3.2. Rule 2

All non-invasive 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.

3.3. Rule 3

All non-invasive devices intended for modifying the biological or chemical composition of human tissues or cells, blood, other body liquids or other liquids intended for implantation or 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.

All non-invasive devices intended to be used for in vitro fertilisation (IVF) or assisted reproduction technologies (ART) which are liable to act with close contact on the inner or outer cells during the IVF/ART, such as washing, separating, sperm immobilising, cryoprotecting solutions, are in class IIb.

3.4. Rule 4

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

– are in class I if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates,

– are in class IIb if they are intended to be used principally with wounds which have breached the dermis and can only heal by secondary intent,

– are in class IIa in all other cases, including devices principally intended to manage the micro-environment of a wound.

4. INVASIVE DEVICES

4.1. Rule 5

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

– are in class I if they are intended for transient use,

– are in class IIa if they are intended for short-term use, except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in a nasal cavity, in which case they are in class I,

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

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

4.2. Rule 6

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

– are intended 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,

– are reusable surgical instruments, in which case they are in class I,

– are intended specifically for use in direct contact with the central nervous system, in which case they are in class III,

– are intended to supply energy in the form of ionising radiation in which case they are in class IIb,

– have a biological effect or are wholly or mainly absorbed in which case they are in class IIb,

– are 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.

4.3. 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,

– are intended specifically for use in direct contact with the central nervous system, in which case they are in class III,

– are intended to supply energy in the form of ionizing radiation in which case they are in class IIb,

– have a biological effect or are wholly or mainly absorbed in which case they are in class III,

– are intended 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.

4.4. Rule 8

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

– are intended to be placed in the teeth, in which case they are in class IIa,

– are intended 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,

– have a biological effect or are wholly or mainly absorbed, in which case they are in class III,

– are intended 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,

– are active implantable medical devices or implantable accessories to active implantable medical devices, in which case they are in class III,

– are breast implants, in which case they are in class III,

– are hip, knee or shoulder total and partial joint replacements, in which case they are in class III, with the exception of ancillary components such as screws, wedges, plates and instruments,

– are spinal disc replacement implants and implantable devices that come into contact with the spinal column, in which case they are in class III.

5. ACTIVE DEVICES

5.1. Rule 9

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

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

All active devices that are intended for controlling, monitoring or directly influencing the performance of active implantable medical devices are in class III.

5.2. Rule 10

Active devices intended for diagnosis are in class IIa:

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

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

5.3. Rule 11

All active devices intended to administer and/or remove medicines, body liquids or other substances to or from the body are in class IIa, unless this is done in a manner that is potentially hazardous, taking account of the nature of the substances involved, of the part of the body concerned and of the mode of application in which case they are in class IIb.

5.4. Rule 12

All other active devices are in class I.

6. SPECIAL RULES

6.1. Rule 13

All devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, as defined in Article 1 of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma, with action ancillary to that of the devices, are in class III.

6.2. Rule 14

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

6.3. Rule 15

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

All devices intended specifically to be used for disinfecting or sterilising medical devices are in class IIa, unless they are disinfecting solutions or washer-disinfectors intended specifically to be used for disinfecting invasive devices, as the end point of processing, in which case they are in class IIb.

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

6.4. Rule 16

Devices specifically intended for recording of diagnostic images generated by X-ray, MRI, ultra-sound or other diagnostic devices are in class IIa.

6.5. Rule 17

All devices manufactured utilising tissues or cells of human or animal origin, or their derivatives, which are non-viable or rendered non-viable are in class III, unless such devices are manufactured utilising tissues or cells of animal origin, or their derivatives, which are non-viable or rendered non-viable that are intended to come into contact with intact skin only.

6.6. Rule 18

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

6.7. Rule 19

All devices incorporating or consisting of nanomaterial are in class III unless the nanomaterial is encapsulated or bound in such a manner that it cannot be released into the patient's or user's body when the device is used within its intended purpose.

6.8. Rule 20

All devices intended to be used for aphaeresis, such as aphaeresis machines, sets, connectors and solutions, are in class III.

6.9. Rule 21

Devices that are composed of substances or combination of substances intended to be ingested, inhaled or administered rectally or vaginally and that are absorbed by or dispersed in the human body are in class III.

ANNEX VIII

CONFORMITY ASSESSMENT BASED ON FULL QUALITY ASSURANCE AND DESIGN EXAMINATION

Chapter I: Full Quality Assurance System

1. The manufacturer shall ensure application of the quality management system approved for the design, manufacture and final inspection of the products concerned, as specified in Section 3 and is subject to audit as laid down in Sections 3.3 and 3.4 and to the surveillance as specified in Section 4.

2. The manufacturer who fulfils the obligations imposed by Section 1 shall draw up and keep an EU declaration of conformity in accordance with Article 17 and Annex III for the device model covered by the conformity assessment procedure. By issuing a declaration of conformity the manufacturer ensures and declares that the devices concerned meet the provisions of this Regulation which apply to them.

3. Quality management system

3.1. The manufacturer shall lodge an application for assessment of his quality management system with a notified body. The application shall include:

- the name and address of the manufacturer and any additional manufacturing site covered by the quality management system, and, if the application is lodged by the authorised representative, his name and address as well,
- all the relevant information on the device or device category covered by the procedure,
- a written declaration that no application has been lodged with any other notified body for the same device-related quality management system, or information about any previous application for the same device-related quality management system that has been refused by another notified body,
- the documentation on the quality management system,
- a description of the procedures in place to fulfil the obligations imposed by the quality management system approved and the undertaking by the manufacturer to apply these procedures,
- a description of the procedures in place to keep the approved quality management system adequate and efficacious and the undertaking by the manufacturer to apply these procedures,
- the documentation on the post-market surveillance plan, including, when applicable, a plan for the post-market clinical follow-up, and the procedures put in place to ensure compliance with the obligations emanating from the provisions on vigilance set out in Articles 61 to 66,

– a description of the procedures in place to keep up to date the post-market surveillance plan, including, when applicable, a plan for the post-market clinical follow-up, and the procedures ensuring compliance with the obligations emanating from the provisions on vigilance set out in Articles 61 to 66 as well as the undertaking by the manufacturer to apply these procedures.

3.2. Application of the quality management system shall ensure that the devices conform to the provisions of this Regulation which apply to them at every stage, from design to final inspection. All the elements, requirements and provisions adopted by the manufacturer for his quality management system shall 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.

Moreover, the documentation to be submitted for the assessment of the quality management system shall include an adequate description of, in particular:

(a) the manufacturer's quality objectives;

(b) the organisation of the business and in particular:

– the organisational structures, the responsibilities of the managerial staff and their organisational authority where quality of design and manufacture of the products is concerned,

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

– where the design, manufacture and/or final inspection and testing of the products, or elements thereof, is carried out by another party, the methods of monitoring the efficient operation of the quality management system and in particular the type and extent of control applied to the other party,

– where the manufacturer does not have a registered place of business in a Member State, the draft mandate for the designation of an authorised representative and a letter of intention of the authorised representative to accept the mandate;

(c) the procedures and techniques for monitoring, verifying, validating and controlling the design of the devices, including the corresponding documentation as well as the data and records arising from those procedures and techniques;

(d) the inspection and quality assurance techniques at the manufacturing stage and in particular:

– the processes and procedures which will be used, particularly as regards sterilisation, purchasing and the relevant documents,

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

(e) the appropriate tests and trials which will be carried out before, during and after manufacture, the frequency with which they will take place, and the test equipment used; it shall be possible to trace back the calibration of the test equipment adequately.

In addition, the manufacturer shall grant the notified body access to the technical documentation referred to in Annex II.

3.3. Audit

(a) The notified body shall audit the quality management system to determine whether it meets the requirements referred to in Section 3.2. Unless duly substantiated, it shall presume that quality management systems which satisfy the relevant harmonised standards or CTS conform to the requirements covered by the standards or CTS.

(b) The assessment team shall include at least one member with past experience of assessments of the technology concerned. The assessment procedure shall include an audit on the manufacturer's premises and, if appropriate, on the premises of the manufacturer's suppliers and/or subcontractors to inspect the manufacturing and other relevant processes.

(c) Moreover, in the case of devices falling into class IIa or IIb the audit procedure shall include an assessment, on a representative basis, of the design documentation within the technical documentation as referred to in Annex II of the device(s) concerned. In choosing representative sample(s) the notified body shall take into account the novelty of the technology, similarities in design, technology, manufacturing and sterilisation methods, the intended use and the results of any previous relevant assessments (e.g. with regard to physical, chemical or biological properties) that have been carried out in accordance with this Regulation. The notified body shall document its rationale for the sample(s) taken.

(d) If the quality management system conforms to the relevant provisions of this Regulation, the notified body shall issue an EU full quality assurance certificate. The decision shall be notified to the manufacturer. It shall contain the conclusions of the audit and a reasoned assessment.

3.4. The manufacturer shall inform the notified body which approved the quality management system of any plan for substantial changes to the quality management system or the product-range covered. The notified body shall assess the changes proposed and verify whether after these changes the quality management system still meets the requirements referred to in Section 3.2. It shall notify the manufacturer of its decision which shall contain the conclusions of the audit and a reasoned assessment. The approval of any substantial change to the quality management system or the product-range covered shall take the form of a supplement to the EU full quality assurance certificate.

4. Surveillance assessment

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

4.2. The manufacturer shall authorise the notified body to carry out all the necessary audits, including inspections, and supply it with all relevant information, in particular:

- the documentation on the quality management system,
- the documentation on the post-market surveillance plan, including a post-market clinical follow-up, as well as, if applicable, any findings resulting from the application of the post-market surveillance plan, including the post-market clinical follow-up, and of the provisions on vigilance set out in Articles 61 to 66,
- the data stipulated in the part of the quality management system relating to design, such as the results of analyses, calculations, tests, the solutions adopted regarding the risk-management as referred to in Section 2 of Annex I , pre-clinical and clinical evaluation,
- the data stipulated in the part of the quality management system relating to manufacture, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.

4.3. The notified body shall periodically, at least once every 12 months, carry out appropriate audits and assessments to make sure that the manufacturer applies the approved quality management system and the post-market surveillance plan, and shall supply the manufacturer with an assessment report. This shall include inspections on the premises of the manufacturer and, if appropriate, of the manufacturer's suppliers and/or subcontractors. At the time of such inspections, the notified body shall, where necessary, carry out or ask for tests in order to check that the quality management system is working properly. It shall provide the manufacturer with an inspection report and, if a test has been carried out, with a test report.

4.4. The notified body shall randomly perform unannounced factory inspections to the manufacturer and, if appropriate, of the manufacturer's suppliers and/or subcontractors, which may be combined with the periodic surveillance assessment referred to in Section 4.3. or be performed in addition to this surveillance assessment. The notified body shall establish a plan for the unannounced inspections which must not be disclosed to the manufacturer.

Within the context of such unannounced inspections, the notified body shall check an adequate sample from the production or the manufacturing process to verify that the manufactured device is in conformity with the technical documentation and/or design dossier. Prior to the unannounced inspection, the notified body shall specify the relevant sampling criteria and testing procedure.

Instead of, or in addition to, the sampling from the production, the notified body shall take samples of devices from the market to verify that the manufactured device is in

conformity with the technical documentation and/or design dossier. Prior to the sampling, the notified body shall specify the relevant sampling criteria and testing procedure.

The notified body shall provide the manufacturer with an inspection report which shall include, if applicable, the result of the sample check.

4.5. In the case of devices classified as class IIa or class IIb, the surveillance assessment shall also include the assessment of the design documentation within the technical documentation of the device(s) concerned on the basis of further representative sample(s) chosen in accordance with the rationale documented by the notified body in accordance with point (c) of Section 3.3.

In the case of devices classified as class III, the surveillance assessment shall also include a check of the approved parts and/or materials that are essential for the integrity of the device, including, where appropriate, the coherence between the quantities of produced or purchased parts and/or materials and the quantities of finished products.

4.6. The notified body shall ensure that the composition of the assessment team assures experience with the technology concerned, continuous objectivity and neutrality; this shall include a rotation of the members of the assessment team at appropriate intervals. As a general rule, a lead auditor shall not lead and attend an audit for more than three consecutive years in respect to the same manufacturer.

4.7. If the notified body establishes a divergence between the sample taken from the production or from the market and the specifications laid down in the technical documentation or the approved design, it shall suspend or withdraw the relevant certificate or impose restrictions on it.

Chapter II: Design dossier examination

5. Examination of the design of the device, applicable to devices classified as class III

5.1. In addition to the obligations imposed by Section 3, the manufacturer shall lodge with the notified body referred to in Section 3.1 an application for examination of the design dossier relating to the device which he plans to manufacture and which falls into the device category covered by the quality management system referred to in Section 3.

5.2. The application shall describe the design, manufacture and performances of the device in question. It shall include the technical documentation as referred to in Annex II; where the technical documentation is voluminous and/or held in different locations, the manufacturer shall submit a summary technical documentation (STED) and grant access to the full technical documentation upon request.

5.3. The notified body shall examine the application employing staff with proven knowledge and experience regarding the technology concerned. The notified body may require the application to be completed by further tests or other evidence to allow assessment of conformity with the requirements of the Regulation. The

notified body shall carry out adequate physical or laboratory tests in relation to the device or request the manufacturer to carry out such tests.

The notified body shall provide the manufacturer with an EU design-examination report.

5.4. If the device conforms to the relevant provisions of this Regulation, the notified body shall issue an EU design-examination certificate. The certificate shall contain the conclusions of the examination, the conditions of validity, the data needed for identification of the approved design, where appropriate, a description of the intended purpose of the device.

5.5. Changes to the approved design shall receive further approval from the notified body which issued the EU design-examination certificate wherever the changes could affect conformity with the general safety and performance requirements of the Regulation or with the conditions prescribed for use of the device. The applicant shall inform the notified body which issued the EU design-examination certificate of any planned changes to the approved design. The notified body shall examine the planned changes, notify the manufacturer of its decision and provide him with a supplement to the EU design-examination report. The approval of any change to the approved design shall take the form of a supplement to the EU design-examination certificate.

6. Specific procedures

6.1. Procedure in the case of devices incorporating a medicinal substance

(a) Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product within the meaning of Article 1 of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma, with action ancillary to that of the device, the quality, safety and usefulness of the substance shall be verified by analogy with the methods specified in Annex I to Directive 2001/83/EC.

(b) Before issuing an EU design-examination certificate, 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 one of the competent authorities designated by the Member States in accordance with Directive 2001/83/EC (hereinafter referred to as 'medicinal products competent authority') or the European Medicines Agency (hereinafter referred to as 'EMA'), acting particularly through its Committee on Human Medicinal Products in accordance with Regulation (EC) No 726/2004, on the quality and safety of the substance including the benefit/risk of the incorporation of the substance into the device. Where the device incorporates a human blood or plasma derivative or a substance that, if used separately may be considered to be a medicinal product falling exclusively within the scope of the Annex of Regulation (EC) No 726/2004, the notified body shall consult the EMA.

(c) When issuing its opinion, the medicinal products 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.

(d) The opinion of the medicinal products competent authority or the EMA shall be drawn up

- within 150 days after receipt of valid documentation if the substance subject to the consultation is authorised in accordance with Directive 2001/83/EC; or
- within 210 days after receipt of valid documentation in other cases.

(e) The scientific opinion of the medicinal products competent authority or the EMA, and any possible update, shall be included in the documentation of the notified body concerning the device. The notified body shall give due consideration to the views expressed in the scientific opinion when making its decision. The notified body shall not deliver the certificate if the scientific opinion is unfavourable. It shall convey its final decision to the medicinal products competent authority concerned or to the EMA.

(f) Before changes are made with respect to an ancillary substance incorporated in a device, in particular related to its manufacturing process, the manufacturer shall inform the notified body of the changes which shall consult the medicinal products competent authority that was involved in the initial consultation, in order to confirm that the quality and safety of the ancillary substance are maintained. The medicinal products 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 of the addition of the substance in the device. It shall provide its opinion within 30 days after receipt of the valid documentation regarding the changes.

(g) When the medicinal products competent authority that was involved in the initial consultation has obtained information on the ancillary substance, which could have an impact on the established benefit/risk of the addition of the substance in the device, it shall provide the notified body with advice whether this information has an impact on the established benefit/risk of the addition of the substance in the device or not. The notified body shall take the updated scientific opinion into account in reconsidering its assessment of the conformity assessment procedure.

6.2. Procedure in the case of devices manufactured utilising tissues or cells of human or animal origin, or their derivatives, that are non-viable or rendered non-viable

(a) For devices manufactured utilising tissues or cells of human origin, or their derivatives, that are covered by this Regulation in accordance with point (e) of Article 1(2), the notified body shall, prior to issuing an EU design-examination certificate, submit to the competent authority designated by the Member State in accordance with Directive 2004/23/EC (hereinafter referred to as 'human tissues and cells competent authority') in which it is established a summary of the preliminary conformity assessment which shall, among others, provide information about the non-viability of the human tissues or cells, their

donation, procurement and testing and the benefit/risk of the incorporation of the human tissues or cells into the device.

(b) Within 90 days after receipt of valid documentation, the human tissues and cells competent authority may submit comments on aspects related to the donation, procurement and testing and/or the benefit/risk of the incorporation of the human tissues or cells into the device.

(c) The notified body shall give due consideration to any comments received in accordance with point (b). It shall convey to the human tissues and cells competent authority an explanation as regards this consideration, including any due justification not to follow the comment received, and its final decision regarding the conformity assessment in question. The comments of the human tissues and cells competent authority shall be included in the documentation of the notified body concerning the device.

7. Batch verification in the case of devices incorporating a medicinal substance which, if used separately, may be considered to be a medicinal product derived from human blood or human plasma referred to in Article 1(4)

Upon completing the manufacture of each batch of devices that incorporate a medicinal substance which, if used separately, may be considered to be a medicinal product derived from human blood or human plasma referred to in the first subparagraph of Article 1(4), 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 or plasma derivative used in the device, issued by a State laboratory or a laboratory designated for that purpose by a Member State in accordance with Article 114(2) of Directive 2001/83/EC.

Chapter III: Administrative provisions

8. The manufacturer or his authorised representative shall, for a period ending at least five years, and in the case of implantable devices at least 15 years, after the last device has been placed on the market, keep at the disposal of the competent authorities:

- the declaration of conformity,
- the documentation referred to in the fourth indent of Section 3.1 and in particular the data and records arising from the procedures referred to in point (c) of Section 3.2,
- the changes referred to in Section 3.4,
- the documentation referred to in Section 5.2, and
- the decisions and reports from the notified body as referred to in Sections 3.3, 4.3, 4.4. 5.3, 5.4. and 5.5.

9. Each Member State shall make provision that this documentation is kept at the disposal of the competent authorities for the period indicated in the first sentence of the preceding paragraph in case the manufacturer, or his authorised representative,

established within its territory goes bankrupt or ceases its business activity prior to the end of this period.

ANNEX IX

CONFORMITY ASSESSEMENT BASED ON TYPE EXAMINATION

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

2. Application

The application shall include:

- the name and address of the manufacturer and, if the application is lodged by the authorised representative, the name and address of the authorised representative,

- the technical documentation referred to in Annex II needed to assess the conformity of the representative sample of the production in question, hereinafter referred to as the 'type', with the requirements of this Regulation; where the technical documentation is voluminous and/or held in different locations, the manufacturer shall submit a summary technical documentation (STED) and grant access to the full technical documentation upon request. The applicant shall 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, or information about any previous application for the same type that has been refused by another notified body.

3. Assessment

The notified body shall:

3.1. examine and assess the technical documentation and verify that the type has been manufactured in conformity with that documentation; it shall also record the items designed in conformity with the applicable specifications of the standards referred to in Article 6 or CTS , as well as the items not designed on the basis of the relevant provisions of the abovementioned standards;

3.2. carry out or arrange for the appropriate assessments and the physical or laboratory tests necessary to verify whether the solutions adopted by the manufacturer meet the general safety and performance requirements of this Regulation if the standards referred to in Article 6 or CTS have not been applied; if the device is to be connected to other device(s) in order to operate as intended, proof shall be provided that it conforms to the general safety and performance requirements when connected to any such device(s) having the characteristics specified by the manufacturer;

3.3. carry out or arrange for the appropriate assessments and the physical or laboratory tests necessary to verify whether, if the manufacturer has chosen to apply the relevant standards, these have actually been applied;

3.4. agree with the applicant on the place where the necessary assessments and tests will be carried out.

4. Certificate

If the type conforms to the provisions of this Regulation, the notified body shall issue an EU type-examination certificate. The certificate shall contain the name and address of the manufacturer, the conclusions of the assessment, the conditions 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 kept by the notified body.

5. Changes to the type

5.1. The applicant shall inform the notified body which issued the EU type-examination certificate of any planned change to the approved type.

5.2. Changes to the approved product shall receive further approval from the notified body which issued the EU type-examination certificate wherever the changes may affect conformity with the general safety and performance requirements or with the conditions prescribed for use of the product. The notified body shall examine the planned changes, notify the manufacturer of its decision and provide him with a supplement to the EU type-examination report. The approval of any change to the approved type shall take the form of a supplement to the initial EU type-examination certificate.

6. Specific procedures

The provisions regarding the specific procedures in the case of devices incorporating a medicinal substance, or devices manufactured utilising tissues or cells of human or animal origin, or their derivatives, that are non-viable or rendered non-viable set out in Annex VIII, Section 6, apply with the proviso that any reference to an EU design-examination certificate shall be understood as reference to an EU type-examination certificate.

7. Administrative provisions

The manufacturer or his authorised representative shall, for a period ending at least five years, and in the case of implantable devices at least 15 years, after the last device has been placed on the market, keep at the disposal of the competent authorities:

– the documentation referred to in the second indent of Section 2,

– the changes referred to in Section 5,

– copies of EU type-examination certificates and their additions.

Section 9 of Annex VIII shall apply.

ANNEX X

CONFORMITY ASSESSEMENT BASED ON PRODUCT CONFORMITY VERIFICATION

1. The objective of the conformity assessment based on product conformity verification is to ensure that devices conform to the type for which an EU type-examination certificate has been issued and meet the provisions of this Regulation which apply to them.

2. Where an EU type-examination certificate has been issued in accordance with Annex IX, the manufacturer can either apply the procedure set out in part A (production quality assurance) or the procedure set out in part B (product verification).

3. By way of derogation from Sections 1 and 2, this Annex can also be applied by manufacturers of devices classified as class IIa coupled with the drawing up of a technical documentation as set out in Annex II.

PART A: PRODUCTION QUALITY ASSURANCE

1. The manufacturer shall ensure application of the quality management system approved for the manufacture of the devices 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 manufacturer who fulfils the obligations imposed by Section 1 shall draw up and keep an EU declaration of conformity in accordance with Article 17 and Annex III for the device model covered by the conformity assessment procedure. By issuing an EU declaration of conformity the manufacturer ensures and declares that the devices concerned conform to the type described in the EU type-examination certificate and meet the provisions of this Regulation which apply to them.

3. Quality management system

3.1. The manufacturer shall lodge an application for assessment of his quality management system with a notified body. The application shall include:

- all elements listed in Section 3.1 of Annex VIII,
- the technical documentation as referred to in Annex II for the types approved; where the technical documentation is voluminous and/or held in different locations, the manufacturer shall submit a summary technical documentation (STED) and grant access to the full technical documentation upon request;
- a copy of the EU-type examination certificates referred to in Section 4 of Annex IX; if the EU-type examination certificates have been issued by the same notified body with which the application is lodged, a reference to the technical documentation and the certificates issued is sufficient.

3.2. Application of the quality management system shall ensure that the devices conform to the type described in the EU type-examination certificate and to the provisions of this Regulation which apply to them at every stage. All the elements, requirements and provisions adopted by the manufacturer for his quality management system shall be documented in a systematic and orderly manner in the form of written policies and procedures such as quality programmes, quality plans, quality manuals and quality records.

It shall, in particular, include an adequate description of all elements listed in points (a), (b), (d) and (e) of Section 3.2 of Annex VIII.

3.3. The provisions of points (a) and (b) of Section 3.3 of Annex VIII apply.

If the quality management system ensures that the devices conform to the type described in the EU type-examination certificate and conforms to the relevant provisions of this Regulation, the notified body shall issue an EU quality assurance certificate. The decision shall be notified to the manufacturer. It shall contain the conclusions of the inspection and a reasoned assessment.

3.4. The provisions of Section 3.4 Annex VIII apply.

4. Surveillance

The provisions of Section 4.1, the first, second and fourth indents of Section 4.2, Section 4.3, Section 4.4, Section 4.6 and Section 4.7 of Annex VIII apply.

In the case of devices classified as class III, the surveillance shall also include a check of the coherence between the quantity of produced or purchased raw material or crucial components approved for the type and the quantity of finished products.

5. Batch verification in the case of devices incorporating a medicinal substance which, if used separately, may be considered to be a medicinal product derived from human blood or human plasma referred to in Article 1(4)

Upon completing the manufacture of each batch of devices that incorporate a medicinal substance which, if used separately, may be considered to be a medicinal product derived from human blood or human plasma referred to in the first subparagraph of Article 1(4), 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 or plasma derivative used in the device, issued by a State laboratory or a laboratory designated for that purpose by a Member State in accordance with Article 114(2) of Directive 2001/83/EC.

6. Administrative provisions

The manufacturer or his authorised representative shall, for a period ending at least five years, and in the case of implantable devices at least 15 years, after the last device has been placed on the market, keep at the disposal of the competent authorities:

– the declaration of conformity,

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

– the documentation referred to in the seventh indent of Section 3.1 of Annex VIII, including the EU type-examination certificate referred to in Annex IX,

– the changes referred to in Section 3.4 of Annex VIII, and

– the decisions and reports from the notified body as referred to in Sections 3.3, 4.3 and 4.4 of Annex VIII.

Section 9 of Annex VIII shall apply.

7. Application to devices classified as class IIa

7.1. By way of derogation from Section 2, by virtue of the EU declaration of conformity the manufacturer ensures and declares that the devices in class IIa are manufactured in conformity with the technical documentation referred to in Annex II and meet the requirements of this Regulation which apply to them.

7.2. For devices in class IIa the notified body shall assess, as part of the assessment in Section 3.3, on a representative basis, the technical documentation as referred in Annex II for compliance with the provisions of this Regulation; where the technical documentation is voluminous and/or held in different locations, the manufacturer shall submit a summary technical documentation (STED) and grant access to the full technical documentation upon request.

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

7.3. If the assessment in accordance with Section 7.2. confirms that the devices in class IIa conform to the technical documentation referred to in Annex II and meet the requirements of this Regulation which apply to them, the notified body shall issue a certificate pursuant to this section of this Annex.

7.4. Further samples shall be assessed by the notified body as part of the surveillance assessment referred to in Section 4.

7.5. By way of derogation from Section 6, the manufacturer or his authorised representative shall, for a period ending at least five years after the last device has been placed on the market, keep at the disposal of the competent authorities:

– the declaration of conformity,

– the technical documentation referred to in Annex II,

– the certificate referred to in Section 7.3.

Section 9 of Annex VIII shall apply.

PART B: PRODUCT VERIFICATION

1. Product verification is the procedure whereby after examination of every manufactured device the manufacturer, by issuing a EU declaration of conformity in accordance with Article 17 and Annex III, ensures and declares that the devices which have been subject to the procedure set out in Sections 4 and 5 conform to the type described in the EU type-examination certificate and meet the requirements of this Regulation which apply to them.

2. The manufacturer shall take all the measures necessary to ensure that the manufacturing process produces devices which conform to the type described in the EU type-examination certificate and to the requirements of the Regulation which apply to them. Before the start of manufacture, the manufacturer shall prepare documents defining the manufacturing process, in particular as regards sterilisation 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 EU type-examination certificate and with the requirements of this Regulation which apply to them.

   In addition, for devices placed on the market in sterile condition, and only for those aspects of the manufacturing process designed to secure and maintain sterility, the manufacturer shall apply the provisions of Sections 3 and 4 of Part A of this Annex.

3. The manufacturer shall undertake to institute and keep up to date a post-market surveillance plan, including a post-market clinical follow-up, and the procedures ensuring compliance with the obligations emanating from the provisions on vigilance set out in Articles 61 to 66.

4. The notified body shall carry out the appropriate examinations and tests in order to verify the conformity of the device with the requirements of the Regulation by examining and testing every product as specified in Section 5.

   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 device is examined individually and the appropriate physical or laboratory tests defined in the relevant standard(s) referred to in Article 6 or equivalent tests shall be carried out in order to verify, where appropriate, the conformity of the devices with the type described in the EU type-examination certificate and with the requirements of this Regulation which apply to them.

5.2. The notified body shall affix, or have affixed its identification number to each approved device and shall draw up an EU product verification certificate relating to the tests carried out.

6. Batch verification in the case of devices incorporating a medicinal substance which, if used separately, may be considered to be a medicinal product derived from human blood or human plasma referred to in Article 1(4)