THE MINISTRY OF HEALTH

1875

Pursuant to Article 9, paragraph 6, Article 13, paragraph 2, Article 30, paragraph 5, Article 35 and Article 41, paragraph 6 of the Medical Devices Act (Official Gazette 76/2013), after having obtained the opinion of the ministry in charge of the economy, the Minister o Health hereby issues the

ORDINANCE

ON ESSENTIAL REQUIREMENTS, CLASSIFICATION, REGISTRATION OF MANUFACTURERS IN THE REGISTER OF MEDICAL DEVICE MANUFACTURERS, REGISTRATION OF MEDICAL DEVICES IN THE REGISTER OF MEDICAL DEVICES AND CONFORMITY ASSESSMENT OF MEDICAL DEVICES

Article 1

This Ordinance lays down the essential requirements for medical devices, the conditions and rules for the classification of medical devices and *in vitro* diagnostic medical devices, the method of registration and the documentation required for the registration in the register of manufacturers, the method of, and the documentation required for, registration of a medical device in the register of medical devices, the content and the method of submission of notification of placing a medical device on the market, the conformity assessment, the content of the declaration of conformity and the CE marking.

Article 2

This Ordinance transposes the following directives into the legal system of the Republic of Croatia:

1. Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (OJ L 189, 20. 7. 1990),

2. Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12. 7. 1993),

3. Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices (OJ L 331, 7. 12. 1998),

4. Directive 2000/70/EC of the European Parliament and of the Council of 16 November 2000 amending Council Directive 93/42/EEC as regards medical devices incorporating stable derivates of human blood or human plasma (OJ L 313, 13. 12. 2000),

5. Directive 2001/104/EC of the European Parliament and of the Council of 7 December 2001 amending Council Directive 93/42/EEC concerning medical devices (OJ L 6, 10. 1. 2002),

6. Commission Directive 2003/12/EC of 3 February 2003 on the reclassification of breast implants in the framework of Directive 93/42/EEC concerning medical devices (OJ L 28, 4. 2. 2003),

5. Commission Directive 2003/32/EC of 23 April 2003 introducing 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 (OJ L 105, 26. 4. 2003),

6. Commission Directive 2005/50/EC of 11 August 2005 on the reclassification of hip, knee and shoulder joint replacements in the framework of Council Directive 93/42/EEC concerning medical devices (OJ L 210, 12. 8. 2005),

7. Directive 2007/47/EZ of the European Parliament and of the Council of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market (OJ L 247, 21. 9. 2007),

8. Council Directive 2011/100/EU of 20 December 2011 amending Directive 98/79/EC of the European Parliament and of the Council on in-vitro diagnostic medical devices (OJ L 341, 22. 12. 2011).

I. REQUIREMENTS FOR MEDICAL DEVICES

Article 3

Medical devices may be placed on the market and put into service in the Republic of Croatia (hereinafter: placing on the market) only if they do not compromise the health and safety of patients, users or other persons and if they are properly manufactured, installed, maintained and used in accordance with their intended purposes.

Article 4

Medical devices must satisfy the essential requirements set out in Annex I concerning medical devices, in Annex I concerning *in vitro* diagnostic medical devices, and in Annex I concerning active implantable medical devices, which are annexed to this Ordinance and form an integral part thereof.

II. CLASSIFICATION OF MEDICAL DEVICES

Article 5

Medical devices are:

– medical devices,

– *in vitro* diagnostic medical devices,

– active implantable medical devices.

Article 6

According to the level of risk they pose to the user, medical devices shall be divided into:

– Class I – medical devices posing a low level of risk to the user,

– Class IIa – medical devices posing a higher level of risk to the user,

– Class IIb – medical devices posing a high level of risk to the user,

– Class III – medical devices posing the highest level of risk to the user.

Article 7

Medical devices shall be divided into classes according to the level of risk they pose to the user pursuant to Article 6 of this Ordinance and in accordance with Annex IX to this Ordinance, which forms an integral part thereof.

Article 8

(1) *In vitro* diagnostic medical devices are classified into:

1. those included in List A in Annex II to this Ordinance concerning *in vitro* diagnostics, which forms an integral part thereof:

– reagents and reagent products, including calibrators and control materials, for determining blood groups of the ABO system, rhesus (C, c, D, E, e) anti-Kell,

– reagents and reagent products, including calibrators and control materials, for the detection, confirmation and quantification of markers of HIV infection (HIV 1 and 2), HTLV I and II, and hepatitis B, C and D in human serum specimens,

– variant Creutzfeldt-Jakob disease (vCJD) assays for blood screening, diagnosis and confirmation,

2. those included in List B in Annex II to this Ordinance concerning *in vitro* diagnostics:

– reagents and reagent products, including calibrators and control materials, for determining these blood groups: anti-Duffy, anti-Kidd,

– reagents and reagent products, including calibrators and control materials, for determining irregular anti-erythrocytic antibodies,

– reagents and reagent products, including calibrators and control materials, for the detection and quantification of the following congenital infections in human samples: rubella and toxoplasmosis,

– reagents and reagent products, including calibrators and control materials, for diagnosing hereditary diseases, such as phenylketonuria,

– reagents and reagent products, including calibrators and control materials, for determining the following infectious diseases: cytomegalovirus and chlamydia,

– reagents and reagent products, including calibrators and control materials, for determining the following HLA tissue groups (tissue antigens): DR, A, B,

– reagents and reagent products, including calibrators and control materials, for determining the following tumour markers: PSA,

– reagents and reagent products, including calibrators, control materials and software, designed specifically for evaluating the risk of trisomy 21,

– the following device for self-diagnosis, including calibrators and control materials: device for the self-measurement of blood sugar.

(2) *In vitro* diagnostic medical devices also include *in vitro* diagnostic medical devices intended for self-testing or evaluation, which are not listed in Annex II to this Ordinance concerning *in vitro* diagnostics.

(3) *In vitro* diagnostic medical devices also include other *in vitro* diagnostic medical devices not intended for self-testing or evaluation and not classified in Annex II to this Ordinance.

Article 9

(1) A manufacturer of a medical device having his registered place of business in the Republic of Croatia may request the Agency for Medicinal Products and Medical Devices (hereinafter: the Agency) to issue an opinion on the classification of the medical device into the appropriate risk class.

(2) The applicant must make the application for the classification of a medical device in the Croatian language.

(3) Together with the application referred to in paragraph 2 of this Article, the applicant shall provide documentation containing a description and the purpose of the medical device.

(4) The Agency shall issue its opinion on the classification of the medical device in accordance with the classification rules laid down in Annex IX to this Ordinance.

(5) If the manufacturer classifies a product as a medical device, while the same product is deemed by the Agency to fall into another product group (medicinal products, cosmetic products, food supplements), the Agency issues a written opinion to that effect.

(6) The costs of the procedure for the classification of a medical device shall be borne by the applicant.

III. REGISTRATION IN THE REGISTER OF MEDICAL DEVICE MANUFACTURERS

Article 10

(1) Within 15 days from the day of commencement of their activities, medical device manufacturers having the registered place of business in the Republic of Croatia and authorised representatives having their registered place of business in the Republic of Croatia shall submit to the Agency an application for registration in the register of medical device manufacturers.

(2) For one medical device, the Agency shall register in the register of medical device manufacturers only one natural or legal person having a registered place of business in the Republic of Croatia.

Article 11

(1) The procedure for registration in the register of medical device manufacturers shall be initiated by submitting a written application to the Agency in accordance with the provisions of the Medical Devices Act, Official Gazette No 76/13 (hereinafter: the Act) and the provisions of this Ordinance.

(2) The applicant must make his application for registration in the register of medical device manufacturers in the Croatian language.

Article 12

Together with the application referred to in Article 11 of this Ordinance, the applicant shall provide:

– a completed form OČ-PR-OS, which is given in Appendix 1 to this Ordinance and forms an integral part thereof,

– proof that the applicant is registered in the court register of the competent commercial court (for legal persons) or in the register of crafts and trades (for natural persons) for the activity concerned,

– proof of the right to represent, for authorised representatives of manufacturers with the registered place of business in the Republic of Croatia,

– proof of ownership or lease of business premises where production for manufacturers with the registered place of business in the Republic of Croatia takes place,

– a list of medical devices and/or groups of medical devices to be manufactured,

– proof of having the necessary number of employees with the appropriate qualifications, depending on the volume of production and the type of medical device,

– proof that there is a responsible person in charge of the vigilance of medical devices in accordance with Article 62 of the Act, with the exception of manufacturers producing custom-made medical devices,

– proof of payment of costs of the procedure,

– proof of payment of an administrative fee.

Article 13

(1) If the Agency establishes that the application referred to in Article 11 of this Ordinance is not correct, it shall request the applicant to remedy the deficiencies identified and submit the requested data and documentation within a period of no more than 30 days from the date of receipt of the conclusion.

(2) If the applicant fails to remedy the deficiencies or fails to submit the requested data and documentation within the period set in paragraph 1 of this Article, the Agency shall refuse registration by a decision that cannot be appealed, but against which administrative proceedings may be instituted.

(3) The provisions of paragraphs 1 and 2 of this Article shall apply accordingly to the procedures for amending and for cancelling the registration in the register of medical device manufacturers, and to the procedure for registration, amendment to or cancellation of the registration of a medical device in the register of medical devices.

Article 14

(1) Within 90 days of receipt of a correct application, the Agency shall issue a decision approving or refusing registration in the register of medical device manufacturers.

(2) In the decision referred to in paragraph 1 of this Article the Agency may indicate the group or groups of medical devices.

Article 15

(1) The holder of registration in the register of medical device manufacturers shall report any amendment to the documentation based on which the Agency made the registration in the register, and, in the case of documents issued for a fixed period of time, he must submit valid documents upon the expiry of that period.

(2) Approval of amendments that do not require amendments to the decision on registration in the register of medical device manufacturers shall be granted by the Agency by means of a written notification.

Article 16

(1) The Agency shall ex officio cancel the entry of a manufacturer or authorised representative from the register of medical device manufacturers if it establishes:

– that the company or trade/craft has been dissolved,

– that the authorised representative no longer has the right to represent the manufacturer established in a third country.

(2) The Agency shall also cancel the entry of a manufacturer or authorised representative from the register of medical device manufacturers on the written substantiated request of the registration holder.

IV. CONFORMITY ASSESSMENT AND CE MARKING

Article 17

(1) The procedures for ensuring compliance of medical devices with the essential requirements are set out in Annexes II – VII to this Ordinance, which form an integral part thereof, and are as follows:

– the conformity assessment procedure given in Annex II to this Ordinance represents a full quality assurance system for medical devices, whereby a notified conformity assessment body (hereinafter: notified body) verifies the application of the approved production process, the implementation of the approved quality assurance system and final inspection of individual medical devices,

– the procedure given in Annex III to this Ordinance is a procedure whereby a notified body examines a particular sample, evaluates the documentation and the sample and approves the device,

– the procedure given in Annex IV to this Ordinance is a procedure whereby a notified body examines every product or conducts the procedure in such a way as to examine and, if necessary, test the product on a statistical basis,

– the procedure given in Annex V to this Ordinance is a procedure whereby a notified body verifies the manufacturing procedure,

– the procedure given in Annex VI to this Ordinance is a procedure whereby a notified body verifies the product quality assurance system,

– the procedure given in Annex VII to this Ordinance is a procedure whereby the manufacturer draws up a declaration of conformity, thus guaranteeing that the medical devices were manufactured in accordance with the provisions of this Ordinance,

– the procedure given in Annex VIII to this Ordinance is a procedure used by the manufacturer or his representative for custom-made devices and for devices intended for clinical investigations. Annex VII also applies to active implantable medical devices.

(2) The procedures for ensuring compliance of *in vitro* diagnostic medical devices with the essential requirements are set out in Annexes II – VII to this Ordinance concerning *in vitro* diagnostics, which form an integral part thereof, and are as follows:

– the procedure given in Annex III to this Ordinance concerning *in vitro* diagnostics is a procedure whereby the manufacturer draws up a declaration of conformity, thus guaranteeing that the *in vitro* diagnostic medical devices were manufactured in accordance with the provisions of this Ordinance,

– the procedure given in Annex IV to this Ordinance concerning *in vitro* diagnostics is a full quality assurance system for *in vitro* diagnostic medical devices, whereby a notified body verifies the application of the approved production process, the implementation of the approved quality assurance system and final inspection of individual *in vitro* diagnostic medical devices,

– the procedure given in Annex V to this Ordinance concerning *in vitro* diagnostics is a procedure whereby a notified body examines a particular sample, evaluates the documentation and the sample and approves the device,

– the procedure given in Annex VI to this Ordinance concerning *in vitro* diagnostics is a procedure whereby a notified body examines every product or conducts the procedure in such a way as to examine and, if necessary, test the product on a statistical basis,

– the procedure given in Annex VII to this Ordinance concerning *in vitro* diagnostics is a procedure whereby a notified body verifies the manufacturing procedure,

– the procedure given in Annex VIII to this Ordinance concerning *in vitro* diagnostics is a procedure used by the manufacturer for *in vitro* diagnostic medical devices intended for evaluation.

(3) The procedures for ensuring compliance of active implantable medical devices with the essential requirements are set out in Annexes II – V to this Ordinance concerning active implantable medical devices, which form an integral part thereof, and are as follows:

– the procedure given in Annex II to this Ordinance concerning active implantable medical devices is a full quality assurance system for active implantable medical devices, whereby a notified body verifies the design, the application of the approved production process, the implementation of the approved quality assurance system and final inspection of individual active implantable medical devices,

– the procedure given in Annex III to this Ordinance concerning active implantable medical devices is a procedure whereby a notified body examines a particular sample, evaluates the documentation and the sample and approves the device,

– the procedure given in Annex IV to this Ordinance concerning active implantable medical devices is a procedure whereby a notified body examines every product or conducts the procedure in such a way as to examine and, if necessary, test the product on a statistical basis,

– the procedure given in Annex V to this Ordinance concerning active implantable medical devices is a procedure whereby a notified body verifies the manufacturing procedure.

Article 18

The implementation of the procedure for assessing the conformity of production and medical devices shall be the responsibility of the notified body, which must meet the requirements set out in Annex XI to this Ordinance

Article 19

For medical devices falling within Class III, other than medical devices which are custom-made or intended for clinical investigations, the manufacturer shall, in order to affix the CE marking, follow:

– the procedure set out in Annex II to this Ordinance,

or

– the procedure set out in Annex III to this Ordinance coupled with one of the following procedures selected by the manufacturer: the procedure set out in Annex IV or V to this Ordinance.

Article 20

For medical devices falling within Class IIa, other than medical devices which are custom-made or intended for clinical investigations, the manufacturer shall, in order to affix the CE marking, follow:

– the procedure set out in Annex II to this Ordinance,

or

– the procedure set out in Annex VII to this Ordinance, coupled with one of the following procedures selected by the manufacturer: the procedure set out in Annex IV, V or VI to this Ordinance.

Article 21

For medical devices falling within Class IIb, other than medical devices which are custom-made or intended for clinical investigations, the manufacturer shall, in order to affix the CE marking, follow:

– the procedure set out in Annex II to this Ordinance (in this case, point 4 of Annex II to this Ordinance is not applicable),

or

– the procedure set out in Annex III to this Ordinance, coupled with one of the following procedures selected by the manufacturer: the procedure set out in Annex IV, V or VI to this Ordinance.

Article 22

(1) For medical devices falling within Class I, other than medical devices which are custom-made or intended for clinical investigations, the manufacturer shall, in order to affix the CE marking, follow the procedure referred to in Annex VII to this Ordinance.

(2) For sterile medical devices or medical devices with a measuring function, the manufacturer must also observe the provisions laid down in Annexes IV, V and VI to this Ordinance.

Article 23

For custom-made medical devices and active implantable medical devices, and for medical devices and active implantable medical devices intended for clinical investigations, the

manufacturer shall follow the procedure referred to in Annex VIII to this Ordinance and draw up the statement set out in that Annex before placing each device on the market.

Article 24

For *in vitro* diagnostic medical devices that are not listed in Annex II to this Ordinance concerning *in vitro* diagnostics and not intended for evaluation, the manufacturer shall, in order to affix the CE marking, follow the procedure referred to in Annex III to this Ordinance concerning *in vitro* diagnostics.

Article 25

For *in vitro* diagnostic medical devices for self-testing that are not listed in Annex II to this Ordinance concerning *in vitro* diagnostics and not intended for evaluation, the manufacturer shall, in order to affix the CE marking, follow:

– the procedure set out in point 6 of Annex III to this Ordinance concerning *in vitro* diagnostics,

or

– the procedure set out in Annex IV to this Ordinance concerning *in vitro* diagnostics,

or

– the procedure set out in Annex V to this Ordinance concerning *in vitro* diagnostics, coupled with Annex VI or VII to this Ordinance concerning *in vitro* diagnostics.

Article 26

For *in vitro* diagnostic medical devices referred to in List A in Annex II to this Ordinance concerning *in vitro* diagnostics, the manufacturer shall, in order to affix the CE marking, follow:

– the procedure set out in Annex IV to this Ordinance concerning *in vitro* diagnostics,

or

– the procedure set out in Annex V to this Ordinance concerning *in vitro* diagnostics, coupled with Annex VII to this Ordinance concerning *in vitro* diagnostics.

Article 27

For *in vitro* diagnostic medical devices referred to in List B in Annex II to this Ordinance concerning *in vitro* diagnostics, the manufacturer shall, in order to affix the CE marking, follow:

– the procedure set out in Annex IV to this Ordinance concerning *in vitro* diagnostics,

or

– the procedure set out in Annex V to this Ordinance concerning *in vitro* diagnostics, coupled with Annex VI or VII to this Ordinance concerning *in vitro* diagnostics.

Article 28

For *in vitro* diagnostic medical devices intended for evaluation, the manufacturer shall follow the procedure referred to in Annex VIII to this Ordinance concerning *in vitro* diagnostics and draw up the statement set out in that Annex before such devices are put into service.

Article 29

For active implantable medical devices, other than those which are custom-made or intended for clinical investigations, the manufacturer shall, in order to affix the CE marking, follow:

– the procedure set out in Annex II to this Ordinance concerning active implantable medical devices,

or

– the procedure set out in Annex III to this Ordinance concerning active implantable medical devices, coupled with one of the following procedures selected by the manufacturer: the procedure set out in Annex IV or V to this Ordinance concerning active implantable medical devices.

Article 30

(1) On the basis of the conformity assessment procedure, the notified body shall issue a certificate of conformity or shall make a report refusing to issue a certificate of conformity.

(2) The documents referred to in paragraph 1 of this Article shall contain at least information on the notified body, the device, the manufacturer, the results of the conformity assessment procedure and the term of validity of the document.

Article 31

(1) For custom-made medical devices and medical devices intended for clinical investigations, the manufacturer shall follow the procedure referred to in Annex VIII to this Ordinance.

(2) The Agency may require the manufacturer to submit a list of medical devices referred to in paragraph 1 of this Article which he has placed on the market in the Republic of Croatia.

Article 32

(1) For the conformity assessment of medical devices, account shall be taken of the results of any assessment and verification operations which have been carried out in accordance with the provisions of this Ordinance.

(2) The conformity assessment procedures referred to in Annexes III, IV, VII and VIII to this Ordinance, Annexes III, V, VI and VIII to this Ordinance concerning *in vitro* diagnostics and

Annexes III, IV and VI to this Ordinance concerning active implantable medical devices may be selected by the authorised representative on behalf of the manufacturer.

(3) The manufacturer or its authorised representative shall independently select the notified body.

Article 33

(1) The notified body may require, where duly justified, any information or data necessary for assessing conformity in view of the chosen procedure.

(2) Decisions taken by the notified body in accordance with Annexes II, III, V and VI to this Ordinance, Annexes III, IV and V to this Ordinance concerning *in vitro* diagnostics, and Annexes II, III and V to this Ordinance concerning active implantable medical devices, shall be valid for a maximum of five years and may be extended on written application for a further period of five years.

V. REGISTRATION OF A MEDICAL DEVICE IN THE REGISTER OF MEDICAL DEVICES

Article 34

An application for the registration of a Class I medical device in the register of medical devices shall be filed by medical device manufacturers having the registered place of business in the Republic of Croatia and the manufacturers' authorised representatives that have the registered place of business in the Republic of Croatia and are registered in the register of medical device manufacturers.

Article 35

(1) The procedure for the registration of a medical device in the register of medical devices shall be initiated by submitting a written application to the Agency in accordance with the provisions of the Act and this Ordinance.

(2) The applicant must make his application for the registration of a medical device in the register of medical devices in the Croatian language.

Article 36

Together with the application referred to in Article 35 of this Ordinance, the applicant shall provide:

– a completed form OČ-MED/PROIZV-I, given in Appendix 2 of this Ordinance, requesting the registration of a Class I medical device in the register of medical devices,

– the manufacturer's declaration of conformity with the essential requirements,

– justification for the classification of the medical device,

– a certificate of conformity issued by the notified body for sterile devices and devices with a measuring function,

– the label and the instructions for use in the Croatian language and, in the case of a device manufactured by a foreign manufacturer, the original label and the instructions for use in English, if applicable,

– a general description of the device, including any variants planned, and its intended use,

– the results of the risk analysis and a list of the standards, applied in full or in part, and a description of the solutions adopted to satisfy the essential requirements of this Ordinance if the standards are not adopted in full,

– the clinical evaluation in accordance with Annex X to this ordinance, which forms an integral part thereof,

– a list of medical devices covered by the application, in electronic format,

– proof of payment of costs of the procedure,

– proof of payment of an administrative fee.

The documents referred to in paragraph 1 of this Article shall be provided as copies, but the Agency may request the applicant to show the original documents.

Article 37

Within 60 days of receipt of a complete application, the Agency shall issue a decision approving or refusing the registration of a medical device in the register of medical devices.

Article 38

(1) The documents and all the information relating to a medical device that have been provided during the procedure for the registration of the medical device shall be treated as confidential, with the exception of information relating to the trademark, intended purpose, information relating to the classification into the relevant class of medical devices, the name of the manufacturer and the name of the holder of registration.

(2) The duty of confidentiality does not apply to informing other countries and notified bodies with regard to mutual information and the dissemination of warnings nor to the obligations of persons providing the necessary information under criminal law.

Article 39

(1) Following the registration of a medical device in the register of medical devices, the registration holder shall report any amendment to the documentation based on which the Agency made the registration, and, in the case of documents issued for a fixed period of time, he must submit valid documents upon the expiry of that period.

(2) The registration holder shall file an application for amendment to the registration in the register.

(3) Approval of amendments that do not require amendments to the decision on the registration of the medical device in the register of medical devices shall be granted by the Agency by means of a written notification.

Article 40

The Agency shall cancel the medical device from the register of medical devices in accordance with the provisions of the Act.

VI. NOTIFICATION OF PLACING A MEDICAL DEVICE ON THE MARKET

Article 41

Notification of placing a medical device on the market shall be submitted by legal and natural persons placing Class IIa, Class IIb and Class III medical devices, *in vitro* diagnostic medical devices and active implantable medical devices on the market in the Republic of Croatia.

Article 42

Notification of placing a medical device on the market shall be submitted to the Agency in writing in accordance with the provisions of the Act and this Ordinance.

Article 43

The documentation to accompany the notification of placing a medical device on the market shall include:

– a completed form MEDPRO-II/III, which is given in Appendix 2 to this Ordinance and forms an integral part thereof,

– the manufacturer's declaration of conformity with the essential requirements,

– a certificate of conformity issued by the notified body,

– the label and the instructions for use, in accordance with Article 12 of the Act,

– a list of medical devices, in electronic format.

Article 44

The documentation to accompany the notification of placing an *in vitro* diagnostic medical device on the market shall include:

– a completed form IVD-MEDPRO, which is given in Appendix 4 to this Ordinance and forms an integral part thereof,

– the manufacturer's declaration of conformity with the essential requirements,

– a certificate of conformity issued by the notified body, if applicable,

– the label and the instructions for use, in accordance with Article 12 of the Act, for *in vitro* diagnostic medical devices referred to in Annex II to this Ordinance concerning *in vitro* diagnostic medical devices, and for *in vitro* diagnostic medical devices for self-testing,

– a list of *in vitro* diagnostic medical devices, in electronic format.

Article 45

Legal and natural persons referred to in Article 41 of this Ordinance must report any amendment to the data and documents provided when submitting the notification, and, in the case of documents issued for a fixed period of time, they must submit valid documents upon the expiry of that period.

VII. TRANSITIONAL AND FINAL PROVISIONS

Article 46

All procedures initiated pursuant to the provisions of the Ordinance on essential requirements, classification, quality, entry in the register of medical device manufacturers and the register of medical devices and on conformity assessment of medical devices (Official Gazette 43/10) shall be completed in accordance with the provisions of this Ordinance.

Article 47

For Class I medical devices, manufacturers of medical devices and authorised representatives with a registered place of business in the Republic of Croatia must comply with the provisions of Article 36 of this Ordinance within one year from the date of entry into force of this Ordinance.

Article 48

On the date of entry into force of this Ordinance, the Ordinance on essential requirements, classification, quality, entry in the register of medical device manufacturers and the register of medical devices, and on conformity assessment of medical devices (Official Gazette 43/10) shall cease to have effect.

Article 49

This Ordinance shall enter into force on the day following that of its publication in the Official Gazette.

Class: 011-02/13-02/86

Reg. No: 534-10-1-2-2/4-13-1

Zagreb, 28 June 2013

The Minister

Rajko Ostojić,
m. p.

ANNEX I CONCERNING MEDICAL DEVICES

ESSENTIAL REQUIREMENTS

I. GENERAL REQUIREMENTS

1. The medical devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended by the manufacturer, 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 scientific and technical progress.

In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order:

– eliminate or reduce risks as far as possible (inherently safe design or construction),

– where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated,

– inform users of the residual risks due to any shortcomings of the protection measures adopted.

3. The medical 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 specified by the manufacturer.

4. The characteristics and performances referred to in Sections 1, 2 and 3 must not be adversely affected by other factors 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 occur during normal conditions of use.

5. The medical 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 clinical data in accordance with Annex X.

II. REQUIREMENTS REGARDING DESIGN AND CONSTRUCTION

7. Chemical, physical and biological properties

7.1. The medical devices must be designed and manufactured in such a way as to guarantee the characteristics and performances referred to in Part I on the 'General requirements' of this Annex.

Particular attention must be paid to:

– the choice of materials used, particularly as regards their toxicity and, where appropriate, flammability,

– the compatibility between the materials used and biological tissues, cells and body fluids, taking account of the intended purpose of the device,

– where appropriate, the results of biophysical research or scientific modelling whose validity has been demonstrated beforehand.

7.2. The medical 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 device. Particular attention must be paid to the tissues exposed and to the duration and frequency of exposure.

7.3. The medical devices must be designed and manufactured in such a way that they can be used safely with the materials, substances and gases with which they enter into contact during their normal use or during routine procedures. If the medical 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 a medical device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product and which is liable to act upon the

body with action ancillary to that of the medical device, the quality, safety and effectiveness of the substance must be verified in accordance with the provisions of the Medicinal Products Act.

For the substances referred to in the first paragraph of this point, the notified body shall, having verified the usefulness of the substance as part of the medical device and taking account of the intended purpose of the device, seek a scientific opinion from one of the competent authorities designated by the Member States or the European Medicines Agency (hereinafter: 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 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 as determined by the notified body. 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, regardless of whether or not this information has an impact on the established benefit/risk profile of the addition of the substance in the medical device. The notified body shall take the updated scientific opinion into account in reconsidering its assessment of the conformity assessment procedure.

7.5. The medical 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.

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 contain phthalates which are classified as carcinogenic, mutagenic or toxic to reproduction, these devices must be labelled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging as a device containing phthalates.

If the intended use of such devices includes treatment of children or treatment of pregnant or nursing women, the manufacturer must provide a justification for the use of these substances with regard to compliance with the essential requirements, in particular of this paragraph, within the technical documentation and, within the instructions for use, information on residual risks for these patient groups and, if applicable, on appropriate precautionary measures.

7.6. The medical 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 environment in which it is intended to be used.

8. Infection and microbial contamination

8.1. The medical 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. Their 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 by implementation of valid methods of elimination or viral inactivation in the course of the manufacturing process.

8.3. Medical 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 opened or damaged.

8.4. Medical devices delivered in a sterile state must have been manufactured and sterilized by an appropriate and validated method.

8.5. Medical 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 quality of packaging must be suitable taking account of the planned 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 sterile or non-sterile condition.

9. Construction and environmental properties

9.1. If the medical 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 packaging or in the instructions for use.

9.2. Medical devices must be designed and manufactured in such a way as to remove or minimize as far as is possible:

– the risk of damage, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features;

– risks connected with 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 treatment;

– 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. Medical devices must be designed and manufactured in such a way as to minimize the risks of fire or explosion during normal use and in 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. Medical devices with a measuring function

10.1. Medical 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. The measurements made by devices with a measuring function must be expressed in legal units.

11. Protection against radiation

11.1. General

11.1.1. Medical devices must be designed and manufactured in such a way that exposure of patients, users and other persons to radiation shall be reduced as far as possible compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.

11.2. Intended radiation

11.2.1. Where medical 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 must be designed and manufactured to ensure reproducibility and tolerance of relevant variable parameters.

11.2.2. Where medical 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. Medical 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 instructions for use of medical 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. Medical devices emitting 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. Medical 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. Medical 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. Medical 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 medical 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. Medical 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. Medical 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. Medical 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. Medical 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 medical devices or equipment in the usual environment.

12.6. Protection against electrical risks

Medical 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. Medical 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. Medical 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. Medical 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 medical 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 user by energy supplies or substances

12.8.1. Medical devices for supplying 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. Medical devices must be fitted with the means of preventing and/or indicating any inadequacies in the flow-rate which could pose a danger.

Medical 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 medical 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 medical device must be accompanied by the information needed to use it safely and properly, taking account of the training and knowledge of the potential users, and to identify the manufacturer.

This information comprises the details on the label and the data in the instructions for use of the medical device.

As far as practicable and appropriate, the information needed to use the medical 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 instructions for use 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, the information about the medical device 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 medical device.

13.3. The label must bear the following particulars:

(a) the name or trade name and address of the manufacturer, as well as the name or trade name and address of the authorised representative where the manufacturer does not have a registered place of business in the European Union;

(b) the details necessary to identify the medical device and the contents of the packaging especially for the users;

(c) for sterile products, 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 can be safely used, expressed as the year and month;

(f) for single use devices, an indication that the device is for single use. A manufacturer's indication of single use must be consistent;

(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 handling conditions for the medical device;

(j) special instructions for use;

(k) warnings and/or precautions to take;

(l) year of manufacture for active devices other than those covered by point (e). This indication may be included in the batch or serial number;

(m) method of sterilization for sterile devices;

(n) in the case of a medical device that contains a blood derivative, 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. Where necessary and practicable, the medical devices and detachable components must be identified, where appropriate in terms of batches, to allow 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 points (d) and (e);

(b) the details of performance referred to in Section 3 and any undesirable risks;

(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 appropriate devices and 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 medical 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 re-sterilization;

(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 to be sterilized before use, the instructions for cleaning and sterilization must be such that, if correctly followed, the device will still comply with the essential requirements in Section I.;

If the device bears an indication that the device is for single use, information on known characteristics and technical factors known to the manufacturer that could pose a risk if the device were to be 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 medical 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 contra-indications and 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 products or substances which are administered by the medical device, including any limitations in the choice of medicinal products;

(n) precautions to be taken against any special, unusual risks related to the disposal of the medical device;

(o) medicinal substances, or human blood derivatives incorporated into the medical 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 assurance system approved for the design, manufacture and final inspection of the medical devices, as specified in Section 3 of

this Annex and laid down in Sections 3 and 4 of this Annex, and the appropriate surveillance as specified in Section 5 of this Annex.

2. The declaration of conformity is the procedure whereby the manufacturer who fulfils the obligations of Section 1 of this Annex ensures and declares that the medical devices concerned meet the provisions of this Ordinance which apply to them.

The manufacturer must affix the CE marking to the medical device and draw up a written declaration of conformity.

This declaration shall cover only the specific listed devices or groups of devices, identified by the name, product code or other unambiguous reference and shall be kept by the manufacturer.

3. Quality system

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

The application must include the following information:

– the name and address of the manufacturer and any additional manufacturer 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 maintain the status and efficacy the approved quality system;

– 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 to this Ordinance, and to implement appropriate means to apply any necessary corrective action. This undertaking must include an obligation for the manufacturer to notify the Agency of the following incidents immediately on learning of them:

a) any malfunction or deterioration in the characteristics and/or performance of a medical 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 state of health;

b) any technical or medical reason connected with the characteristics or performance of a medical device leading for the reasons referred to in point (a) to recall of medical devices of the same type by the manufacturer.

3.2. Application of the quality system must ensure that the products conform to the provisions of this Ordinance which apply to them at every stage, from design to final inspection. 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 policies and procedures such as quality programmes, quality plans, quality manuals and quality records.

It must include the corresponding documentation, data and records arising from the procedures referred to in point (c).

It shall include in particular an adequate description of:

(a) the level of quality that the manufacturer wants to attain;

(b) the organization of the business and 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 to that requirement,

– 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, and 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 adopted standards 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 medical device(s) in order to operate as intended, proof must be provided that it conforms to the essential requirements when connected to 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 the 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,

– the solutions adopted as referred to in Annex I, Part I, Section 2,

– non-clinical data,

– the clinical data referred to in Annex X,

– a proposal for the label and, where appropriate, for the instructions for use.

(d) the inspection and quality assurance procedures at the manufacturing stages and in particular:

– the processes and procedures which will be used, particularly the procedures which will be used 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 all stages of manufacture;

(e) the appropriate tests and trials carried out before, during and after manufacture, the frequency with which they take place, and the test equipment used; it must be possible to adequately trace back when and how the test equipment was calibrated.

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 examine whether the quality assurance 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 technological process. 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 justified cases, on the premises of the manufacturer's suppliers and/or subcontractors to inspect their manufacturing processes.

The decision shall be notified to the manufacturer. The decision 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 assurance system or the product range covered by the changes to the manufacturing process. The notified body must assess the changes proposed and verify whether after these changes the quality assurance 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 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. It must include the documents needed to assess whether the product conforms to the requirements of this Ordinance, as referred to in Section 3.2 (c).

4.3. The notified body must examine the application and, if the product conforms to the relevant provisions of this Ordinance, issue a 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 Ordinance. The design-examination certificate must contain the results 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 medical devices referred to in Annex I, Section 7.4, second paragraph, the notified body shall, as regards the aspects referred to in that section, consult one of the competent authorities or the EMA before taking a decision. The opinion of the competent national authority or the EMA must be drawn up within 210 days after receipt of valid documentation. The scientific opinion of the competent national authority or the EMA 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 designated competent authority.

In the case of medical devices referred to in Annex I, Section 7.4, third paragraph, the scientific opinion of the EMA must be included in the documentation concerning the device. The opinion of the EMA must be drawn up within 210 days after receipt of valid documentation. The notified body will give due consideration to the opinion of the EMA when making its decision. It will convey its final decision to the EMA.

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

5. Surveillance

5.1. The aim of surveillance is to ensure that the manufacturer fulfils the obligations resulting from 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 Annex I, Chapter I, Section 2, non-clinical and clinical data, 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 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 the fourth indent of Section 3.1 and in particular the documentation, data and records referred to in the second paragraph of Section 3.2,

– the changes referred to in Section 3.4,

– the documentation referred to in Section 4.2, and

– 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 Articles 20 and 21 of this Ordinance, 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 in Section 3.3, the technical documentation as described in Section 3.2(c) for at least one representative sample for each device sub-category for compliance with the provisions of this Ordinance.

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

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

Ordinance. The notified body shall document and keep available to the competent authorities its rationale for the sample(s) taken.

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

8. Application to medical devices containing human blood derivative

Upon completing the manufacture of each batch of devices containing human blood derivative, 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 the State.

ANNEX III

TYPE-EXAMINATION

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

2. The application must include:

– the name and address of the manufacturer and the name and address of the manufacturer's 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, hereinafter referred to as the ‘type’, with the requirements of this Ordinance. 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 information:

– a general description of the type, including any variants planned, and its intended uses,

– 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 applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements if the standards 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 medical 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 the 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,

– the solutions adopted as referred to in Annex I, Part I, Section 2.,

– non-clinical data,

– clinical data referred to in Annex X,

– a proposal for the label and, where appropriate, for the 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, 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 Ordinance if the standards 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 Ordinance, the notified body issues the applicant with a 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 medical devices referred to in Annex I, Section 7.4, second paragraph, the notified body shall, as regards the aspects referred to in that section, consult one of the authorities or the EMA before taking a decision. The opinion of the competent national authority or the EMA must be drawn up within 210 days after receipt of valid documentation. The scientific opinion of the competent national authority or the EMA must be included in the documentation concerning the medical 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 designated competent authority.

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

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

Changes to the approved product must receive approval from the notified body which issued the 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 take the form of a supplement to the initial type-examination certificate.

7. Administrative provisions

7.2. Other notified bodies may obtain a copy of the type-examination certificates and/or the supplements thereto. The additions 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 authorised representative must keep with the technical documentation copies of 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

VERIFICATION

1. Verification is the procedure whereby the manufacturer or his 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 type-examination certificate and satisfy the requirements of this Ordinance which directly apply to them.

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 type-examination certificate and to the requirements of this Ordinance which apply to them. 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 type-examination certificate and with the requirements of this Ordinance which apply to them. The manufacturer must affix the CE marking to the product 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 Annex V, Sections 3 and 4 of this Ordinance.

3. The manufacturer must undertake to institute and keep up to date a procedure for systematic review based on 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 Agency of the following incidents immediately on learning of them:

(i) any malfunction or deterioration in the characteristics and/or performance of a medical 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 medical device for the reasons referred to in subparagraph (i) leading to systematic recall of medical 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 this Ordinance either by examining and testing every product as specified in Section 5 or by examining and testing products on the basis of sampling 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 medical device is examined individually and the appropriate methods defined in the relevant standards or equivalent tests must be carried out in order to verify, where appropriate, the conformity of the products with the type described in the type-examination certificate and with the requirements of the Ordinance which apply to them.

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) or

equivalent tests must be carried out to verify, where appropriate, the conformity of the products with the type described in the type-examination certificate and with the requirements of the Ordinance which apply to those products 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, taking account of the specific nature of the product category 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 product in the sample which failed to conform.

If a batch is rejected, , the 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

The manufacturer or his authorised representative must, for a period of at least five years, and in the case of implantable medical devices for a period of at least 15 years, make available to the competent 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.

8. Application to medical devices in Class IIa

In line with Article 20 of this Ordinance, this Annex applies 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 requirements of this Ordinance which apply to them;

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 medical devices containing medicated substances

In the case of Section 5, upon completing the manufacture of each batch of medical devices containing medicated substances, 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 the competent laboratory.

ANNEX V

DECLARATION OF CONFORMITY (PRODUCTION QUALITY ASSURANCE)

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

2. The declaration of conformity is the part of the procedure whereby the manufacturer who fulfils the obligations of Section 1 declares and ensures that the products concerned conform to the type described in the type-examination certificate and meet the provisions of this Ordinance which apply to them.

The manufacturer must affix the CE marking to the product 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 quality system with the 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 approved quality system,

– 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 type-examination certificate,

– 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 measures to apply any necessary corrective action. This undertaking must include an obligation for the manufacturer to notify the Agency 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 performance of a device for the reasons referred to in (i) leading to a systematic recall of devices of the same type by the manufacturer.

3.2. Application of the quality system must ensure that the products conform to the type described in the 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 operations and in particular:

– a description of the organizational structure, the responsibilities of the managerial staff and their organizational authority where manufacture of the products is concerned,

– a description of the methods of monitoring the efficient operation of the quality system and in particular the ability of the control system to achieve the desired quality of product, including control of products which fail to conform to the requirements,

– where the manufacture and/or final inspection and testing of the products are carried out, in part or in whole, by a third party, a description of 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) a description of the inspection and quality assurance techniques at the manufacturing stage and in particular:

– a description of the processes and procedures which will be used, particularly as regards sterilization, purchasing and the relevant documents,

– a description of the product identification procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture;

(d) a description of 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. The notified body 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 after the final inspection and 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. The 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 authorizes the notified body to carry out all the necessary inspections and must supply the notified body 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, etc.

4.3. The notified body must periodically carry out appropriate inspections and analyses 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 of at least five years, and in the case of implantable medical devices at least 15 years, after the last product has been manufactured, make available to the competent authorities:

– the declaration of conformity,

– the documentation referred to in the fourth indent of Section 3.1,

– the changes referred to in Section 3.4,

– the documentation referred to in the seventh indent 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 accordance with Article 20, this Annex may apply to products in Class IIa, subject to the following conditions:

6.1. By way of derogation from Sections 2, 3.1 and 3.2, by virtue of the declaration of conformity the manufacturer declares and ensures 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 requirements of this Ordinance which apply to them.

6.2. For devices in Class IIa the notified body shall assess, as part of the assessment 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 Ordinance.

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 Ordinance. The notified body shall document and keep available to the competent authority its methods for choosing the sample(s).

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

7. Application to medical devices containing medicated substances

Upon completing the manufacture of each batch of devices containing medicated substances, the manufacturer shall inform the notified body of the release of the batch of devices and the notified body shall send to the competent laboratory the official certificate concerning the release of the batch of devices containing human blood derivative.

ANNEX VI

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 Annex V, Sections 3 and 4.

2. The declaration of conformity is the part of the procedure whereby the manufacturer who fulfils the obligations of Section 1 declares and ensures that the products concerned conform to the type described in the type-examination certificate and meet the provisions of this Ordinance which apply to them.

The manufacturer shall affix the CE marking 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 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 the 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 implement the approved quality system in an adequate and efficient manner,

– where appropriate, the technical documentation on the types approved and a copy of the 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 post-production phase, including the provisions referred to in Annex X, and to implement appropriate measures to apply any

necessary corrective action. This undertaking must include an obligation of the manufacturer to notify the Agency 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 subparagraph (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) or equivalent tests are carried out to ensure that the products conform to the type described in the type-examination certificate and fulfil the provisions of this Ordinance which apply to those products. 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.

The documentation must include in particular an adequate description of:

– the quality objectives and a description of the organizational structure, responsibilities and powers of the managerial staff with regard to product quality,

– a description of 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.

– a description of the methods of monitoring the efficient operation of the quality system,

– a description of 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 of these procedures, are carried out by a third party, a description of 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. The notified body 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 after the final inspection and 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 the notified body shall 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 the notified body 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, 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 requirements of the Ordinance which apply to it. 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) or equivalent tests must be carried out. Where one or more of the samples fails to conform to the requirements, 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 of at least five years, and in the case of implantable medical devices at least 15 years, after the last product has been manufactured, make available to the competent authorities:

– the declaration of conformity,

– the documentation referred to in the seventh indent 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 accordance with Article 20 of this Ordinance, this Annex may apply to products in Class IIa, subject to the following conditions:

6.1. By way of derogation from Sections 2, 3.1 and 3.2, by virtue of the declaration of conformity the manufacturer declares and ensures 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 requirements of this Ordinance which apply to them.

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

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 Ordinance. The notified body shall document and keep available to the competent authorities the information concerning the methods used for choosing the sample(s).

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

DECLARATION OF CONFORMITY

1. The 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 declares and ensures that the products concerned meet the provisions of this Ordinance which apply to them.

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

implantable medical 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 Ordinance. It must include in particular:

– a general description of the product, including any variants planned and its intended use,

– 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, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the Ordinance if the standards have not been adopted in full,

– in the case of products placed on the market in a sterile condition, a 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 Annex I, Chapter I, Section 2,

– the non-clinical evaluation,

– the clinical evaluation in accordance with Annex X,

– the labelling 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 measures to apply any necessary corrective actions, taking account of the nature of the product and risks in relation to the product. He shall notify the Agency 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 on the performance of a device for the reasons referred to in subparagraph (i) leading to systematic recall of devices of the same type by the manufacturer.

5. In the case of 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. 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 accordance with Article 20, 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 declare and ensure that the product design meets the provisions of this Ordinance which apply to it.

ANNEX VIII

STATEMENT CONCERNING MEDICAL DEVICES FOR SPECIAL PURPOSES

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

2. The statement must contain the following information:

2.1. for custom-made medical devices:

– the name and address of the manufacturer,

– data allowing identification of the medical device,

– a statement that the medical 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 healthcare institution concerned,

– the specific characteristics of the product as indicated by the prescription,

– a statement that the medical device 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 the statement must contain:

– data allowing identification of the medical device,

– the clinical investigation plan,

– the instructions for the investigators,

– the confirmation of insurance of subjects,

– the documents used to obtain informed consent,

– a statement indicating whether or not the medical 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 medical device is manufactured utilising tissues of animal origin, except for active implantable medical devices,

– the opinion of the competent ethics committee and details of the aspects covered by the opinion of the ethics committee,

– the name of the medical practitioner or other authorized person and the name of the institution responsible for the investigations,

– the place, starting date and scheduled duration for the investigations,

– a statement that the medical device 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 Ordinance.

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 the first paragraph;

3.2. For medical 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, a list of the standards applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of this Ordinance if the standards 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 documentation must contain 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 the documentation must contain the risk management measures in this connection which have been applied to reduce the risk of infection, except for active implantable medical devices,

– 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 the first paragraph 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 medical 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 measures to apply any necessary corrective action. This undertaking shall include an obligation for the manufacturer to notify the Agency of the following incidents immediately on learning of them and 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 subparagraph (i) leading to systematic recall of devices of the same type by the manufacturer.

6.3. This Annex also applies to active implantable medical devices.

ANNEX IX

CLASSIFICATION RULES

I. DEFINITIONS

1. Definitions for the classification rules

1.1. Duration

T r a n s i e n t

Normally intended for continuous use for less than 60 minutes.

S h o r t t e r m

Normally intended for continuous use for not more than 30 days.

L o n g t e r m.

Normally intended for continuous use for more than 30 days.

1.2. Invasive medical devices

I n v a s i v e d e v i c e

A medical device which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body.

B o d y o r i f i c e

Any natural opening in the body, as well as the external surface of the eyeball, or any permanent artificial opening, such as a stoma.

S u r g i c a l l y i n v a s i v e m e d i c a l d e v i c e

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 Ordinance devices other than those referred to in the previous subparagraph and which produce penetration other than through an established body orifice, shall be treated as surgically invasive medical devices.

I m p l a n t a b l e m e d i c a l d e v i c e

Any medical 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, and to remain in place after the procedure,

Any medical 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 medical implantable device.

1.3. Reusable surgical instrument

Instrument intended to be used surgically, without being connected to an active medical device, for cutting, drilling, sawing, scratching, scraping, clamping or similar procedures and which can be reused after appropriate procedures have been carried out.

1.4. Active medical device

Any medical device 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 therapeutic medical 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 medical 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 Ordinance, ‘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 Ordinance, ‘central nervous system’ means brain, meninges and spinal cord.

II. IMPLEMENTING RULES

2. Implementing rules

2.1. Application of the rules for the classification of medical devices shall be governed by the intended purpose of the devices.

2.2. If the medical device is intended to be used in combination with another medical device, the classification rules shall apply separately to each of the devices. Accessories are classified in their own right separately from the medical 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 risk 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 classified on the basis of the most critical specified use.

2.5. If several rules apply to the same medical 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 of this Annex, 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 medical devices

1.1. Rule 1

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

1.2. Rule 2

All non-invasive medical devices intended for channelling or storing blood, body liquids or tissues, 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 medical 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 absorption of exudates,

– are in Class IIb if they are intended to be used principally for wounds that 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 medical devices

2.1. Rule 5

All invasive medical devices intended to be used to penetrate a body orifice, 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 medical 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:

– 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.

– 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 by the body, 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 medical 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 medical devices

3.1. Rule 9

All active therapeutic medical 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 medical 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 medical 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, activity of the central nervous system, in which case they are in Class IIb.

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

3.3. Rule 11

All active medical 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, the part of the body and the mode of application, in which case they are in Class IIb.

3.4. Rule 12

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

4.3. Rule 15

All medical devices used for disinfecting, cleaning, rinsing or, when applicable, hydrating contact lenses are in Class IIb.

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

Medical devices specifically intended to be used to record X-ray diagnostic images are in Class IIa.

4.5. Rule 17

All medical devices manufactured utilizing animal tissues or derivatives rendered non-viable 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.

SPECIAL RULES

1. By derogation from other rules, mammary implants are in Class III.

2. By derogation from other rules, hip, knee and shoulder total joint replacements are classified, due to the complexity of the joint function to be replaced and the increased risk of their use, classified in Class III.

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 side-effects 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 points 1.1.1 and 1.1.2 of this Annex.

1.1a In the case of implantable medical devices and medical 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 non-clinical evaluation alone has to be duly substantiated.

1.2. All the data must remain confidential.

2. Clinical investigations

2.1. Objectives

The objectives of clinical investigation 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 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 written 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.

3. This Annex, except for Section 1.1a, also applies to active implantable medical devices.

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 notified 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 Ordinance, and, in particular, the provisions 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 Ordinance.

3. The notified body must be able to carry out all the tasks assigned to such bodies by one of Annexes II to VI to this Ordinance and for which it has been notified, whether these tasks are carried out by the notified body itself or under the responsibility of the notified body. In particular, the notified body 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 that the notified body has 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 Ordinance and, in particular, the requirements set out in Annex I to this Ordinance. The notified body 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. The remuneration of the notified body must not depend on the number of inspections carried out, nor on the results of the inspections.

6. The notified 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.

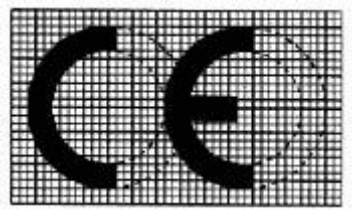
7. The staff of the notified body are bound to observe professional secrecy with regard to all information gained in the course of their duties (except vis-à-vis the competent administrative authorities of the State in which their activities are carried out) pursuant to this Ordinance or any provision of national legislation putting it into effect.

8. This Annex also applies to *in vitro* diagnostic medical devices and to active implantable medical devices.

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.

This Annex also applies to *in vitro* diagnostic medical devices and to active implantable medical devices.

ANNEX I CONCERNING *IN VITRO* DIAGNOSTICS

ESSENTIAL REQUIREMENTS

A) GENERAL REQUIREMENTS

1. *In vitro* diagnostic medical devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended by the manufacturer, they will not compromise, directly or indirectly, the clinical condition or the safety of the patients or other persons. The risk/benefit ratio must be acceptable and compatible with a high level of protection of health and safety.

2. In selecting appropriate solutions, the manufacturers must take account of scientific and technical developments and the following safety principles:

– eliminate or reduce risks by using inherently safe design and construction,

– take protection measures including alarms in relation to risks that cannot be eliminated,

– inform users of the residual risks that cannot be eliminated by the protection measures.

3. *In vitro* diagnostic medical devices must achieve the performances as specified by the manufacturer, taking account of the generally acknowledged state of the art, and they must be designed, manufactured and packed in such a way that they are suitable for the purpose specified by the manufacturer. The must achieve the necessary level of analytical and diagnostic sensitivity, analytical and diagnostic specificity, accuracy, repeatability, including control of known relevant interference, and limits of detection, stated by the manufacturer. The traceability of values assigned to calibrators and/or control materials must be assured

through available reference measurement procedures and/or available reference materials of a higher order.

4. The characteristics and performances of *in vitro* diagnostic medical devices must not be adversely affected by other factors to such a degree that the clinical conditions and safety of the usres or other persons are compromised during the lifetime of the device, under normal conditions of use.

5. *In vitro* diagnostic medical 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 by transport and storage taking account of the instructions and information provided by the manufacturer.

B) DESIGN AND MANUFACTURING REQUIREMENTS

– relating to the design and manufacture of *in vitro* diagnostic medical devices

In vitro diagnostic medical devices satisfy the requirements in respect of the following:

– chemical and physical properties of *in vitro* diagnostic medical devices;

– microbiological quality of *in vitro* diagnostic medical devices;

– manufacturing and environmental properties of *in vitro* diagnostic medical devices;

– special requirements for *in vitro* diagnostic medical devices with a measuring function;

– protection against radiation;

– requirements for *in vitro* diagnostic medical devices connected to or equipped with an energy source;

– protection against mechanical and thermal risks;

– requirements for *in vitro* diagnostic medical devices for self-testing;

– labelling and instructions for use of *in vitro* diagnostic medical devices.

1. Chemical and physical properties of *in vitro* diagnostic medical devices

1.1. *In vitro* diagnostic medical devices must be designed and manufactured in such a way as to achieve the characteristics and performances referred to in section A of this Annex. The manufacturer must take into account the possibility of impairment of analytical performance due to incompatibility between the materials used and the specimens (such as biological tissues, cells, body fluids and micro-organisms) intended to be used with the *in vitro* diagnostic medical device, taking account of its intended purpose.

1.2. *In vitro* diagnostic medical devices must be designed, manufactured and packed in such a way as to reduce as far as possible the risk of leakage, contamination and impact on the

persons exposed to them during transport and storage and on the users of the device when used in accordance with the instructions given by the manufacturer.

2. Requirements concerning the microbiological quality of *in vitro* diagnostic medical devices (infection and microbial contamination)

2.1. *In vitro* diagnostic medical devices and their manufacturing processes must be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the patients, users or other persons.

They must be designed in a way that allows easy handling, prevents leakage and the possibility of contamination of the device by the user and, in the case of specimen receptacles, the risk of contamination.

2.2. Where a device incorporates biological substances, the risk must be reduced as far as possible by selecting appropriate donors and substances and by using appropriate, validated inactivation, conservation, test and control procedures.

2.3. *In vitro* diagnostic medical devices that are sterile or have a special microbiological state must be designed, manufactured and packed according to procedures ensuring that they remain in the appropriate microbiological state indicated on the packaging, under the specified storage and transport conditions, until the expiry of their shelf life or until the packaging is opened or damaged.

2.4. *In vitro* diagnostic medical devices that are sterile or have a special microbiological state must have been manufactured by an appropriate, validated method.

2.5. Non-sterile *in vitro* diagnostic medical devices must be packed in such a way as to ensure protection against microbial contamination, as indicated by the manufacturer.

If non-sterile *in vitro* diagnostic medical devices are to be sterilised prior to use, they must be packed in such a way that, prior to sterilisation, they are adequately protected against microbial contamination.

2.6. *In vitro* diagnostic medical devices intended to be sterilized must be manufactured in appropriately controlled (e. g. environmental) conditions.

2.7. The packaging system must be suitable taking account of the method of sterilization indicated by the manufacturer.

3. Manufacturing and environmental properties of *in vitro* diagnostic medical devices

3.1. If an *in vitro* diagnostic medical 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 packaging or in the instructions for use.

3.2. *In vitro* diagnostic medical devices must be designed and manufactured in such a way as to reduce as far as possible the risks linked to their use in conjunction with materials, substances and gases with which they may come into contact during normal conditions of use.

3.3. *In vitro* diagnostic medical devices must be designed and manufactured in such a way as to remove or reduce as far as possible:

– the risk of damage linked to their physical features, including the volume/pressure ratio, its effects and properties linked to the dimensions of the device,

– risks linked to foreseeable external influences, such as magnetic fields, external electrical effects, electrostatic discharge, pressure, humidity, temperature, variations in pressure or acceleration or accidental penetration of substances into the device;

– *in vitro* diagnostic medical devices must be designed and manufactured in such a way as to prevent electromagnetic disturbances from affecting the intended operation of the device.

3.4. *In vitro* diagnostic medical devices must be designed and manufactured in such a way as to reduce as far as possible 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 substances which could cause burns.

3.5. *In vitro* diagnostic medical devices must be designed and manufactured in such a way as to facilitate the management of safe waste disposal.

3.6. The measuring, monitoring and display scale (including colour change and other visual indicators) must be designed and manufactured in line with their function, taking account of the intended purpose of the device.

4. *In vitro* diagnostic medical devices with a measuring function

4.1. *In vitro* diagnostic medical devices, instruments or apparatus having a primary analytical measuring function, must be designed and manufactured in such a way as to provide adequate stability and accuracy of measurement within appropriate accuracy limits, taking into account the intended purpose of the device and of available and appropriate reference measurement procedures and materials. The accuracy limits have to be specified by the manufacturer.

4.2. When values are expressed numerically, they must be given in units conforming to a special regulation.

5. Protection against radiation

5.1. *In vitro* diagnostic medical devices must be designed, manufactured and packaged in such a way that exposure of users and other persons to the emitted radiation is minimised.

5.2. *In vitro* diagnostic medical devices emitting potentially hazardous, visible and/or invisible radiation must as far as possible be:

– designed and manufactured in such a way as to ensure that the characteristics and the quantity of radiation emitted can be controlled and/or adjusted,

– fitted with visual displays and/or audible warnings of such emissions.

5.3. The instructions for use of i*n vitro* diagnostic medical devices emitting radiation must give detailed information as to the nature of the emitted radiation, means of protecting the user, and on ways of avoiding misuse and of eliminating the risks during the use and installation of the device.

6. Requirements for i*n vitro* diagnostic medical devices connected to or equipped with an energy source

6.1. *In vitro* diagnostic medical devices incorporating electronic programmable systems, including software, must be designed to ensure the repeatability, reliability and efficiency of these systems.

6.2. *In vitro* diagnostic medical devices must be designed and manufactured in such a way as to minimise the risks of creating electromagnetic perturbation which could impair the operation of other medical devices or equipment in the usual environment.

6.3. *In vitro* diagnostic medical 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 and maintained correctly.

6.4. Protection against mechanical and thermal risks

6.4.1. *In vitro* diagnostic medical devices must be designed and manufactured in such a way as to protect the patient and the user against mechanical risks. Devices must be sufficiently stable under the foreseen operating conditions, and they must withstand stresses inherent in the foreseen working environment. They must retain this resistance during the expected life of the devices, subject to maintenance requirements and procedures as indicated by the manufacturer. Where there are risks due to the presence of moving parts, risks due to break-up or detachment, or leakage of substances, then appropriate protection measures must be taken. Any protective means, in particular those providing protection against moving parts, must be secure and must not interfere with the normal operation of the device, or restrict routine maintenance of the device as intended by the manufacturer.

6.4.2. *In vitro* diagnostic medical 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, unless the vibrations are part of the specified performance.

6.4.3. *In vitro* diagnostic medical devices must be designed and manufactured in such a way as to reduce as far as possible 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.

6.4.4. Terminals and connectors to electricity, gas or hydraulic and pneumatic energy supplies which the user has to handle must be designed and manufactured in such a way as to minimise all possible risks.

6.4.5. Accessible parts of the *in vitro* diagnostic medical devices (excluding products intended to supply heat or reach given temperatures) and their surroundings must not attain potentially dangerous temperatures under normal use.

7. Requirements for *in vitro* diagnostic medical devices for self-testing

In vitro diagnostic medical devices for self-testing must be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills of users and the possible variations in the method and place of use.

7.1. *In vitro* diagnostic medical devices must be designed and manufactured in such a way as to:

– ensure that the device is able to be used by lay users;

– reduce the risk of user error in the handling of the device and in the interpretation of the results;

7.2. *In vitro* diagnostic medical devices for self-testing must, where possible, include user control, i.e. a procedure by which the user can verify that, at the time of use, the product will perform as intended.

8. Labelling and instructions for *in vitro* diagnostic medical devices, to be supplied by the manufacturer

8.1. Labelling of *in vitro* diagnostic medical devices means providing information about an *in vitro* diagnostic medical device on its packaging and/or on the device itself, if it is practical and appropriate. Each device must be accompanied by the information needed to use it safely and properly, taking account of the training and knowledge of the potential users, and to identify the manufacturer. This information comprises the data on the label and in the instructions for use. As far as practicable and appropriate, the information needed to use the *in vitro* diagnostic medical device must be set out on the device itself and/or on the packaging of each unit. If individual labelling of each unit is not practicable, this information must be set out in the instructions for use supplied with each device. Instructions for use must be included in the packaging of one or more devices. Exceptionally, no instructions for use are needed for *in vitro* diagnostic medical devices that can be used safely without them.

8.2. Where appropriate, the information about an *in vitro* diagnostic medical device may be in the form of symbols. Any symbol and identification colour must conform to the accepted standards. In areas for which no standards exist, the symbols and colours must be described in the documentation supplied with the medical device.

8.3. In the case of potentially hazardous devices, relevant symbols and signs conforming to the accepted standards must be used to warn of hazards. Where there is insufficient space to indicate all the information on the potentially hazardous device in accordance with the previous point, this information must be given in the instructions for use.

8.4. The following information must be indicated on the packaging:

a) the name or trade name and address of the manufacturer, as well as the name or trade name and address of the authorised representative where the manufacturer does not have a registered place of business in the European Union;

b) the details necessary for the user to identify the device and the contents of the packaging;

c) for sterile products, the indication 'sterile' or a statement indicating a special microbiological state or state of cleanliness;

d) the batch number;

e) expiration date (year, month);

f) in case of devices for evaluation, the words ‘for evaluation only’;

g) where appropriate, a statement indicating the *in vitro* use of the device;

h) storage and handling conditions for the *in vitro* diagnostic medical device;

i) any special instructions for use;

j) warnings and/or precautions to take;

k) if the device is intended for self-testing, that fact must be clearly stated;

8.5. If the intended purpose of the device is not obvious to the user, the manufacturer must clearly state the intended purpose in the instructions for use and on the packaging. The instructions for use must be written in an understandable manner enabling safe use by the user.

8.6. Where applicable, the *in vitro* diagnostic medical devices and their detachable components must be identified by the batch number to allow appropriate action to detect any potential risk posed by the *in vitro* diagnostic medical device and its detachable components.

8.7. The instructions for use must contain:

a) the details referred to in Section 8.4 of this Annex, with the exception of points 8.4.(d) and 8.4.(e);

b) composition of the reagent product by nature and amount or concentration of the active ingredient(s) of the reagent(s) or kit as well as a statement, where appropriate, that the device contains other ingredients which might influence the measurement;

c) the storage conditions and shelf life following the first opening of the packaging, together with the storage conditions and stability of working reagents;

d) the performances referred to in section 3 of the Essential Requirements of this Annex;

e) details of any special equipment required for the use of the device and instructions for use of such equipment;

f) details of the type of specimen to be used, any special conditions of collection, pre-treatment and, if necessary, storage conditions and instructions for the preparation of the patient before the collection of the specimens;

g) a detailed description of the procedures to be followed in using the device;

h) the measurement procedure to be followed, including:

– the principle of the method;

– the specific analytical characteristics (e.g. sensitivity, specificity, accuracy, repeatability, limits of detection and measurement range, including information needed for the examination of known relevant interferences), limitations of the method and information about the use of available reference measurement procedures and materials;

– the details of any further procedure or handling needed before the device can be used (incubation, dilution, etc.). Where the device is to be resterilized before use, the instructions for cleaning and sterilization must be such that, if correctly followed, the specimen will still comply with the essential requirements;

– the indication whether any particular training of the user is required;

i) the mathematical approach upon which the calculation of the analytical result is made;

j) measures to be taken in the event of changes in the analytical characteristics of the *in vitro* diagnostic medical device;

k) information appropriate to users on:

– internal quality control including the necessary validation procedures;

– the traceability of the calibration of the device;

l) the reference intervals for the quantities being determined, including a description of the appropriate reference population;

m) if the *in vitro* diagnostic medical device is intended to be used connected to or in combination with other medical devices or equipment, the instructions for use must contain a detailed description of characteristics to identify the correct devices or equipment to use in safe combination;

n) 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 device operates properly and safely; information about safe waste disposal;

o) details of any further handling or procedures needed before the device can be used (e.g. sterilisation, final assembly);

p) the necessary instructions in the event of damage to the protective packaging and details of appropriate methods of re-sterilisation or decontamination;

q) if the device is intended to be reused, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and re-sterilisation or decontamination, and any restriction on the number of reuses;

r) precautions to be taken as regards exposure to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, fire sources...

s) precautions to be taken against any special, unusual risks related to the use or disposal of the *in vitro* diagnostic medical device, including special protective measures; where the device includes substances of human or animal origin, attention must be drawn to their potential infectious nature;

t) additional information for *in vitro* diagnostic medical devices for self-testing:

– the results need to be expressed and presented in a way that is readily understood by a lay person; information needs to be provided to the user on action to be taken in case of positive, negative or indeterminate result and on the possibility of false positive or false negative result;

– certain particulars may be omitted provided that the other information supplied by the manufacturer is sufficient for the safe use of the device and for understanding the results obtained;

– a statement clearly indicating that the user should first consult his or her medical practitioner before taking any decision of medical relevance;

– – the indication that when the *in vitro* diagnostic medical device for self-testing is used for the monitoring of an existing disease, the patient should only adapt the treatment if he has received the appropriate training to do so;

u) date of issue or latest revision of the instructions for use.

ANNEX II CONCERNING *IN VITRO* DIAGNOSTICS

LISTS A AND B OF *IN VITRO* DIAGNOSTIC MEDICAL DEVICES

LIST A

– Reagents and reagent products, including calibrators and control materials, for determining the following blood groups: ABO system, rhesus (C, c, D, E, e) anti-Kell,

– reagents and reagent products, including calibrators and control materials, for the detection, confirmation and quantification in human specimens of markers of HIV infection (HIV 1 and 2), HTLV I and II, and hepatitis B, C and D,

– screening, diagnostic and confirmatory assays for variant Creutzfeldt-Jakob disease (vCJD).

LIST B

– Reagents and reagent products, including calibrators and control materials, for determining the following blood groups: anti-Duffy and anti-Kidd,

– reagents and reagent products, including calibrators and control materials, for determining irregular anti-erythrocyte antibodies,

– reagents and reagent products, including calibrators and control materials, for the detection and quantification in human samples of the following congenital infections: rubella, toxoplasmosis,

– reagents and reagent products, including calibrators and control materials, for diagnosing the following hereditary disease: phenylketonuria,

– reagents and reagent products, including calibrators and control materials, for determining the following infections: cytomegalovirus, chlamydia,

– reagents and reagent products, including calibrators and control materials, for determining the following HLA tissue groups: DR, A, B,

– reagents and reagent products, including calibrators and control materials, for determining the following tumour marker: PSA,

– reagents and reagent products, including calibrators, control materials and software, designed specifically for evaluating the risk of trisomy 21,

– *in vitro* diagnostic medical devices for self-diagnosis, including calibrators and control materials: devices for the measurement of blood sugar.

ANNEX III CONCERNING *IN VITRO* DIAGNOSTICS

DECLARATION OF CONFORMITY

1. The declaration of conformity is the procedure whereby the manufacturer or his authorised representative who fulfils the obligations defined in Sections 2, 3, 4 and 5 of this Annex and, in the case of *in vitro* diagnostic medical devices for self-testing, in Section 6 of this Annex, ensures and declares that the products meet the provisions of this Ordinance. The manufacturer must mark the product in accordance with Annex XII.

2. The manufacturer must prepare the technical documentation described in Section 3 of this Annex and ensure that the manufacturing process follows the principles of quality assurance as set out in section 4 of this Annex.

3. The technical documentation must allow assessment of the conformity of the product with the requirements of this Ordinance. The documentation must contain the following information:

– a general description of the product, including any variants designed;

– the documentation of the quality system;

– design information, including the determination of the characteristics of the basic materials, characteristics and limitation of the performance of the devices, methods of manufacture and, in the case of instruments, design drawings and diagrams of components, sub-assemblies, circuits, etc.;

– in the case of *in vitro* diagnostic medical devices containing tissues of human origin or substances derived from such tissue, information on the origin of such material and on the conditions in which it was collected;

– the descriptions and explanations necessary to understand the above-mentioned characteristics, drawings and diagrams and the operation of the product;

– the results of the risk analysis and a list of the adopted standards that are applied in full or in part, and a description of the solutions adopted to meet the essential requirements of this Ordinance, if the adopted standards have not been applied in full;

– in the case of sterile products or products with a special state of cleanliness or a special microbiological state, a description of the methods used;

– the results of the design calculations and of the inspections carried out...;

– proof that the *in vitro* diagnostic medical device conforms to the essential requirements when connected to another medical device having the characteristics specified by the manufacturer;

– the test results;

– performance evaluation data for the *in vitro* diagnostic medical device, showing that the performances claimed by the manufacturer are supported by a reference system, and information on the reference methods and materials of known reference values, the accuracy and measurement units used; such data should originate from studies in a clinical or other appropriate environment or result from relevant biographical references;

– the packaging and instructions for use;

– the results of stability studies.

4. The manufacturer must ensure that the manufacturing process follows the principles of quality assurance. The quality assurance system must include a description of:

– the organisational structure, the responsibilities and powers of the managerial staff;

– the manufacturing process and continuous quality control of production;

– the method of monitoring the performance of the quality system.

5. The manufacturer must take account of scientific and technical developments and experience gained in the area of *in vitro* diagnostic medical devices, introduce appropriate means to apply any necessary corrective actions, taking account of the nature of the products and risks in relation to the product, and notify the Agency of the changes relating to:

a) any malfunction, or deterioration in the operation and/or performance of a medical 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 user a deterioration in his state of health;

b) any technical or medical reason connected with the characteristics or the performance of an *in vitro* diagnostic medical device which, for the reasons referred to in subparagraph 1 of this point, lead to recall of *in vitro* diagnostic medical devices of the same type by the manufacturer.

6. For *in vitro* diagnostic medical devices for self-testing the manufacturer shall lodge an application for examination of the design with a notified body.

6.1. The application must enable the design of the device to be properly understood and shall enable conformity with the requirements of this Ordinance to be assessed.

The application must include:

– test results including (where appropriate) results of studies carried out with lay persons,

– data showing the handling suitability of the device in view of its intended purpose for self-testing,

– the information provided on the packaging and in the instructions for use.

6.2. The notified body shall examine and assess the application. If the design conforms to the provisions of this Ordinance, it shall issue the applicant with a design-examination certificate. The notified body may require further tests or proof to allow assessment of conformity with the design-related requirements of this Ordinance. The design-examination certificate must contain the conclusions of the examination of the design, the conditions of validity, the data needed for identification of the design and, where appropriate, a description of the intended purpose of the product.

6.3. The applicant shall inform the notified body of any significant change made to the approved design, which relate to the design examination. Changes to the approved design must receive approval from the notified body wherever the changes could affect conformity with the essential requirements of this Ordinance or with the conditions prescribed for use of the *in vitro* diagnostic medical device. This new certificate must be issued in the form of a supplement to the initial design-examination certificate.

ANNEX IV CONCERNING *IN VITRO* DIAGNOSTICS

DECLARATION OF CONFORMITY

(FULL QUALITY ASSURANCE SYSTEM)

1. The manufacturer must ensure application of the quality assurance system approved for the design, manufacture and final inspection of *in vitro* diagnostic medical devices, as specified in Section 3 of this Annex, and is subject to audit referred to in Section 3.3 of this Annex, and to ensure the appropriate surveillance as specified in Section 5 of this Annex. In addition, the manufacturer must follow, for *in vitro* diagnostic medical devices covered by List A of Annex II concerning *in vitro* diagnostics, the procedures laid down in Sections 4 and 6 of this Annex.

2. The declaration of conformity is the procedure whereby the manufacturer who fulfils the obligations imposed by Section 1 of this Annex ensures and declares that the diagnostic

medical devices meet the provisions of this Ordinance. The manufacturer must mark the device in accordance with Annex XII to this Ordinance and must draw up a written declaration of conformity. This declaration shall cover only the specific listed devices or groups of devices and shall be kept by the manufacturer.

3. Quality system

3.1. The manufacturer must lodge an application for assessment of his 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 concerned,

– all relevant information on the device or the type of device covered by the procedure,

– a written declaration that no such application has been lodged with any other notified body for the same device-related quality system,

– the documentation on the quality system,

– an undertaking by the manufacturer to maintain the status and efficacy the approved quality system,

– an undertaking by the manufacturer to keep the approved quality system adequate and efficacious,

– the manufacturer must take account of scientific and technical developments and experience gained in the area of *in vitro* diagnostic medical devices, and introduce procedures for their improvement, as referred to in Section 5 of Annex III concerning *in vitro* diagnostics.

3.2. The manufacturer's quality assurance system must cover all stages of the manufacture of *in vitro* diagnostic medical devices, from design to final inspection. All the requirements and decision relating to the quality assurance system must be documented by the manufacturer in writing, in a systematic and orderly manner in the form of rules and procedures, such as quality system plans, programmes, manuals and records.

It must include an adequate description of:

a) the level of quality that the manufacturer wants to attain;

b) the organization of the business and in particular:

– the organisational structures, the responsibilities of the managerial staff and their authority concerning the quality, design and manufacture of *in vitro* diagnostic medical devices,

– the methods of monitoring the efficiency of the quality system, including control of devices which fail to conform to these requirements;

c) the following procedures for monitoring and verifying the design of the devices:

– a general description of the device, including its different variants,

– all documentation referred to in indents 3 to 13 of Section 3 of Annex III concerning *in vitro* diagnostics,

– for *in vitro* diagnostic medical devices for self-testing, the information referred to in Section 6.1 of Annex III concerning *in vitro* diagnostics,

– the techniques used to control and verify the design, the processes and systematic measures which will be used when the devices are being designed;

d) the inspection and quality assurance procedures at the manufacturing stages and in particular:

– the procedures which will be used, particularly as regards sterilisation,

– the procedures in relation to purchasing,

– the product identification procedures drawn up and kept up to date from drawings, specifications or other relevant information;

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, which must be calibrated.

The manufacturer shall carry out the controls and tests according to the latest technological developments. The controls and tests shall cover the manufacturing processes including the characterisation of the raw material and the individual devices or each batch of devices manufactured.

In testing the devices covered by List A in Annex II concerning *in vitro* diagnostics, the manufacturer shall take into account the most recent available information, in particular as regards the biological complexity and variability of the specimens to be tested with the *in vitro* diagnostic medical device concerned.

3.3. The notified body must audit the quality system to determine whether it meets the requirements referred to in section 3.2 of this Annex. It must presume that quality assurance systems which implement the relevant standards conform to the requirements. The assessment team, appointed by the notified body, must have at least one member with experience in assessments of the technological process and one member who is an inspector. 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 their manufacturing processes. The notified body shall issue a report notifying the manufacturer about the results of the inspection. The report must contain the conclusions of the inspection and a reasoned assessment.

3.4. The manufacturer must inform the notified body of any changes to the quality assurance system ot to the product. The notified body must assess the changes proposed and verify whether after these changes the quality assurance system still meets the requirements referred

to in Section 3.2 of this Annex, and must notify the manufacturer of the conclusions of the inspection and of the assessment.

4. Examination of the design of the product

4.1. For medical devices covered by List A in Annex II concerning *in vitro* diagnostics, in addition to the obligations referred to in Section 3 of this Annex, the manufacturer must lodge with the notified body an application for examination of the design dossier relating to the device which he plans to manufacture and which falls into the category referred to in Section 3.1 of this Annex.

4.2. The application must contain a description of the design, manufacture and performances of the device, as well as the documents needed to assess whether the device conforms to the requirements of this Ordinance, as referred to in Section 3.2.c of this Annex.

4.3. The notified body must examine the application and, if the device conforms to the provisions of this Ordinance, issue a design-examination certificate. The notified body may require the application to be completed by additional proof to allow assessment of conformity with the requirements of this Ordinance. The design-examination certificate must contain the results of the examination, the conditions of validity, the data on the design and, where appropriate, a description of the intended purpose of the device.

4.4. Changes to the approved design must receive further approval from the notified body wherever the changes could affect conformity with the essential requirements of the Ordinance or with the conditions prescribed for use of the device. The applicant must inform the notified body of any changes made to the approved design. This new approval must be issued in the form of a supplement to the design-examination certificate.

4.5. The manufacturer must inform the notified body without delay if it has obtained information about changes to the pathogen and markers of infections to be tested, in particular as a consequence of biological complexity and variability. The manufacturer shall inform the notified body whether such changes are likely to affect the performance of the *in vitro* diagnostic medical device concerned.

5. Surveillance

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

5.2. The manufacturer must authorise the notified body to carry out all the necessary inspections and supply it with:

– 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, calculation, tests....,

– the data stipulated in the part of the quality system relating to manufacture (inspection reports and test data, calibration data, qualification reports of the personnel....).

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. The notified body may pay unannounced inspection visits to the manufacturer. In addition, it 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 a report containing the results of the inspection and tests carried out.

6. Verification of manufactured *in vitro* diagnostic medical devices covered by List A in Annex II concerning *in vitro* diagnostics.

6.1. For *in vitro* diagnostic medical devices covered by List A in Annex II concerning *in vitro* diagnostics, the manufacturer must forward to the Agency without delay after the conclusion of the controls and tests the reports on the tests carried out on the manufactured medical devices or each batch of devices. Furthermore, in accordance with pre-agreed conditions and modalities, the manufacturer shall prepare the samples of manufactured medical devices or batches of devices as required by the Agency.

6.2. The manufacturer may propose that the *in vitro* diagnostic medical device be entered in the register, unless the Agency communicates to the manufacturer within the agreed time-frame, but not later than 30 days after reception of the samples, a different decision, including conditions of validity of issued certificates of conformity.

ANNEX V CONCERNING *IN VITRO* DIAGNOSTICS

TYPE-EXAMINATION OF SAMPLES

1. Type-examination is the procedure whereby the notified body ascertains and certifies that the tested representative sample-type of the product (hereinafter: the type) of the production meets the requirements of this Ordinance.

2. The application for type-examination shall be lodged by the manufacturer or by his authorised representative with the notified body. The application shall include:

– the name and the address of the manufacturer or the name and the address of the manufacturer's representative,

– the documentation described in Section 3 of this Annex needed to assess the conformity of the type with the requirements of this Ordinance. The applicant shall make a sample available to the notified body, and 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 product.

3. The documentation must allow an understanding of the design, the manufacture and the performances of the device and must contain the following information:

– a general description of the type, including any variants designed,

– all documentation referred to in indents 3 to 13 of Section 3 of Annex III to this ordinance concerning *in vitro* diagnostics,

– in the case of *in vitro* diagnostic medical devices for self testing, the information referred to in Section 6.1 of Annex III concerning *in vitro* diagnostics.

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 shall also record the products designed in conformity with the applicable provisions of the adopted standards, as well as the products not designed on the basis of the relevant provisions of the adopted standards;

4.2. perform or subcontract the performance of appropriate examinations and the tests necessary to verify whether the solutions adopted by the manufacturer meet the essential requirements of this Ordinance, if the standards have not been applied; if the medical device is used in combination with other medical devices, proof must be provided that it conforms to the essential requirements of this Ordinance when combined, and that it maintains the characteristics specified by the manufacturer.

4.3. carry out or ask for the appropriate examinations and the tests necessary to verify whether, if the manufacturer has chosen to apply the adopted standards, these have actually been applied;

4.4. carry out the necessary examinations and tests in agreement with the applicant.

5. If the type conforms to the provisions of this Ordinance, the notified body shall issue the applicant with a type-examination certificate. This certificate shall contain the name and address of the manufacturer, the conclusions of the examination, the conditions and term of validity and the data needed for identification of the type approved. The relevant parts of the documentation shall be annexed to the certificate and a copy shall be kept by the notified body.

6. The applicant must inform the notified body without delay if it has obtained information about changes to the pathogen and markers of infections to be tested, in particular as a consequence of biological complexity and variability. The manufacturer shall inform the notified body whether such changes are likely to affect the performance of the *in vitro* diagnostic medical device concerned.

6.1. The applicant must inform the notified body of any significant change. Changes to the approved type must receive approval from the notified body wherever the changes may affect conformity with the essential requirements of this Ordinance or with the conditions prescribed for use of the *in vitro* diagnostic medical device. This new certificate shall be issued in the form of a supplement to the initial type-examination certificate.

7. Additional requirements

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

ANNEX VI CONCERNING *IN VITRO* DIAGNOSTICS

VERIFICATION (EC VERIFICATION)

1. Verification is the procedure whereby the manufacturer or the representative of the manufacturer ensures and declares that the products which have been subject to the procedure set out in Section 4 of this Annex conform to the type described in the type-examination certificate and meet the requirements of this Ordinance.

2.1. The manufacturer must take all the measures necessary to ensure that the manufacturing process produces products which conform to the type described in the type-examination certificate and the requirements of this Ordinance. Before the start of manufacture, the manufacturer must prepare all documentation defining the manufacturing process, in particular as regards sterilisation and the suitability of starting materials used and, where necessary, all other procedures according to the latest technical developments. The manufacturer must implement all the pre-established provisions to ensure homogeneous production and conformity of the products with the type described in the type-examination certificate and with the requirements of this Ordinance.

2.2. If certain procedures for the testing of final products according to Section 6.3 of this Annex are not appropriate, adequate testing, monitoring and control procedures and methods shall be established by the manufacturer with the approval of the notified body. The provisions of Section 5 of Annex IV concerning *in vitro* diagnostics shall apply in relation to the abovementioned approved methods.

3. The manufacturer must take account of scientific and technical developments and experience gained in the area of *in vitro* diagnostic medical devices and must introduce procedures for their improvement, as referred to in Section 5 of Annex III concerning *in vitro* diagnostics.

4. The notified body must carry out the appropriate examinations and tests referred to in Section 2.2 of this Annex in order to verify the conformity of the medical device with the requirements of this Ordinance either by examining and testing every product as specified in Section 5 of this Annex or by examining and testing products on a statistical basis as specified in Section 6 of this Annex, as the manufacturer decides. When carrying out statistical verification according to Section 6 of this Annex, the notified body shall decide on statistical procedures to be applied for lot-by-lot verification or isolated lot verification. Such decisions must be taken in consultation with the manufacturer. If statistical verification is deemed not to be appropriate, examinations and tests shall be carried out on a random basis provided that such procedure in conjunction with the measures referred to in Section 2.2 of this Annex ensures an equivalent level of conformity.

5. Verification by examination and testing of every product

5.1. For every product, appropriate tests shall be defined and implemented according to the adopted standards, or equally specific and sensitive tests shall be carried out to in order to verify the conformity of the products with the type described in the type-examination certificate and with the requirements of this Ordinance.

5.2. The notified body shall issue its identification number for each approved medical device draw up a written certificate of conformity relating to the tests carried out.

6. Statistical verification

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

6.2. Samples shall be taken from each batch. For products which make up the sample, appropriate tests shall be defined in the adopted standards or equally specific and sensitive tests shall be carried out to in order to verify the conformity of the products with the type described in the type-examination certificate and with the requirements of this Ordinance.

6.3. Statistical control of products shall be based on the sampling scheme which ensures a high level of safety and performance according to the state of the art. The sampling method shall be based on the adopted standards, taking account of the specific nature of the product groups.

6.4. . If the batch of products is accepted, the notified body shall approve the marking of each product with its identification number and shall draw 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 the batch is rejected the notified body must take appropriate measures to prevent the batch from being placed on the market.

ANNEX VII CONCERNING *IN VITRO* DIAGNOSTICS

DECLARATION OF CONFORMITY (PRODUCTION QUALITY ASSURANCE)

1. The manufacturer must ensure application of the quality system approved for the manufacture of *in vitro* diagnostic medical devices and carry out the final inspection, as specified in Section 3 of this Annex and is subject to the surveillance referred to in Section 4 of this Annex.

2. The declaration of conformity is the part of the procedure whereby the manufacturer who fulfils the obligations imposed by section 1 of this Annex ensures and declares that the medical devices conform to the type described in the type-examination certificate and meet the provisions of this Ordinance.

The manufacturer must mark the device in accordance with Annex XII to this Ordinance and draw up a written declaration of conformity.

3. Quality system

3.1. The manufacturer must lodge an application for assessment of his quality system with the notified body. The application must include:

– all documentation referred to in Section 3.1 of Annex IV concerning *in vitro* diagnostics;

– all the technical documentation on the approved types of *in vitro* diagnostic medical devices and a copy of the type-examination certificates.

3.2. The quality assurance system must ensure that the medical devices conform to the type described in the type-examination certificate. All the 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 instructions and procedures. This quality system documentation must permit uniform interpretation of the quality principles and procedures such as programmes, plans, manuals and records. It must include an adequate description of:

a) the level of quality that the manufacturer wants to attain;

b) the organisation of the business and in particular:

– the organisational structures, the responsibilities of the managerial staff and their authority where quality of design and manufacture of *in vitro* diagnostic medical devices is concerned,

– the methods of monitoring the efficiency of the quality system, including control of devices which fail to conform to these requirements;

c) the inspection and quality assurance procedures at the manufacturing stage and in particular:

– the procedures which will be used, particularly as regards sterilisation,

– the procedures in relation to purchasing,

– the product identification procedures drawn up 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, which must be calibrated.

3.3. The notified body must audit the quality system to determine whether it meets the requirements referred to in section 3.2 of this Annex. It must presume that quality assurance systems which implement the relevant standards conform to the requirements.

The assessment team, appointed by the notified body, must have at least one member with experience in assessments of the technological process. 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 their manufacturing processes. The notified body shall issue a report notifying the manufacturer about the results of the inspection.

3.4. The manufacturer must inform the notified body of any changes to the quality assurance system. The notified body must assess the changes proposed and verify whether after these changes the quality assurance system still meets the requirements referred to in Section 3.2 of this Annex. 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

The provision of Section 5 of Annex IV to this Ordinance concerning *in vitro* diagnostics shall apply.

5. Verification of *in vitro* diagnostic medical devices covered by List A in Annex II concerning *in vitro* diagnostics

5.1. For *in vitro* diagnostic medical devices covered by List A in Annex II concerning *in vitro* diagnostics, the manufacturer shall forward to the notified body without delay after the conclusion of the controls and tests the reports on the tests carried out on the manufactured medical devices or each batch of devices. Furthermore, the manufacturer shall make the samples of manufactured *in vitro* diagnostic medical devices or batches of devices available in accordance with pre-agreed conditions and modalities.

5.2. The manufacturer may propose that the *in vitro* diagnostic medical device be assessed for conformity, unless the notified body communicates to the manufacturer within the agreed time-frame, but not later than 30 days after reception of the samples, a different decision, including conditions of validity of issued certificates of conformity.

ANNEX VIII CONCERNING *IN VITRO* DIAGNOSTICS

STATEMENT AND PROCEDURES CONCERNING PERFORMANCE EVALUATION

1. For performance evaluation of *in vitro* diagnostic medical devices, the manufacturer or the manufacturer's representative shall draw up the statement containing the information specified in Section 2 of this Annex and ensure that the provisions of this Ordinance are met.

2. The statement must contain the following information:

– data allowing identification of the *in vitro* diagnostic medical device;

– an evaluation plan stating in particular the purpose, scientific, technical or medical grounds, objective of the evaluation and number of *in vitro* diagnostic medical devices concerned;

– the list of laboratories or other institutions taking part in the evaluation procedure;

– the starting date and scheduled duration for the evaluations and, in the case of *in vitro* diagnostic medical devices for self-testing, the addresses and number of lay persons involved;

– a statement that the *in vitro* diagnostic medical device conforms to the requirements of this Ordinance which apply to it and that every precaution has been taken to protect the health and safety of the patient, user and other persons.

3. The manufacturer must keep the documentation 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 Ordinance. The manufacturer must keep the documentation for at least five years after the end of the performance evaluation and must make it available to the competent authority at its request.

The manufacturer shall ensure that the products manufactured conform to the documentation mentioned in the first paragraph of this Section.

4. The provisions of Articles 41, 42, 44 and 45 of this Ordinance shall also apply to *in vitro* diagnostic medical devices for performance evaluation.

ANNEX I CONCERNING ACTIVE IMPLANTABLE MEDICAL DEVICES

ESSENTIAL REQUIREMENTS

I. GENERAL REQUIREMENTS

1. The medical devices must be designed and manufactured in such a way that, when implanted under the conditions and for the purposes anticipated, they do not compromise the clinical condition or the safety of patients. The medical devices must not present any risk to the persons implanting them or, where applicable, to other persons.

2. The medical devices must achieve the performances intended by the manufacturer, i.e. be designed and manufactured in such a way that they are suitable for one or more of the functions specified by the manufacturer.

3. The characteristics and performances referred to in Sections 1 and 2 must not be adversely affected to such a degree that the clinical condition and safety of the patients or, where applicable, of other persons are compromised during the lifetime of the device anticipated by the manufacturer, where the device is subjected to stresses which may occur during normal conditions of use.

4. The medical devices must be designed, manufactured and packed in such a way that their characteristics and performances are not adversely affected in the storage and transport conditions laid down by the manufacturer (temperature, humidity, etc.).

5. Any side effects or undesirable conditions must not adversely affect the intended performances of the medical device.

5a. Demonstration of conformity with the essential requirements must include a clinical evaluation in accordance with Annex X.

II. REQUIREMENTS REGARDING DESIGN AND CONSTRUCTION

6. The solutions adopted by the manufacturer for the design and construction of the devices must comply with safety principles taking account of the generally acknowledged state of the art.

7. Implantable medical devices must be designed, manufactured and packed in a non-reusable pack according to the procedure that ensures that they are sterile when placed on the market and that the medical devices remain sterile in the storage and transport conditions stipulated by the manufacturer until the packaging is removed and they are implanted.

8. Medical devices must be designed and manufactured in such a way as to remove or minimize as far as possible:

– the risk of physical injury in connection with their physical, including dimensional, features,

– the risk connected with the use of energy sources with particular reference, where electricity is used, to insulation, leakage currents and overheating of the medical device,

– the risk connected with relatively acceptable environmental conditions such as magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure and acceleration,

– the risk connected with medical procedures, in particular the risk resulting from the use of defibrillators or high-frequency surgical equipment,

– risks connected with ionising radiation from radioactive substances included in the device, in compliance with the protection requirements laid down in Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation and Council Directive 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionising radiation in relation to medical exposure,

– the risk which may arise where maintenance and calibration are impossible, including:

– excessive increase of leakage currents,

– ageing of the materials used,

– excess heat generated by the medical device,

– decreased accuracy of a measuring or control mechanism.

9. The medical devices must be designed and manufactured in such a way as to guarantee the characteristics and performances referred to in I. 'General requirements', with particular attention being paid to:

– the choice of materials used, particularly as regards toxicity,

– compatibility between the materials used and biological tissues, cells and body fluids, account being taken of the anticipated use of the medical device,

– compatibility of the medical device with the substances they are intended to administer,

– the quality of the connections, particularly in respect of safety,

– the reliability of the source of energy,

– if applicable, that they are leakproof,

– proper functioning of the programming and control systems, including software. For medical 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.

10. Where a medical device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product and which is liable to act upon the body with action ancillary to that of the medical device, the quality, safety and effectiveness of the substance must be verified in accordance with the provisions of the Medicinal Products Act.

For the substances referred to in the first paragraph of this Section, the notified body shall, having verified the usefulness of the substance as part of the medical device and taking account of the intended purpose of the device, seek a scientific opinion from one of the competent authorities designated by the Member States or the 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 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 device and taking account of 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 as determined by the notified body. 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 the 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 to the medical device, it shall provide the notified body with advice, regardless of whether this information has an impact on the established benefit/risk profile of the addition of the substance to the medical device or not. The notified body shall take the updated scientific opinion into account in considering its assessment of the conformity assessment procedure.

11. The medical devices and, if appropriate, their component parts must be identified to allow the necessary measure to be taken following the discovery of a potential risk in connection with the medical device and its component parts.

12. Medical devices must bear a code by which the medical devices and their manufacturer can be unequivocably identified (particularly with regard to the type of medical device and year of manufacture); it must be possible to read this code, if necessary, without the need for a surgical operation.

13. When a medical device or its accessories bear instructions for use required for the operation of the medical device or indicate operating or adjustment parameters, by means of a visual system, such information must be understandable to the user and, as appropriate, the patient.

14. Every medical device must bear, legibly and indelibly, the following particulars, where appropriate in the form of generally known symbols:

14.1. On the sterile pack:

– the method of sterilization,

– an indication permitting this packaging to be recognized as such,

– the name and address of the manufacturer,

– a description of the medical device,

– if the medical device is intended for clinical investigations, the words: ‘exclusively for clinical investigations’,

– if the medical device is custom-made, the words ‘custom-made medical device’,

– a declaration that the implantable device is in a sterile condition,

– the month and year of manufacture,

– an indication of the time limit for implanting a device safely.

14.2. On the sales packaging:

– the name or trade name and address of the manufacturer and the name or trade name and address of the authorised representative, where the manufacturer does not have a registered place of business in the European Union,

– a description of the medical device,

– the purpose of the medical device,

– the relevant characteristics for its use,

– if the medical device is intended for clinical investigations, the words: ‘exclusively for clinical investigations’,

– if the medical device is custom-made, the words: ‘custom-made medical device’,

– a declaration that the implantable medical device is in a sterile condition,

– the month and year of manufacture,

– an indication of the time limit for implanting a device safely,

– the conditions for transporting and staring the medical device,

– in the case of a medical device containing a blood derivative, an indication that the device contains a human blood derivative.

15. When placed on the market, each medical device must be accompanied by instructions for use giving the following particulars:

– the year of authorization to affix the CE mark,

– the details referred to in 14.1 and 14.2, with the exception of those referred to in the eighth and ninth indents,

– the performances referred to in Section 2 and any undesirable risks,

– information allowing the physician to select a suitable medical device and suitable software and accessories,

– information contained in the instructions for use allowing the physician and, where appropriate, the patient to use the medical device and its accessories correctly, as well as information on the nature, scope of application and times for operating controls and trials and, where appropriate, maintenance measures,

– information allowing, if appropriate, certain risks in connection with implantation of the medical device to be avoided,

– information regarding the risks of reciprocal interference in connection with the presence of the medical device during specific investigations or treatment,

– the instructions to be followed in the event of the sterile pack being damaged and, where appropriate, details of appropriate methods of re-sterilization,

– an indication, if appropriate, that a medical device can be reused only if it is reconditioned under the responsibility of the manufacturer to comply with the essential requirements.

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

– information about the lifetime of the medical device and about the energy source,

– precautions to be taken should changes occur in the device's performance,

– precautions to be taken as regards exposure, in relatively foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, etc.,

– adequate information regarding the medicinal products administered by the medical device,

– date of issue of the latest revision of the instructions for use.

16. Confirmation that the medical device satisfies the requirements in respect of characteristics and performances, as referred to in I. 'General requirements', in normal conditions of use, and the evaluation of the side effects or undesirable effects must be based on clinical data established in accordance with Annex X.

ANNEX II CONCERNING ACTIVE IMPLANTABLE MEDICAL DEVICES

EC DECLARATION OF CONFORMITY (COMPLETE QUALITY ASSURANCE SYSTEM)

1. The manufacturer must apply the quality system approved for the design, manufacture and final inspection of the medical devices concerned as specified in Sections 3 and 4, which is subject to surveillance as specified in section 5.

2. The declaration of conformity is the procedure by means of which the manufacturer who satisfies the obligations of Section 1 ensures and declares that the medical devices concerned meet the provisions of this Ordinance which apply to them.

The manufacturer or his authorized representative shall affix the CE marking and shall draw up a written declaration of conformity.

This declaration shall cover one or more devices clearly identified by means of product name, product code or other unambiguous reference and shall be kept by the manufacturer.

The CE marking shall be accompanied by the identification number of the notified body responsible.

3. Quality system

3.1. The manufacturer shall make an application for evaluation of his quality system to the notified body.

The application shall include:

– all the appropriate information about the category of products manufacture of which is envisaged,

– the quality-system documentation,

– an undertaking by the manufacturer to fulfil the obligations arising from the quality system as approved,

– an undertaking by the manufacturer to apply the approved quality system in such a way that the medical device remains adequate and efficacious,

– an undertaking by the manufacturer to institute and follow a post-marketing surveillance system including the provisions referred to in Annex X. The undertaking must include an obligation for the manufacturer to notify the competent authorities of the following incidents immediately on learning of them:

(i) any deterioration in the characteristics or performances, and any inaccuracies in the instructions for use of a medical device which might lead to or have led to the death of a patient or a deterioration in his state of health;

(ii) any technical or medical reason resulting in withdrawal of a device from the market by the manufacturer.

3.2. The application of the quality system must ensure that the medical devices conform to the provisions of this Ordinance which apply to them at every stage, from design to final controls.

All the elements, requirements and provisions adopted by the manufacturer for his quality system shall be documented in a systematic and orderly manner in the form of written policies and procedures. The quality-system documentation must make possible a uniform interpretation of the quality policies and procedures such as quality programmes, plans, manuals and records. The quality system shall include in the corresponding documentation, data and records arising from the procedures referred to in point (c).

The quality system must include in particular a description of:

a) the manufacturer's quality objectives;

b) the organization of the business and in particular:

– the organizational structures, the responsibilities of the managerial staff and their organizational authority where quality of design and manufacture of the medical device is concerned,

– the methods of monitoring the efficient operation of the quality system and in particular its ability to achieve the desired quality of the design and of the medical device, including control of devices which do not 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 the extent of control applied to the third party.

c) the procedures for monitoring and verifying the design of the medicinal product and in particular:

– the design specifications, including the standards which will be applied and a description of the solutions adopted to fulfil the essential requirements which apply to the products when the standards are not applied in full,

– the techniques of control and verification of the design, the processes and systematic actions which will be used when the medicinal device is being designed;

– a statement indicating whether or not the device incorporates, as an integral part, a substance or a human blood derivative referred to in Section 10 of Annex I and the data on the tests conducted in this connection required to assess the safety, quality and efficiency of that substance or human blood derivative, taking account of the intended purpose of the device,

– the pre-clinical evaluation,

– the clinical evaluation referred to in Annex X.

d) the techniques of control and of quality assurance at the manufacturing stage and in particular:

– the processes and procedures in relation to sterilization, purchasing and the relevant documents,

– 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.

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 examine whether the quality assurance systems which implement the relevant harmonized standards conform to these requirements.

The evaluation team entrusted with the evaluation of the quality system must include at least one member who has already had experience of evaluations of the technology concerned. The evaluation procedure shall 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 shall be notified to the manufacturer after the final inspection. The decision shall contain the conclusions of the inspection and a reasoned evaluation.

3.4. The manufacturer shall inform the notified body which has approved the quality system of any plan to alter the quality system.

The notified body shall evaluate the proposed modifications and shall verify whether the quality system so modified would meet the requirements referred to in Section 3.2; the notified body shall notify the manufacturer of its decision. This decision shall contain the conclusions of the control and a reasoned evaluation.

4. Examination of the design of the medicinal device

4.1. In addition to the obligations incumbent on him under Section 3, the manufacturer shall make an application for examination of the design dossier relating to the medical device which he plans to manufacture and which falls into the category referred to in Section 3.1.

4.2. The application shall describe the design, manufacture and performances of the device in question, and it must include the documents needed to assess whether the device conforms to the requirements of this Ordinance, and in particular Annex II, Section 3.2, third paragraph, points (c) and (d).

The application shall include inter alia:

– the design specifications, including the standards which have been applied,

– the necessary proof of their appropriations, in particular where the standards have not been applied in full. This proof must include the results of the appropriate tests carried out by the manufacturer or carried out under his responsibility,

– a statement as to whether or not the device incorporates, as an integral part, a substance as referred to in Section 10 of Annex I, whose action in combination with the medical device may result in its bioavailability, together with data on the relevant trials conducted,

– the clinical evaluation referred to in Annex X,

– the draft instructions for use.

4.3. The notified body shall examine the application and, where the device complies with the relevant provisions of this Ordinance, shall issue the applicant with an EC design examination certificate. The notified body may require the application to be supplemented by further tests or proof so that compliance with the requirements of the Ordinance may be evaluated. The certificate must contain the conclusions of the examination, the conditions of its validity, the data needed for identification of the approved design and, where appropriate, a description of the intended use of the medical device.

4.4. The applicant shall inform the notified body which issued the EC design examination certificate of any modification made to the approved design. Modifications made to the approved design must obtain supplementary approval from the notified body which issued the EC design examination certificate where such modifications may affect conformity with the essential requirements of this Ordinance or the conditions prescribed for the use of the medical device. This supplementary approval shall be given in the form of an addendum to the EC design examination certificate.

In the case of devices referred to in Annex I, Section 10, second paragraph, the notified body shall, as regards the aspects referred to in that section, consult one of the competent authorities or the EMA before taking a decision. The opinion of the competent national authority or the EMA shall be drawn up within 210 days after receipt of valid documentation concerning the device. The scientific opinion of the competent national authority or the EMA 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 Annex I, Section 10, third paragraph, the scientific opinion of the EMA must be included in the documentation concerning the device. The opinion shall be drawn up within 210 days after receipt of valid documentation. The notified body will give due consideration to the opinion of the EMA when making its decision. The

notified body may not deliver the certificate if the EMA's scientific opinion is unfavourable. It will convey its final decision to the EMA.

5. Surveillance

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

5.2. The manufacturer shall authorize the notified body to carry out the necessary inspections and shall supply it with appropriate data/information, in particular:

– the quality-system documentation,

– the data stipulated in the part of the quality system relating to design, such as the results of analyses, calculations, tests, 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 reports concerning inspections, tests, standardizations/calibrations and the qualifications of the staff concerned, etc.

5.3. The notified body shall periodically carry out appropriate inspections and evaluations in order to ascertain that the manufacturer is applying the approved quality system, and shall supply the manufacturer with an evaluation report.

5.4. In addition, the notified body may make unannounced visits to the manufacturer, and shall supply him with an inspection report.

6. Administrative provisions

6.1. For at least 15 years from the last date of manufacture of the product, the manufacturer or his authorised representative shall keep available for the national authorities:

– the declaration of conformity,

– the documentation referred to in the second indent of Section 3.1, and in particular the documentation, data and records referred to in the second paragraph of Section 3.2,

– the amendments referred to in Section 3.4,

– the amendments referred to in Section 4.2,

– the decisions and reports of the notified body referred to in Sections 3.4, 4.3, 5.3 and 5.4.

6.2. The notified body may make available to the other notified bodies all relevant information on approvals of quality systems issued, refused or withdrawn.

7. Application to medical devices containing a human blood derivative

Upon completing the manufacture of each batch of devices containing a human blood derivative, 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 the State.

ANNEX III CONCERNING ACTIVE IMPLANTABLE MEDICAL DEVICES

EC TYPE-EXAMINATION

1. EC type-examination is the procedure whereby a notified body observes a test sample of the production envisaged and certifies that it satisfies the relevant provisions of this Ordinance.

2. The application for EC type-examination shall be made by the manufacturer, or by his authorized representative established in the Community, to a notified body.

The application must include:

– the name and address of the manufacturer and the name and address of the authorized representative if the application is made by the latter,

– a written declaration specifying that an application has not been made to any other notified body,

– the documentation referred to in Section 3 needed to allow an evaluation to be made of the conformity of a representative sample of the production concerned, hereinafter referred to as 'type', with the requirements of this Ordinance.

The applicant shall make a 'type' available to the notified body. The notified body may request other samples as necessary.

3. The documentation must provide information about the design, the manufacturer and the performances of the medical device. The documentation shall contain in particular:

– a general description of the type, including any variants designed, and its intended use(s),

– design drawings, methods of manufacture envisaged, in particular as regards sterilization, and diagrams of parts, sub-assemblies, circuits, etc.,

– the description and explanations necessary for the understanding of the abovementioned drawings and diagrams and of the operation of the medical device,

– a list of the standards applied in full or in part, and a description of the solutions adopted to satisfy the essential requirements where the standards have not been applied,

– the results of design calculations, risk analysis, investigations and technical tests carried out, etc.,

– a declaration stating whether or not the device incorporates, as an integral part, a substance or a human blood derivative as referred to in Section 10 of Annex I and the data on the tests conducted in this connection required to assess the safety, quality and effectiveness of that substance or human blood derivative, taking account of the intended purpose of the device,

– the pre-clinical evaluation,

– the clinical evaluation referred to in Annex X,

– the draft instructions for use.

4. The notified body shall:

4.1. examine and evaluate the documentation, verify that the type has been manufactured in accordance with the documentation; the notified body shall also keep records of the products which have been designed in accordance with the applicable provisions of the standards, as well as the products for which the design is not based on the relevant provisions of the said standards;

4.2. carry out or have carried out the inspections and tests necessary to verify whether the solutions adopted by the manufacturer satisfy the essential requirements of this Ordinance where the standards have not been applied;

4.3. carry out or have carried out the appropriate inspections and tests necessary to verify whether, where 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. Where the type meets the provisions of this Ordinance, the notified body shall issue an EC type-examination certificate to the applicant. The certificate shall contain the name and address of the manufacturer, the conclusions of the control, the conditions under which the certificate is valid and the information necessary for identification of the type approved.

The significant parts of the documentation shall be attached to the certificate and a copy shall be kept by the notified body.

In the case of devices referred to in Annex I, Section 10, second paragraph, the notified body shall, as regards the aspects referred to in that section, consult one of the competent authorities or the EMA before taking a decision. The opinion of the competent national authority or the EMA shall be drawn up within 210 days after receipt of valid documentation. The scientific opinion of the competent national authority or the EMA 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 authority concerned.

In the case of devices referred to in Annex I, Section 10, third paragraph, the scientific opinion of the EMA must be included in the documentation concerning the device. The opinion shall be drawn up within 210 days after receipt of valid documentation. The notified body will give due consideration to the opinion of the EMA when making its decision. The

notified body may not deliver the certificate if the EMA's scientific opinion is unfavourable. It will convey its final decision to the EMA.

6. The applicant shall inform the notified body which issued the EC type-examination certificate of modifications made to the approved medical device.

Modifications to the approved medical device must receive further approval from the notified body which issued the EC type-examination certificate where such modifications may affect conformity with the essential requirements or with the conditions of use specified for the device in question. The new approval shall be issued, where appropriate, in the form of a supplement to the initial EC type-examination certificate.

7. Administrative provisions

7.1. On request, each notified body shall make available to the other notified bodies ll relevant information on EC type-examination certificates and addenda issued, refused or withdrawn.

7.2. Other notified bodies may obtain a copy of the EC type-examination certificates and/or the addenda to them. The annexes to the certificates shall be made available to the other notified bodies when a reasoned application is made and after the manufacturer has been informed.

7.3. The manufacturer or his authorized representative shall keep with the technical documentation a copy of the EC type-examination certificates and the supplements to them for a period ending at least 15 years after the last product has been manufactured.

ANNEX IV CONCERNING ACTIVE IMPLANTABLE MEDICAL DEVICES

EC VERIFICATION

1. EC verification is the procedure whereby the manufacturer or his authorized representative established within the European Union ensures and declares that the products subject to the provisions of Section 3 are in conformity with the type as described in the type-examination certificate and satisfy the requirements of this Ordinance that apply to them.

2. The manufacturer or his authorized representative established within the Community shall take all measures necessary in order that the manufacturing process ensures conformity of the products to the type as described in the EC type-examination certificate and to the requirements of this Ordinance that apply to them. 3. The manufacturer or his authorized representative established within the Community shall affix the CE marking to each product and draw up a declaration of conformity.

3. The manufacturer shall, before the start of manufacture, prepare documents defining the manufacturing processes, in particular as regards sterilization, together with the routine procedures, pre-established provisions to be implemented to ensure uniformity of production and conformity of the products with the type as described in the EC type-examination certificate as well as with the relevant requirements of this Ordinance.

4. The manufacturer shall undertake to institute and keep up-dated a post-marketing surveillance system including the provisions referred to in Annex X. This undertaking shall include the obligation on the part of the manufacturer to notify the competent authorities of the following events immediately on learning of them:

(i) any change in the characteristics or performances and any inaccuracies in the instruction leaflet which might lead to or have led to the death of a patient or deterioration in his state of health;

(ii) any technical or medical reason resulting in the withdrawal of a device from the market by the manufacturer.

5. The authorised body shall carry out the appropriate examinations and tests in order to check the conformity of the products to the requirements of this Ordinance by examination and testing of products on a statistical basis, as specified in section 6. The manufacturer must authorize the authorised body to evaluate the efficiency of the measures taken pursuant to section 3, by an independent auditor where appropriate.

6. Statistical verification

6.1. Manufacturers shall present the products manufactured in the form of uniform batches and shall take all necessary measures in order that the manufacturing process ensures the uniformity of each batch manufactured.

6.2. A random sample shall be taken from each batch. Products in a sample shall be individually examined and appropriate tests, as set out in the standard(s), or equivalent tests shall be carried out to verify their conformity to the type as described in the EC type-examination certificate, based on which a batch is accepted or rejected.

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

6.4. Where a batch is accepted, the authorised body shall affix, or cause to be affixed, its identification number to each product and draw up a written certificate of conformity based on the tests carried out. All products in the batch may be placed on the market except for those products from the sample which were found not to be in conformity.

Where a batch is rejected, the authorised body shall take necessary measures to prevent the placing on the market of that batch. In the event of frequent rejection of batches the authorised body may suspend the statistical verification.

The manufacturer may, under the responsibility of the authorised body, affix the latter's identification number during the manufacturing process.

6.5. The manufacturer or his authorized representative shall ensure that he is able to supply the authorised body's certificates of conformity on request.

7. Application to devices containing a human blood derivative

Upon completing the manufacture of each batch of devices containing a human blood derivative, 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 the competent laboratory.

ANNEX V CONCERNING ACTIVE IMPLANTABLE MEDICAL DEVICES

EC DECLARATION OF CONFORMITY TO TYPE (ASSURANCE OF PRODUCTION QUALITY)

1. The manufacturer shall apply the quality system approved for the manufacture and shall conduct the final inspection of the medical devices concerned as specified in 3; the manufacturer shall be subject to the surveillance referred to in Section 4.

2. The declaration of conformity is the procedure whereby the manufacturer who satisfies the obligations of Section 1 guarantees and declares that the medical devices concerned conform to the type described in the EC type-examination certificate and meet the provisions of this Ordinance which apply to them.

The manufacturer or his authorized representative established within the Community shall affix the CE marking in accordance with the provisions of this Ordinance and of the Act and draw up a written declaration of conformity. This declaration, which shall cover the devices manufactured, clearly identified by means of product name, product code or other unambiguous reference, must be kept by the manufacturer. The CE marking shall be accompanied by the identification number of the notified body responsible.

3. Quality system

3.1. The manufacturer shall make an application for evaluation of his quality system to a notified body.

The application must include:

– all appropriate information concerning the medical devices intended to be manufactured,

– the quality-system documentation,

– an undertaking by the manufacturer to fulfil the obligations arising from the quality system as approved,

– an undertaking by the manufacturer to implement the approved quality system in such a way that it remains adequate and efficacious,

– where appropriate, the technical documentation relating to the approved type and a copy of the EC type-examination certificate,

– an undertaking by the manufacturer to institute and follow a post-marketing surveillance system including the provisions referred to in Annex X. The undertaking shall include an obligation for the manufacturer to notify the competent authorities of the following adverse events immediately on learning of them:

i(i) any deterioration in the characteristics or performances, and any inaccuracies in the instructions for use of a medical device which might lead to or have led to the death of a patient or a deterioration in his state of health;

(ii) any technical or medical reason resulting in withdrawal of a medical device from the market by the manufacturer.

3.2. 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 shall be documented in a systematic and orderly manner in the form of written policies and procedures. The quality-system documentation must make possible a uniform interpretation of the quality policies and procedures such as quality programmes, plans, manuals and records.

The quality system must include in particular an adequate description of:

a) the manufacturer's quality objectives;

b) the organization of the business and in particular:

– the organizational structures, the responsibilities of the managerial staff and their organizational authority where manufacture of the medical device is concerned,

– the methods of monitoring the efficient operation of the quality system and in particular its ability to achieve the desired quality of the products, including control of medical devices which do not 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 control of the quality system and quality assurance at the manufacturing stage and in particular:

– the processes and procedures in relation to sterilization, purchasing and the relevant documents,

– medical device identification procedures drawn up and followed on the basis of drawings, specifications or other relevant documents at every stage of manufacture;

d) 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.

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

The evaluation team entrusted with the evaluation of the quality system must include at least one member who has already had experience of evaluations of the technology concerned. The evaluation procedure shall include an inspection on the manufacturer's premises.

The decision shall be notified to the manufacturer after the final inspection. The decision must contain the conclusions of the control and a reasoned evaluation.

3.4. The manufacturer shall inform the notified body which has approved the quality system of any plan to alter the quality system.

The notified body shall evaluate the proposed modifications and shall verify whether the quality system so modified would meet the requirements of Section 3.2; the notified body shall notify the manufacturer of its decision. The decision must contain the conclusions of the inspection and a reasoned evaluation.

4. Surveillance

4.1. The aim of surveillance is to ensure that the manufacturer duly fulfils the obligations which arise from the approved quality system.

4.2. The manufacturer shall authorize the notified body to carry out the necessary inspection and shall supply it with appropriate information, in particular:

– the technical documentation,

– the quality-system documentation,

– the data stipulated in the part of the quality system relating to manufacture, such as reports concerning inspections, tests, standardizations/calibrations and the qualifications of the staff, etc.

4.3. The notified body shall periodically carry out appropriate inspections and evaluations in order to ascertain that the manufacturer is applying the approved quality system, and shall supply the manufacturer with an evaluation report.

4.4. In addition, the notified body may make unannounced visits to the manufacturer, and shall supply him with an inspection report.

5. The notified body may communicate to the other notified bodies all relevant information concerning approvals of quality systems issued, refused or withdrawn.

6. Application to devices containing a human blood derivative

Upon completing the manufacture of each batch of devices containing a human blood derivative, the manufacturer shall inform the notified body of the release of that 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 the competent laboratory.

APPENDIX 1

FORM OČ-PR

Form for registration in the register of medical device manufacturers

A Administrative information	
Type of application	
☐ First application ☐ Modification of data	
First application reference number (in the case of modification):	Date:

B Applicant information
Status of the applicant ☐ Manufacturer
☐ Authorised representative

C Manufacturer information	
Name of the manufacturer:	
Manufacturer's contact person:	
Address:	
Postal code:	City:
Telephone:	Fax:
E-mail:	Country:

D Authorised representative information	
Name of the authorised representative:	
Authorised representative's contact person:	
Address:	
Postal code:	City:
Telephone:	Fax:
E-mail:	Country:

E Details of the person responsible for manufacture (to be completed by the manufacturers established in the Republic of Croatia)
First name and family name:

Address:	
Postal code:	City:
Telephone:	Fax:
E-mail:	

F Details of the person responsible for vigilance	
First name and family name:	
Address:	
Postal code:	City:
Telephone:	Fax:
E-mail:	Country:

G Note

I affirm that the information given in this form is accurate to the best of my knowledge.

……
Signature and stamp

In _____, _____ year.

APPENDIX 2

FORM OČ-MEDPRO-I

Form for registration of Class I medical device in the register

A Administrative information	
Type of application	
☐ First application ☐ Modification of data	
First application reference number (in the case of modification)	Date
Reference number of registration in the register of manufacturers	Date

B Medical device information	
Medical device: ☐ Class I	☐ System or set

☐ Class Is ☐ Class Im	
Nomenclature system (GMDN if available)	
Nomenclature code	
Nomenclature text	
Generic name	
Commercial name /brand name/make	
Alternative name	
Description and intended use of the medical device	
C Notified body information	
Name of the notified body	
Identification number of the notified body	
Certificate of conformity number	
Type of the certificate of conformity	
Date of issue of the certificate of conformity	Date of expiry of the certificate of conformity
Scope of the certificate of conformity	
D Note	

I affirm that the information given in this form is accurate to the best of my knowledge.

……
Signature and stamp

In _____, _____ year.

APPENDIX 3

FORM MEDPRO-II/III

Form for information about a medical device

A Administrative information
Type of application
☐ First application

☐ Modification of data

First application reference number (in the case of modification)	Date

B Applicant information

Status of the applicant ☐ Manufacturer ☐ Authorised representative ☐ Others (identify the role):

C Manufacturer information
Name of the manufacturer
Manufacturer's contact person
Address

Postal code	City
Telephone	Fax
E-mail	Country

D Authorised representative information
Name of the authorised representative
Authorised representative's contact person
Address

Postal code	City
Telephone	Fax
E-mail	Country

E Submitter's information (if different from C or D)
Name
Contact person
Address

Postal code	City
Telephone	Fax
E-mail	Country

F Medical device information

Medical device: ☐ Class III ☐ Class IIb ☐ Class IIa	☐ Active implantable medical device ☐ System or set
Nomenclature system (GMDN if available)	
Nomenclature code	
Nomenclature text	
Generic name	
Commercial name /brand name/make	
Alternative name	
Description and intended use of the medical device	

G Notified body information	
Name of the notified body	
Identification number of the notified body	
Certificate of conformity number	
Type of the certificate of conformity	
Date of issue of the certificate of conformity	Date of expiry of the certificate of conformity
Scope of the certificate of conformity	

H Note

I affirm that the information given in this form is accurate to the best of my knowledge.

……
Signature and stamp

In _____, _____ year.

APPENDIX 4

FORM IVD-MEDPRO

FORM FOR INFORMATION ABOUT AN *IN VITRO* DIAGNOSTIC MEDICAL DEVICE

A. Details of the nation competent authority		
Name of the nation competent authority		
Address of the nation competent authority		
B. Type of application		
Indicate whether this is the first registration in the register, modification of data or removal from the register:		
☐ first registration	☐ change of address	☐ removal from the register
	☐ significant change of product	☐ withdrawal by the competent authority
First application reference number (in the case of modification):		
Indicate the status of the applicant:		
☐ manufacturer	☐ Manufacturer's representative	
C. Manufacturer information		
Manufacturer's full name		
Manufacturer's short name		
Country of the manufacturer		
City		Postal code
Street and number		PO box
Manufacturer's contact person		
First name and family name		Telephone
Fax		E-mail
D. Authorised representative information		
Name of the representative		
City		Postal code
Street and number		PO box
Manufacturer's contact person		
First name and family name		Telephone
Fax		E-mail
E. *In vitro* diagnostic medical device information		
Indicate classification:		
☐ List A, Annex II		

☐ List B, Annex II
☐ For self-testing, not listed in Annex II
☐ Other (all devices except Annex II and self-testing devices)
New device
Category code
06
Category code:
In Croatian
In vitro diagnostički medicinski proizvod
In English
In vitro diagnostic devices
E.1 Information related to reagents, calibrators and control materials: In terms of common technological characteristics and/or analytes
Nomenclature system used
☐ GMDN☐ EDMS

Generic device group code		Generic device group term		
		In Croatian		In English

Short description

In Croatian		In English

E.2 Information related to other *in vitro* diagnostic medical devices
Nomenclature system used
☐ GMDN ☐ EDMS

Generic device group code		Generic device group term		
		In Croatian		In English

Short description

In Croatian		In English

E.3 Additional information for Annex II and self-testing devices:		
Device type		
☐Conformity confirmed by the conformity assessment body		Conformity assessment body identification number
☐In conformity with common technical specifications (for Annex II List A devices)		

I affirm that the information provided is accurate to the best of my knowledge.

……
Signature and stamp

In _____, _____ year.