appear in the product specification made available to the user, e.g. in brochures, catalogues and the like.

1.2. Reference to previous and similar generations of the device

(a) an overview of the manufacturer's previous generation(s) of the device, if such exist;

(b) an overview of the manufacturer's similar devices available on the EU or international markets, if such exist.

2. INFORMATION SUPPLIED BY THE MANUFACTURER

(a) a complete set of

- the label(s) on the device and on its packaging;
- the instructions for use;

(b) a list of the language variants for the Member States where the device is envisaged to be marketed.

3. DESIGN AND MANUFACTURING INFORMATION

(a) Information to allow a general understanding of the design stages applied to the device and the manufacturing processes such as production, assembly, final product testing, and packaging of the finished device. More detailed information needs to be provided for the audit of the quality management system or other applicable conformity assessment procedures;

(b) identification of all sites, including suppliers and sub-contractors, where design and manufacturing activities are performed.

4. GENERAL SAFETY AND PERFORMANCE REQUIREMENTS

The documentation shall contain information regarding the solutions adopted to meet the general safety and performance requirements laid down in Annex I. This information may take the form of a checklist identifying

(a) the general safety and performance requirements that apply to the device and why others do not apply;

(b) the method(s) used to demonstrate conformity with each applicable general safety and performance requirement;

(c) the harmonised standards or CTS applied or other method(s) employed;

(d) the precise identity of the controlled documents offering evidence of conformity with each harmonised standard, CTS or other method employed to demonstrate conformity with the general safety and performance requirements.

This information shall incorporate a cross-reference to the location of such evidence within the full technical documentation and, if applicable, the summary technical documentation.

5. RISK/BENEFIT ANALYSIS AND RISK MANAGEMENT

The documentation shall contain a summary of

(a) the risk/benefit analysis referred to in Sections 1 and 5 of Annex I, and

(b) the solutions adopted and the results of the risk management referred to in Section 2 of Annex I.

6. PRODUCT VERIFICATION AND VALIDATION

The documentation shall contain the results of verification and validation testing and/or studies undertaken to demonstrate conformity of the device with the requirements of this Regulation and in particular the applicable general safety and performance requirements.

6.1. Pre-clinical and clinical data

(a) results of (engineering, laboratory, simulated use, animal) tests and evaluation of published literature applicable to the device or substantially similar devices regarding the pre-clinical safety of the device and its conformity with the specifications;

(b) detailed information regarding test design, complete test or study protocols, methods of data analysis, in addition to data summaries and test conclusions regarding

- biocompatibility (identifying all materials in direct or indirect contact with the patient or user);
- physical, chemical and microbiological characterisation;
- electrical safety and electromagnetic compatibility;
- software verification and validation (describing the software design and development process and evidence of the validation of the software, as used in the finished device. This information should typically include the summary results of all verification, validation and testing performed both in-house and in a simulated or actual user environment prior to final release. It should also address all of the different hardware configurations and, where applicable, operating systems identified in the information supplied by the manufacturer);
- stability/shelf life.

Where applicable, conformity with the provisions of Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the

harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances[63] shall be demonstrated.

Where no new testing has been undertaken, the documentation shall incorporate a rationale for that decision, e.g. biocompatibility testing on the identical materials was conducted when these were incorporated in a previous version of the device that has been legally placed on the market or put into service;

(c) the report on the clinical evaluation in accordance with Article 49(5) and Part A of Annex XIII;

(d) the PMCF plan and PMCF evaluation report in accordance with Part B of Annex XIII or any justification why a PMCF is not deemed necessary or appropriate.

6.2. Additional information in specific cases

(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, referred to in the first subparagraph of Article 1(4), a statement indicating this fact. In this case, the documentation shall identify the source of that substance and contain the data of the tests conducted to assess its safety, quality and usefulness, taking account of the intended purpose of the device.

(b) Where a device is manufactured utilising tissues or cells of human or animal origin, or their derivatives, that are covered by this Regulation in accordance with point (e) of Article 1(2), a statement indicating this fact. In this case, the documentation shall identify all materials of human or animal origin used and provide detailed information concerning the conformity with Sections 10.1. or 10.2., respectively, of Annex I.

(c) In the case of devices placed on the market in a sterile or defined microbiological condition a description of the environmental conditions for the relevant manufacturing steps. In the case of devices placed on the market in a sterile condition, a description of the methods used, including the validation reports, with respect to packaging, sterilisation and maintenance of sterility. The validation report shall address bioburden testing, pyrogen testing and, if applicable, testing for sterilant residues.

(d) In the case of devices placed on the market with a measuring function, a description of the methods used in order to ensure the accuracy as given in the specifications.

(e) If the device is to be connected to other device(s) in order to operate as intended, a description of this combination including proof that it conforms to

---

63 OJ L 50, 20.2.2004, p. 44.

the general safety and performance requirements when connected to any such device(s) having regard to the characteristics specified by the manufacturer.

ANNEX III

EU DECLARATION OF CONFORMITY

1. Name, registered trade name or registered trade mark of the manufacturer and, if applicable, his authorised representative, and the address of their registered place of business where they can be contacted and their location be established;

2. A statement that the declaration of conformity is issued under the sole responsibility of the manufacturer;

3. The UDI device identifier as referred to in item (i) of point (a) of Article 24(1) as soon as identification of the device that is covered by the declaration shall be based on a UDI system;

4. Product or trade name, product code, catalogue number or other unambiguous reference allowing identification and traceability of the device that is covered by the declaration (it may include a photograph, where appropriate). Except for the product or trade name, the information allowing identification and traceability may be provided by the device identifier referred to in point 3;

5. Risk class of the device in accordance with Annex VII;

6. A statement that the device that is covered by the present declaration is in conformity with this Regulation and, if applicable, with other relevant Union legislation that make provision for the issuing of a declaration of conformity;

7. References to the relevant harmonised standards or CTS used in relation to which conformity is declared;

8. Where applicable, name and identification number of the notified body, description of the conformity assessment procedure performed and identification of the certificate(s) issued;

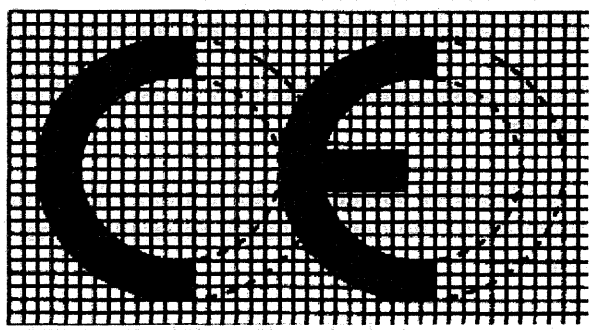
9. Where applicable, additional information;

10. Place and date of issue, name and function of the person who signs as well as indication for and on behalf of whom he/she signs, signature.

ANNEX IV

CE MARKING OF CONFORMITY

1. The CE marking shall consist of the initials 'CE' taking the following form:



2. If the CE marking is reduced or enlarged the proportions given in the above graduated drawing shall be respected.

3. The various components of the CE marking shall have substantially the same vertical dimension, which may not be less than 5 mm. This minimum dimension may be waived for small-scale devices.

ANNEX V

INFORMATION TO BE SUBMITTED WITH THE REGISTRATION OF DEVICES AND ECONOMIC OPERATORS IN ACCORDANCE WITH ARTICLE 25

AND

DATA ELEMENTS OF THE UDI DEVICE IDENTIFIER IN ACCORDANCE WITH ARTICLE 24

PART A
INFORMATION TO BE SUBMITTED WITH THE REGISTRATION OF DEVICES IN ACCORDANCE WITH ARTICLE 25

Manufacturers or, when applicable, authorised representatives, and, when applicable, importers shall submit the following information:

1. economic operator's role (manufacturer, authorised representative, or importer),

2. name, address and contact details of the economic operator,

3. where submission of information is completed by another person on behalf of any of the economic operators mentioned under point 1, the name, address and contact details of this person,

4. UDI device identifier, or where identification of the device is not yet based on a UDI system, the data elements laid down in points 5 to 21 of Part B of this Annex,

5. type, number and expiry date of certificate and name or identification number of the notified body that has issued the certificate (and link to the information on the certificate entered by the notified body in the electronic system on certificates),

6. Member State where the device shall or has been placed on the market in the Union,

7. in case of devices classified as classes IIa, IIb or III: Member States where the device is or shall be made available,

8. in case of imported device: country of origin,

9. risk class of the device,

10. reprocessed single use device (y/n),

11. presence of a substance which, if used separately, may be considered to be a medicinal product and name of this substance,

12. presence of a substance which, if used separately, may be considered a medicinal product derived from human blood or human plasma and name of this substance,

13. presence of human tissues or cells, or their derivatives (y/n),

14. presence of animal tissues or cells, or their derivatives, as referred to in Commission Regulation (EU) No 722/2012 (y/n),

15. where applicable, single identification number of the clinical investigation(s) conducted in relation to the device (or link to the clinical investigation registration in the electronic system regarding clinical investigations),

16. in case of devices listed in Annex XV, specification whether the intended purpose of the device is other than a medical purpose,

17. in case of devices designed and manufactured by another legal or natural person as referred in Article 8(10), the name, address and contact details of that legal or natural person,

18. in case of devices classified as class III or implantable devices, the summary of safety and clinical performance,

19. status of the device (on the market, no longer manufactured, withdrawn from the market, recalled).

PART B

DATA ELEMENTS OF THE UDI DEVICE IDENTIFIER IN ACCORDANCE WITH ARTICLE 24

The UDI device identifier shall provide access to the following information related to the manufacturer and the device model:

1. quantity per package configuration,

2. if applicable, alternative or additional identifier(s),

3. the way how the device production is controlled (expiration date or manufacturing date, lot or batch number, serialisation number),

4. if applicable, the unit of use device identifier (when a UDI is not assigned to the device at the level of its unit of use, a 'unit of use' device identifier shall be assigned to associate the use of a device with a patient),

5. name and address of the manufacturer (as indicated on the label),

6. if applicable, name and address of the authorised representative (as indicated on the label),

7. Global Medical Device Nomenclature (GMDN) code or internationally recognised nomenclature code,

8. if applicable, trade/brand name,

9. if applicable, device model, reference, or catalogue number,

10. if applicable, clinical size (including volume, length, gauge, diameter),

11. additional product description (optional),

12. if applicable, storage and/or handling conditions (as indicated on the label or in the instructions for use),

13. if applicable, additional trade names of the device,

14. labelled as single use device (y/n),

15. if applicable, restricted number of reuses,

16. device packaged sterile (y/n),

17. need for sterilisation before use (y/n),

18. labelled as containing latex (y/n),

19. labelled as containing DEHP (y/n),

20. URL for additional information, e.g. electronic instructions for use (optional),

21. if applicable, critical warnings or contraindications.

ANNEX VI

MINIMUM REQUIREMENTS TO BE MET BY NOTIFIED BODIES

1. ORGANISATIONAL AND GENERAL REQUIREMENTS

1.1. Legal status and organisational structure

1.1.1. A notified body shall be established under the national law of a Member State, or under the law of a third country with which the Union has concluded an agreement in this respect, and shall have full documentation of its legal personality and status. This shall include information about ownership and the legal or natural persons exercising control over the notified body.

1.1.2. If the notified body is a legal entity that is part of a larger organisation, the activities of this organisation as well as its organisational structure and governance, and the relationship with the notified body shall be clearly documented.

1.1.3. If the notified body wholly or partly owns legal entities established in a Member State or in a third country, the activities and responsibilities of those entities, as well as their legal and operational relationships with the notified body, shall be clearly defined and documented.

1.1.4. The organisational structure, distribution of responsibilities and operation of the notified body shall be such that it assures confidence in the performance and results of the conformity assessment activities conducted.

The organisational structure and the functions, responsibilities and authority of its top-level management and of other personnel with influence upon the performance and results of the conformity assessment activities shall be clearly documented.

1.2. Independence and impartiality

1.2.1. The notified body shall be a third-party body that is independent of the manufacturer of the product in relation to which it performs conformity assessment activities. The notified body shall also be independent of any other economic operator having an interest in the product as well as of any competitor of the manufacturer.

1.2.2. The notified body shall be organised and operated so as to safeguard the independence, objectivity and impartiality of its activities. The notified body shall have procedures in place that effectively ensure identification, investigation and resolution of any case in which a conflict of interests may arise, including involvement in consultancy services in the field of medical devices prior to taking up employment with the notified body.

1.2.3. The notified body, its top-level management and the personnel responsible for carrying out the conformity assessment tasks shall not

– be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the products, nor the authorised representative of any of those

parties. This shall not preclude the purchase and use of assessed products that are necessary for the operations of the notified body (e.g. measuring equipment), the conduct of the conformity assessment or the use of such products for personal purposes;

– be directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of the products which they assess, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified;

– offer or provide any service which may jeopardise the confidence in their independence, impartiality or objectivity. In particular, they shall not offer or provide consultancy services to the manufacturer, his authorised representative, a supplier or a commercial competitor as regards the design, construction, marketing or maintenance of the products or processes under assessment. This does not preclude general training activities relating to medical device regulations or related standards that are not client specific.

1.2.4. The impartiality of the notified bodies, of their top level management and of the assessment personnel shall be guaranteed. The remuneration of the top level management and assessment personnel of a notified body shall not depend on the results of the assessments.

1.2.5. If a notified body is owned by a public entity or institution, independence and absence of any conflict of interests must be ensured and documented between, on the one hand, the national authority responsible for notified bodies and/or competent authority and, on the other hand, the notified body.

1.2.6. The notified body shall ensure and document that the activities of its subsidiaries or subcontractors, or of any associated body, do not affect its independence, impartiality or objectivity of its conformity assessment activities.

1.2.7. The notified body shall operate in accordance with a set of consistent, fair and reasonable terms and conditions, taking into account the interests of small and medium-sized enterprises as defined by Commission Recommendation 2003/361/EC.

1.2.8. The requirements of this section in no way preclude exchanges of technical information and regulatory guidance between a notified body and a manufacturer seeking their conformity assessment.

1.3. Confidentiality

The personnel of a notified body shall observe professional secrecy with regard to all information obtained in carrying out their tasks under this Regulation, except in relation to the national authorities responsible for notified bodies, competent authorities or the Commission. Proprietary rights shall be protected. To this end, the notified body shall have documented procedures in place.

1.4. Liability

The notified body shall take out appropriate liability insurance that corresponds to the conformity assessment activities for which it is notified, including the possible suspension, restriction or withdrawal of certificates, and the geographic scope of its activities, unless liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment.

1.5. Financial requirements

The notified body shall have at its disposal the financial resources required to conduct its conformity assessment activities and related business operations. It shall document and provide evidence of its financial capacity and its sustainable economic viability, taking into account specific circumstances during an initial start-up phase.

1.6. Participation in coordination activities

1.6.1. The notified body shall participate in, or ensure that its assessment personnel is informed of the relevant standardisation activities and the activities of the notified body coordination group and that its assessment and decision making personnel are informed of all relevant legislation, guidance and best practice documents adopted in the framework of this Regulation.

1.6.2. The notified body shall adhere to a code of conduct, addressing among other things, ethical business practices for notified bodies in the field of medical devices that is accepted by the national authorities responsible for notified bodies. The code of conduct shall provide for a mechanism of monitoring and verification of its implementation by notified bodies.

2. QUALITY MANAGEMENT REQUIREMENTS

2.1. The notified body shall establish, document, implement, maintain and operate a quality management system that is appropriate to the nature, area and scale of its conformity assessment activities and capable of supporting and demonstrating the consistent achievement of the requirements of this Regulation.

2.2. The quality management system of the notified body shall at least address the following:

- policies for assignment of personnel to activities and their responsibilities;
- decision-making process in accordance with the tasks, responsibilities and role of the top-level management and other notified body personnel;
- control of documents;
- control of records;
- management review;
- internal audits;

– corrective and preventive actions;

– complaints and appeals.

3. RESOURCE REQUIREMENTS

3.1. General

3.1.1. A notified body shall be capable of carrying out all the tasks assigned to it by this Regulation with the highest degree of professional integrity and the requisite technical competence in the specific field, whether those tasks are carried out by the notified body itself or on its behalf and under its responsibility.

In particular, it shall have the necessary personnel and shall possess or have access to all equipment and facilities needed to perform properly the technical and administrative tasks entailed in the conformity assessment activities in relation to which it has been notified.

This presupposes the availability within its organisation of sufficient scientific personnel who possess experience and knowledge sufficient to assess the medical functionality and performance of devices for which it has been notified, having regard to the requirements of this Regulation and, in particular, those set out in Annex I.

3.1.2. At all times and for each conformity assessment procedure and each kind or category of products in relation to which it has been notified, a notified body shall have within its organisation the necessary administrative, technical and scientific personnel with technical knowledge and sufficient and appropriate experience relating to medical devices and the corresponding technologies to perform the conformity assessment tasks, including the assessment of clinical data.

3.1.3. The notified body shall clearly document the extent and the limits of the duties, responsibilities and authorities in relation of the personnel involved in conformity assessment activities and inform the personnel concerned about it.

3.2. Qualification criteria in relation to personnel

3.2.1. The Notified Body shall establish and document qualification criteria and procedures for selection and authorisation of persons involved in conformity assessment activities (knowledge, experience and other competence required) and the required training (initial and ongoing training). The qualification criteria shall address the various functions within the conformity assessment process (e.g. auditing, product evaluation/testing, design dossier/file review, decision-making) as well as the devices, technologies and areas (e.g. biocompatibility, sterilisation, tissues and cells of human and animal origin, clinical evaluation) covered by the scope of designation.

3.2.2. The qualification criteria shall refer to the scope of the notified body's designation in accordance with the scope description used by the Member State for the notification referred to in Article 33, providing sufficient level of detail for the required qualification within the subdivisions of the scope description.

Specific qualification criteria shall be defined for the assessment of biocompatibility aspects, clinical evaluation and the different types of sterilisation processes.

3.2.3. The personnel responsible for authorising other personnel to perform specific conformity assessment activities and the personnel with overall responsibility for the final review and decision-making on certification shall be employed by the notified body itself and shall not be subcontracted. These personnel altogether shall have proven knowledge and experience in the following:

- Union medical devices legislation and relevant guidance documents;
- the conformity assessment procedures in accordance with this Regulation;
- a broad base of medical device technologies, the medical device industry and the design and manufacture of medical devices;
- the notified body's quality management system and related procedures;
- the types of qualifications (knowledge, experience and other competence) required for carrying out conformity assessments in relation to medical devices as well as the relevant qualification criteria;
- training relevant to personnel involved in conformity assessment activities in relation to medical devices;

– the ability to draw up certificates, records and reports demonstrating that the conformity assessments have been appropriately carried out.

3.2.4. *Notified bodies shall have available personnel with clinical expertise. This personnel shall be integrated in the notified body's decision-making process in a steady way in order to:*

– identify when specialist input is required for the assessment of the clinical evaluation conducted by the manufacturer and identify appropriately qualified experts;

– appropriately train external clinical experts in the relevant requirements of this Regulation, delegated and/or implementing acts, harmonised standards, CTS and guidance documents and ensure that the external clinical experts are fully aware of the context and implication of their assessment and advice provided;

– be able to discuss the clinical data contained within the manufacturer's clinical evaluation with the manufacturer and with external clinical experts and to appropriately guide external clinical experts in the assessment of the clinical evaluation;

– be able to scientifically challenge the clinical data presented, and the results of the external clinical experts' assessment of the manufacturer's clinical evaluation;

– be able to ascertain the comparability and consistency of the clinical assessments conducted by clinical experts;

– be able to make an objective clinical judgement about the assessment of the manufacturer's clinical evaluation and make a recommendation to the notified body's decision maker.

3.2.5. *The personnel responsible for carrying out product related review (e.g. design dossier review, technical documentation review or type examination including aspects such as clinical evaluation, biological safety, sterilisation, software validation) shall have the following proven qualification:*

– successful completion of a university or a technical college degree or equivalent qualification in relevant studies, e.g. medicine, natural science or engineering;

– four years professional experience in the field of healthcare products or related sectors (e.g. industry, audit, healthcare, research experience) whilst two years of this experience shall be in the design, manufacture, testing or use of the device or technology to be assessed or related to the scientific aspects to be assessed;

– appropriate knowledge of the general safety and performance requirements laid down in Annex I as well as related delegated and/or implementing acts, harmonised standards, CTS and guidance documents;

- appropriate knowledge and experience of risk management and related medical device standards and guidance documents;

- appropriate knowledge and experience of the conformity assessment procedures laid down in Annexes VIII to X, in particular of those aspects for which they are authorised, and adequate authority to carry out those assessments.

3.2.6. The personnel responsible for carrying out audits of the manufacturer's quality management system shall have the following proven qualification:

- successful completion of a university or a technical college degree or equivalent qualification in relevant studies, e.g. medicine, natural science or engineering;

- four years professional experience in the field of healthcare products or related sectors (e.g. industry, audit, healthcare, research experience) whilst two years of this experience shall be in the area of quality management;

- appropriate knowledge of the medical devices legislation as well as related delegated and/or implementing acts, harmonised standards, CTS and guidance documents;

- appropriate knowledge and experience of risk management and related medical device standards and guidance documents;

- appropriate knowledge of quality management systems and related standards and guidance documents

- appropriate knowledge and experience of the conformity assessment procedures laid down in Annexes VIII to X, in particular of those aspects for which they are authorised, and adequate authority to carry out the audits;

- training in auditing techniques enabling them to challenge quality management systems.

3.3. Documentation of qualification, training and authorisation of personnel

3.3.1. The notified body shall have a process in place to fully document the qualification of each personnel involved in conformity assessment activities and the satisfaction of the qualification criteria referred to in Section 3.2. Where in exceptional circumstances the fulfilment of the qualification criteria set out in Section 3.2 cannot be fully demonstrated, the notified body shall appropriately justify the authorisation of these personnel to carry out specific conformity assessment activities.

3.3.2. For its personnel referred to in Sections 3.2.3 to 3.2.6, the notified body shall establish and maintain up to date:

- a matrix detailing the responsibilities of the personnel in respect of the conformity assessment activities;

– records demonstrating the required knowledge and experience for the conformity assessment activity for which they are authorised.

3.4. Subcontractors and external experts

3.4.1. Without prejudice to the limitations emanating from Section 3.2., notified bodies may subcontract clearly defined parts of the conformity assessment activities. The subcontracting of the auditing of quality management systems or of product related reviews as a whole is not allowed.

3.4.2. Where a notified body subcontracts conformity assessment activities either to an organisation or an individual, it shall have a policy describing the conditions under which subcontracting may take place. Any subcontracting or consultation of external experts shall be properly documented and be subject to a written agreement covering, among others, confidentiality and conflict of interests.

3.4.3. Where subcontractors or external experts are used in the context of the conformity assessment, in particular regarding novel, invasive and implantable medical devices or technologies, the notified body shall have adequate own competence in each product area for which it is designated to lead the conformity assessment, to verify the appropriateness and validity of expert opinions and make the decision on the certification.

3.4.4. The notified body shall establish procedures for assessing and monitoring the competence of all subcontractors and external experts used.

3.5. Monitoring of competences and training

3.5.1. The notified body shall appropriately monitor the satisfactory performance of the conformity assessment activities by its personnel.

3.5.2. It shall review the competence of its personnel and identify training needs in order to maintain the required level of qualification and knowledge.

4. PROCESS REQUIREMENTS

4.1. The notified body's decision-making process shall be clearly documented, including the process for the issue, suspension, reinstatement, withdrawal or refusal of conformity assessment certificates, their modification or restriction and the issue of supplements.

4.2. The notified body shall have in place a documented process for the conduct of the conformity assessment procedures for which it is designated taking into account their respective specificities, including legally required consultations, in respect of the different categories of devices covered by the scope of notification, ensuring transparency and the ability of reproduction of those procedures.

4.3. The notified body shall have in place documented procedures covering at least:

– the application for conformity assessment by a manufacturer or by an authorised representative,

– the processing of the application, including the verification of the completeness of the documentation, the qualification of the product as device and its classification,

– the language of the application, of the correspondence and of the documentation to be submitted,

– the terms of the agreement with the manufacturer or authorised representative,

– the fees to be charged for conformity assessment activities,

– the assessment of relevant changes to be submitted for prior approval,

– the planning of surveillance,

– the renewal of certificates.

ANNEX VII

CLASSIFICATION CRITERIA

I. SPECIFIC DEFINITIONS FOR THE CLASSIFICATION RULES

1. DURATION OF USE

1.1. 'Transient' means normally intended for continuous use for less than 60 minutes.

1.2. 'Short term' means normally intended for continuous use for between 60 minutes and 30 days.

1.3. 'Long term' means normally intended for continuous use for more than 30 days.

2. INVASIVE AND ACTIVE DEVICES

2.1. 'Body orifice' means any natural opening in the body, as well as the external surface of the eyeball, or any permanent artificial opening, such as a stoma or permanent tracheotomy.

2.2. 'Surgically invasive device' means

(a) 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;

(b) a device which produces penetration other than through a body orifice.

2.3. 'Reusable surgical instrument' means an instrument intended for surgical use by cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar procedures, without connection to any active medical device and which are intended by the manufacturer to be reused after appropriate procedures for cleaning and/or sterilization have been carried out.

2.4. 'Active therapeutic device' means 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 disability.

2.5. 'Active device intended for diagnosis' means 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.

2.6. 'Central circulatory system' means the following blood 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.

2.7. 'Central nervous system' means the brain, meninges and spinal cord.

II. Implementing rules for the classification rules

1. Application of the classification rules shall be governed by the intended purpose of the devices.

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

3. Stand alone software, which drives a device or influences the use of a device, falls automatically in the same class as the device. If stand alone software is independent of any other device, it is classified in its own right.

4. If the device is not intended to be used solely or principally in a specific part of the body, it shall be considered and classified on the basis of the most critical specified use.

5. If several rules, or within the same rule several sub-rules, apply to the same device based on the device's intended purpose, the strictest rule and/or sub-rule resulting in the higher classification shall apply.

6. In calculating the duration referred to in Chapter I, Section 1 continuous use means:

   (a) The entire duration of use of the same device without regard to temporary interruption of use during a procedure or temporary removal for purposes such as cleaning or disinfection of the device. Whether the interruption of use or the removal is temporary shall be established in relation to the duration of the use prior and after the period when the use is interrupted or the device removed.

   (b) The accumulated use of a device that is intended by the manufacturer to be replaced immediately with another of the same type.

7. A device is considered to allow direct diagnosis when it provides the diagnosis of the disease or condition by itself or when it provides decisive information for the diagnosis.

III. Classification rules

3. NON-INVASIVE DEVICES

3.1. Rule 1

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