated with the device utilising such tissues or derivatives, taking into account the intended use and the benefit of the device.

The safety of a device, in terms of its potential for passing on a transmissible agent, is dependent on all the factors described in sections 1.2.1 to 1.2.7, which must be analysed, evaluated and managed. These measures in combination determine the device safety.

There are two key steps that must be considered.

These are:

- selecting starting materials (tissues or derivatives) considered appropriate regarding their potential contamination with transmissible agents (see sections 1.2.1, 1.2.2 and 1.2.3), taking into account further processing,
- applying a production process to remove or inactivate transmissible agents on controlled sourced tissues or derivatives (see section 1.2.4).

Furthermore, the characteristics of the device and its intended use must be taken into account (see sections 1.2.5, 1.2.6 and 1.2.7).

In performing the risk analysis and risk management strategy, due consideration must be given to opinions adopted by the relevant scientific committees, and where appropriate to the opinions of the Committee for Proprietary Medicinal Products (CPMP), the references of which have been published in the Official Journal of the European Union.

##### 1.2.1. Animals as a source of material.

The TSE risk is related to the source species, strains and nature of the starting tissue. As the accumulation of TSE infectivity occurs over an incubation period of several years, sourcing from young healthy animals is considered to be a factor reducing the risk. Risk animals such as fallen stock, emergency slaughtered and TSE suspected animals must be excluded.

##### 1.2.2. Geographical sourcing.

Pending the classification of countries according to the BSE status in Regulation (EC) No. 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies, the Geographical BSE risk (GBR) is used when assessing the risk of the source country. The GBR is a qualitative indicator of the likelihood of the presence of one or more cattle being infected with BSE, pre-clinically as well as clinically, at a given point in time, in a country. Where presence is confirmed, the GBR gives an indication of the level of infection as specified in the table below.

GBR level	Presence of one or more cattle clinically or pre-clinically infected with the BSE agent in a geographical region/country
I	Highly unlikely
II	Unlikely but not excluded
III	Likely but not confirmed or confirmed, at a lower level
IV	Confirmed, at a higher level

Certain factors influence the geographical risk of BSE infection associated with the use of raw tissues or derivatives from individual countries. These factors are defined in item 1 of Article 2.3.13.2 of the International Animal Health Code of the OIE (Office International des Épizooties), which is available on the webpage [www.oie.int/eng/normes/Mcode/A\\_00067.html](http://www.oie.int/eng/normes/Mcode/A_00067.html).

The Scientific Steering Committee has made an assessment of Geographical BSE Risk (GBR) of several third countries and Member States, and will continue to do so for all the countries which applied for BSE status categorisation, taking the main OIE factors into account.

### 1.2.3. Nature of starting tissue.

The manufacturer must take into account the classification of the hazards relating to different types of starting tissue. Sourcing of animal tissue must be subject to control and individual inspection by a veterinarian and the animal carcass must be certified as fit for human consumption.

The manufacturer must ensure that no risk of cross-contamination occurs at the time of slaughtering.

The manufacturer must not source animal tissue or derivatives classified as potentially high TSE infectivity, unless sourcing of these materials is necessary in exceptional circumstances, taking into account the important benefit for the patient and the absence of an alternative starting tissue.

In addition, the provisions of Regulation (EC) No. 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption must be applied.

#### 1.2.3.1. Sheep and goats.

A classification of infectivity in tissues for sheep and goats has been established based on actual knowledge on the basis of the titres of transmissible agents in tissues and body fluids from naturally infected sheep and goats with clinical scrapie. A table was presented in the Scientific Steering Committee (SSC) opinion of 22 and 23 July 1999 on “The policy of breeding and genotyping of sheep” (as an annex), see [http://europa.eu.int/comm/food/fs/sc/ssc/outcome\\_en.html](http://europa.eu.int/comm/food/fs/sc/ssc/outcome_en.html), and further updated in the opinion of the SSC on “TSE infectivity distributed in ruminant tissues state of knowledge December 2001”, adopted on 10 and 11 January 2002, see [http://europa.eu.int/comm/food/fs/sc/ssc/outcome\\_en.html](http://europa.eu.int/comm/food/fs/sc/ssc/outcome_en.html).

The classification may be reviewed in the light of new scientific evidence (for example using relevant opinions from the Scientific Committees, the Committee for Proprietary Medicinal Products (CPMP) and Commission Measures regulating the use of material presenting risks as regards TSE). A review of the references to relevant documents/opinions will be published in the Official Journal of the European Union and will be listed after a Commission Decision has been taken.

#### 1.2.3.2. Cattle.

The list of specified risk material (SRM) laid down in Regulation (EC) No. 999/2001 shall be considered as potentially high TSE infective.

### 1.2.4. Inactivation or removal of transmissible agents.

1.2.4.1. For devices which cannot withstand an inactivation/elimination process without undergoing unacceptable degradation, the manufacturer must rely principally on the control of sourcing.

1.2.4.2. For other devices, if claims are made by the manufacturer for the ability of manufacturing processes to remove or inactivate transmissible agents, these will have to be substantiated by appropriate documentation.

Relevant information from an appropriate scientific literature search and analysis can be used to support inactivation/elimination factors, where the specific processes referred to in the literature are comparable to those used for the device. This search and analysis should also cover the available scientific opinions that may have been adopted by an EU Scientific Committee. These opinions shall serve as a reference, in cases where there are conflicting opinions.

When the literature search fails to substantiate the claims, the manufacturer must set up a specific inactivation and/or elimination study on a scientific basis and the following needs to be considered:

- the identified hazard associated with the tissue,
- the identification of the relevant model agents,
- the rationale for the choice of the particular combinations of model agents,
- the identification of the stage chosen to eliminate and/or inactivate the transmissible agents,
- the calculation of the reduction factors.

A final report must identify manufacturing parameters and limits that are critical to the effectiveness of the inactivation or elimination process.

Appropriate documented procedures must be applied to ensure that the validated processing parameters are applied during routine manufacture.

### 1.2.5. Quantities of animal starting tissues or derivatives required to produce one unit of the medical device.

The manufacturer must evaluate the quantity of raw tissues or derivatives of animal origin required to produce a single unit of the medical device. Where a purification process is involved, the manufacturer

must assess whether it may have the potential to concentrate levels of transmissible agents present in the animal starting tissues or derivatives.

1.2.6. Tissues or derivatives of animal origin coming into contact with the patients and users.

The manufacturer must consider:

- i. the quantity of animal tissues or derivatives;
- ii. the contact area: its surface, type (e.g. skin, mucous tissue, brain) and condition (e.g. healthy or damaged);
- iii. the type of the tissues or derivatives coming into contact with the patients and/or users; and
- iv. how long the device is intended to remain in contact with the body (including a bioresorption effect).

The number of medical devices that could be used in a given procedure shall be taken into account.

1.2.7. Route of administration.

The manufacturer must take into account the route of administration recommended in the product information, from the highest risk down to the lowest.

1.3. Review of the assessment.

The manufacturer must establish and maintain a systematic procedure to review information gained about their medical device or similar devices in the post-production phase. The information must be evaluated for possible relevance to safety, especially:

- a) if previously unrecognised hazards are detected;
- b) if the estimated risk arising from a hazard is no longer acceptable;
- c) if the original assessment is otherwise invalidated.

If any of the above applies, the results of the evaluation shall be fed back as an input to the risk management process.

In the light of this new information, a review of the appropriate risk management measures for the device must be considered (including the rationale for choosing an animal tissue or derivative). If there is a potential that the residual risk or its acceptability has changed, the impact on previously implemented risk control measures must be re-evaluated and justified.

The results of this evaluation must be documented.

## II. EVALUATION OF CLASS III MEDICAL DEVICES BY NOTIFIED BODIES

For devices falling into Class III under rule 17 of Annex IX, manufacturers must provide to the notified bodies referred to in Article 27 of this Regulation all relevant information to allow evaluation of their current risk analysis and risk management strategy. Any new information on TSE risk, collected by the manufacturer and relevant for their devices must be sent to the notified body for information.

Any change in relation to processes of sourcing, collection, handling and inactivation/elimination and that could modify the result of the manufacturer's risk management dossier must be transmitted to the notified body for the purpose of an additional approval prior to its implementation.

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