

UNOFFICIAL TRANSLATION

**Decision of the Ministry of Social Affairs and Health  
concerning active implantable medical devices**

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**UNOFFICIAL PUBLICATION****1994:67****Decision of the Ministry of Social Affairs and Health  
concerning active implantable medical devices**

Issued in Helsinki on 29 December 1994

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Having regard to § 23 of the Medical Devices Decree (1506/94), passed on 29 December 1994, the Ministry of Social Affairs and Health has decided the following:

**§ 1***European Community Acts enforced by this decision*

Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, as amended by the Directives 93/42/EEC and 93/68/EEC, given in Annex II of the Agreement on the European Economic Area shall be enforced by this decision.

**§ 2***Scope*

This decision shall apply to the essential requirements and conformity assessment procedures relating to active implantable medical devices.

Active implantable medical device means any medical device functioning on the basis of electrical energy or any source of power other than that directly generated by the human body or gravity which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain in place after the procedure.

### § 3

#### *Essential requirements*

The essential requirements concerning active implantable medical devices are laid down in Annex 1 of this decision.

### § 4

#### *Conformity assessment procedures*

In the case of devices other than custom-made devices and devices intended for clinical investigation, the manufacturer shall, in order to affix the CE marking, either:

1) follow the procedure relating to the EC declaration of conformity as set out in Annex 2 of this decision, or

2) follow the procedure relating to the EC type-examination as set out in Annex 3 of this decision, and:

the procedure relating to the EC verification as set out in Annex 4 of this decision, or

the procedure relating to the EC declaration of conformity with type as set out in Annex 5 of this decision.

### § 5

#### *Devices designed for special purposes*

In the case of custom-made devices and devices intended for clinical investigation, a

manufacturer shall follow the procedure set out in Annex 6 of this decision.

## § 6

### *Clinical evaluation*

The clinical evaluation carried out to confirm the conformity with the requirements must meet the requirements laid down in Annex 7 of this decision.

## § 7

### *Notified body*

Specific provisions concerning requirements that must be met by notified bodies and approval of the bodies are laid down in Annex 8.

## § 8

### *Application instructions*

Where appropriate, the National Agency for Medicines shall give instructions concerning the application of this decision.

## § 9

### *Coming into force*

This decision will come into force on 1 January 1995.

This decision will abrogate the decision of the Ministry of Social Affairs and Health concerning the essential requirements relating to active implantable medical devices and approval of the devices issued on 20 January 1994.

Helsinki, 29 December 1994

Minister of Social Affairs and Health *Jorma Huuhtanen*

Government Counsellor *Mauno Lindroos*

*Annex 1*

## ESSENTIAL REQUIREMENTS

### A. GENERAL REQUIREMENTS

1. The devices must be designed and manufactured in such a way that, when implanted under the conditions and for the purposes laid down, their use does not compromise the clinical condition or the safety of patients. They must not present any risk to the persons implanting them or, where applicable, to other persons.
2. The devices must achieve the performances intended by the manufacturer, viz. be designed and manufactured in such a way that they are suitable for one or more of the functions referred to in § 3 point 1 of the Medical Devices Act as 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, as appropriate, 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 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.

5. Any side effects or undesirable conditions must constitute acceptable risks when weighed against the performances intended.

## B. 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. Devices must be designed, manufactured and packed in a non-reusable pack according to appropriate procedures to ensure they are sterile when placed on the market and, in the storage and transport conditions stipulated by the manufacturer, remain so until the packaging is removed and they are implanted.
8. Devices must be designed and manufactured in such a way as to remove or minimize as far as possible:
  - a) the risk of physical injury in connection with their physical, including dimensional, features;
  - b) risks connected with the use of energy sources with particular reference, where electricity is used, to insulation, leakage currents and overheating of the devices;
  - c) risks connected with reasonably foreseeable environmental conditions such as magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure and acceleration;
  - d) risks connected with medical treatment, in particular those resulting from the use of defibrillators or high-frequency surgical equipment;
  - e) risks connected with ionizing radiation from radioactive substances included in the device, in compliance with the protection requirements laid down in directive 80/836/Euratom, as amended by directives 84/467/Euratom and 84/466/Euratom; and
  - f) risks 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 device, decreased accuracy of any measuring or control mechanism.
9. The devices must be designed and manufactured in such a way as to guarantee the characteristics and performances referred to in A. 'General requirements', with particular attention being paid to:
  - a) the choice of materials used, particularly as regards toxicity aspects;
  - b) mutual compatibility between the materials used and biological tissues, cells and body fluids, account being taken of the anticipated use of the device;
  - c) compatibility of the devices with the substances they are intended to administer;
  - d) the quality of the connections, particularly in respect of safety;
  - e) the reliability of the source of energy;
  - f) if appropriate, that they are leakproof; and
  - e) proper functioning of the programming and control systems, including software.
10. Where a device incorporates, as an integral part, a substance which, when used

separately, is likely to be considered to be a medicinal product as defined in article 1 of directive 65/65/EEC, and whose action in combination with the device may result in its bioavailability, the safety, quality and usefulness of the substance, account being taken of the purpose of the device, must be verified by analogy with the appropriate methods specified in directive 75/318/EEC, as last amended by directive 89/341/EEC.

11. The devices and, if appropriate, their component parts must be identified to allow any necessary measure to be taken following the discovery of a potential risk in connection with the devices and their component parts.
12. Devices must bear a code by which they and their manufacturer can be unequivocally identified. The code must particularly state the type of 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 device or its accessories bear instructions required for the operation of the 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 device must bear, legibly and indelibly, the following particulars, where appropriate in the form of generally recognized symbols:
  - 14.1. On the sterile pack
    - a) the method of sterilization;
    - b) an indication permitting this packaging to be recognized as sterile;
    - c) the name and address of the manufacturer;
    - d) a description of the device;
    - e) if the device is intended for clinical investigations, the words: 'exclusively for clinical investigations';
    - f) if the device is custom-made, the words 'custom-made device';
    - g) a declaration that the implantable device is in a sterile condition;
    - h) the month and year of manufacture; and
    - i) an indication of the time limit for implanting a device safely.
  - 14.2. On the sales packaging
    - a) the name and address of the manufacturer;
    - b) a description of the device;
    - c) the purpose of the device;
    - d) the relevant characteristics for its use;
    - e) if the device is intended for clinical investigations, the words: 'exclusively for clinical investigations';
    - f) if the device is custom-made, the words: 'custom-made device';
    - g) a declaration that the implantable device is in a sterile condition;
    - h) the month and year of manufacture;
    - i) an indication of the time limit for implanting a device safely; and
    - j) the conditions for transporting and storing the device.
15. When placed on the market, each device must be accompanied by instructions for use

giving the following particulars:

- a) the year of authorization to affix the CE marking;
- b) the details referred to in 14, with the exception of those referred to in points h and i;
- c) the performances referred to in Section 2 and any undesirable side effects;
- d) information allowing the physician to select a suitable device and the corresponding software and accessories;
- e) information constituting the instructions for use allowing the physician and, where appropriate, the patient to use the device, its accessories and software correctly, as well as information on the nature, scope and times for operating controls and trials and, where appropriate, maintenance measures;
- f) information allowing, if appropriate, certain risks in connection with implantation of the device to be avoided;
- g) information regarding the risks of reciprocal interference in connection with the presence of the device during specific investigations or treatment;
- h) the necessary instructions in the event of the sterile pack being damaged and, where appropriate, details of appropriate methods of resterilization; and
- i) an indication, if appropriate, that a device can be reused only if it is reconditioned under the responsibility of the manufacturer to comply with the essential requirements.

The instruction leaflet must also include details allowing the physician to brief the patient on the contra-indications and the precautions to be taken. These details should cover in particular:

- a) information allowing the lifetime of the energy source to be established;
- b) precautions to be taken should changes occur in the device's performance;
- c) 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; and
- d) adequate information regarding the medicinal products which the device in question is designed to administer.

16. Confirmation that the device satisfies the requirements in respect of characteristics and performances, as referred to in A. '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 7 of this decision.

*Annex 2***EC DECLARATION OF CONFORMITY**  
(Full quality assurance system)

1. The manufacturer shall apply the quality system approved for the design, manufacture and final inspection of the products concerned as specified in Sections 3 and 4 and shall be 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 products concerned meet the provisions of this decision which apply to them.  
The manufacturer or his authorized representative established in the European Economic Area shall affix the CE marking in accordance with § 17 of the Medical Device Decree and shall draw up a written declaration of conformity. This declaration shall cover one or more identified examples of the product and shall be kept by the manufacturer or his authorized representative established in the European Economic Area. 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 shall include

- a) all the appropriate items of information for the category of products manufacture of which is envisaged;
- b) the quality-system documentation;
- c) an undertaking to fulfil the obligations arising from the quality system as approved;

d) an undertaking to maintain the approved quality system in such a way that it remains adequate and efficacious;

e) an undertaking by the manufacturer to institute and keep up-dated a post-marketing surveillance system. The undertaking shall include an obligation for the manufacturer to notify the National Agency for Medicines of the following incidents immediately on learning of them:

I) any deterioration in the characteristics or performances, and any inaccuracies in the instruction leaflet for a device which might lead to or have led to the death of a patient or a deterioration in his state of health; and

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 products conform to the provisions of this decision 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. This quality-system documentation must make possible a uniform interpretation of the quality policies and procedures such as quality programmes, quality plans, quality manuals and quality records.

It shall 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 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 the design and of the products, including control of products which do not conform;

c) the procedures for monitoring and verifying the design of the products 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 referred to in Subsection 1 of § 8 of the Medical Devices Decree 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 products are being designed;

d) the techniques of control and of quality assurance at the manufacturing stage and in particular the processes and procedures which will be used, particularly as regards 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; and

e) the appropriate tests and trials which will be effected before, during and after production, the frequency with which they will take place, and the test equipment used.

3.3. The notified body shall effect an audit of the quality system to determine whether it meets the requirements referred to in 3.2. It shall presume conformity with these requirements for the quality systems which use the corresponding harmonized standards.

The team entrusted with the evaluation shall 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. It shall 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 referred to in 3.2; it 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 product**

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 product which he plans to manufacture and which falls into the category referred to in 3.1.

4.2. The application shall describe the design, manufacture, and performances of the product in question and shall include the necessary particulars which make it possible to evaluate whether it complies with the requirements of this decision.

It shall include inter alia:

- a) the design specifications, including the standards which have been applied;
- b) the necessary proof of their appropriations, in particular where the standards referred to in Subsection 1 of § 8 of the Medical Devices Decree 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;
- c) a statement as to whether or not the device incorporates, as an integral part, a substance as referred to in Section 10 of Annex 1, whose action in combination with the device may result in its bioavailability, together with data on the relevant trials conducted;
- d) the clinical data referred to in Annex 7; and
- e) the draft instruction leaflet.

4.3. The notified body shall examine the application and, where the product complies with the relevant provisions of this decision, 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 directive may be evaluated. The certificate shall 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 product.

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 directive or the conditions prescribed for the use of the product. This supplementary approval shall be given in the form of an addendum to the design examination certificate.

## **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 all necessary inspections and shall supply it with all appropriate 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 and tests, 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.
- 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. The manufacturer must, for a period ending at least five years after the last product has been manufactured, keep at the disposal of the National Agency for Medicines:
- a) the declaration of conformity;
  - b) the documentation referred to in Section 3.1 b;
  - c) the amendments referred to in Section 3.4;
  - d) the documentation referred to in Section 4.2; and
  - e) 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 must make available to the other notified bodies and the National Agency for Medicines on request, all relevant information concerning quality system approvals issued, refused or withdrawn.
- 6.3. Where neither the manufacturer nor his authorized representative is established in the European Economic Area, the obligation to keep available the technical documentation shall fall to the person responsible for placing the device on the European Economic Area market.

*Annex 3*

## EC TYPE-EXAMINATION

1. EC type-examination is the procedure whereby a notified body observes and certifies that a representative sample of the production envisaged satisfies the relevant provisions of this decision.
2. The application for EC type-examination shall be made by the manufacturer, or by his authorized representative established in the European Economic Area, to a notified body.

The application shall 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 described in Section 3 needed to allow an evaluation to be made of the conformity of a representative sample of the production in question, hereinafter referred to as 'type', with the requirements of this decision.

The applicant shall make a 'type' available to the notified body. The notified body may request other samples as necessary.
3. The documentation must make it possible to understand the design, the manufacture and the performances of the product. The documentation shall contain the following items in particular:
  - a) a general description of the type;
  - b) design drawings, methods of manufacture envisaged, in particular as regards sterilization, and diagrams of parts, sub-assemblies, circuits;
  - c) the descriptions and explanations necessary for the understanding of the abovementioned drawings and diagrams and of the operation of the product;
  - d) a list of the standards referred to in Subsection 1 of § 8 of the Medical Devices Decree, applied in full or in part, and a description of the solutions adopted to satisfy the essential requirements where the standards referred to in Subsection 1 of § 8 of the Medical Devices Decree have not been applied;
  - e) the results of design calculations, investigations and technical tests carried out, a statement as to whether or not the device incorporates, as an integral part, a substance as referred to in Section 10 of Annex 1, whose action in combination with the device may result in its bioavailability, together with data on the relevant trials conducted;
  - f) the clinical data referred to in Annex 7; and
  - g) the draft instruction leaflet.

4. The notified body shall:
  - a) examine and evaluate the documentation, verify that the type has been manufactured in accordance with that documentation. It shall also record the items which have been designed in accordance with the applicable provisions of the standards referred to in Subsection 1 of § 8 of the Medical Devices Decree, as well as the items for which the design is not based on the relevant provisions of the said standards;
  - b) carry out or have carried out the appropriate inspections and the tests necessary to verify whether the solutions adopted by the manufacturer satisfy the essential requirements of this decision where the standards referred to in Subsection 1 of § 8 of the Medical Devices Decree have not been applied;
  - c) carry out or have carried out the appropriate inspections and the tests necessary to verify whether, where the manufacturer has chosen to apply the relevant standards, these have actually been applied; and
  - d) 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 decision, 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.
  
6. The applicant shall inform the notified body which issued the EC type-examination certificate of any modification made to the approved product.

Modifications to the approved product 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 product. This 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. The notified body must make available to the other notified bodies on request, all relevant information on EC type-examination certificates and supplements issued, refused or withdrawn.
- 7.2. Other notified bodies may obtain a copy of the EC type-examination certificates and/or the supplements thereto. The annexes to the certificates must be made available to other notified bodies on reasoned application, after the manufacturer has been informed.
- 7.3. The manufacturer or his authorized representative must keep with the technical documentation copies of EC type-examination certificates and their additions for a period ending at least five years after the last device has been manufactured.

- 7.4. When neither the manufacturer nor his authorized representative is established in the European Economic Area, the obligation to keep available the technical documentation shall fall to the person responsible for placing the device on the European Economic Area market.

## EC VERIFICATION

1. EC verification is the procedure whereby the manufacturer or his authorized representative established within the European Economic Area ensures and declares that the products subject to the provisions of Section 3 are in conformity to the type described in the EC type-examination certificate and meet the requirements of this decision which apply to them.
2. The manufacturer or his authorized representative established within the European Economic Area shall take all the measures necessary to ensure that the manufacturing process produces products which conform to the type described in the EC type-examination certificate and to the requirements of this decision which apply to them. The manufacturer or his authorized representative established within the European Economic Area shall affix the CE marking to each product and draw up a written declaration of conformity. The CE marking must be accompanied by the identification number of the notified body that is responsible for the tasks of this Annex.
3. Before the start of manufacture, the manufacturer shall prepare documents defining the manufacturing processes, in particular as regards sterilization, together with all the routine, pre-established provisions to be implemented to ensure uniformity of production and conformity of the products with the type described in the EC type-examination certificate as well as with the requirements of this decision.
4. The manufacturer shall undertake to institute and keep up to date a post-marketing surveillance system. This undertaking shall include an obligation for the manufacturer to notify the National Agency for Medicines of the following incidents immediately on learning of them:
  - I) any change in the characteristics or performances and any inaccuracies in the instruction leaflet for a device 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 resulting in the withdrawal of a device from the market by the manufacturer.
5. The notified body shall carry out the appropriate examinations and tests in order to verify the conformity of the product with the requirements of this decision by examination and testing of products on a statistical basis as specified in Section 6. The manufacturer must authorize the notified body to evaluate the efficiency of the measures

taken pursuant to Section 3, by audit where appropriate.

## 6. Statistical verification

- 6.1. The manufacturer must present the manufactured products in the form of uniform batches and shall take all necessary measures in order that the manufacturing process ensures the uniformity of each batch produced.
- 6.2. A random sample shall be taken from each batch. The products which make up the sample shall be examined individually and appropriate tests as defined in the standards referred to in Subsection 1 of § 8 of the Medical Devices Decree, or equivalent tests shall be carried out to verify their conformity to the type as described in the EC type-examination certificate in order to determine whether a batch is to be accepted or rejected.
- 6.3. Statistical control of products shall be based on attributes, entailing a sampling system with the following characteristics:
- a) a level of quality corresponding to a probability of acceptance of 95 %, with a non-conformity percentage of between 0,29 and 1 %; and
  - b) a limit quality corresponding to a probability of acceptance of 5 %, with a non-conformity percentage of between 3 and 7 %.
- 6.4. If the batch is accepted, the notified body shall affix or cause to be affixed, its identification number to each product and draw up a written certificate of conformity relating to 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.
- If a batch is rejected, the notified body shall 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.
- 6.5. The manufacturer or his authorized representative shall ensure that he is able to supply the notified body's certificates of conformity on request.

**EC DECLARATION OF CONFORMITY TO TYPE**  
(Production quality assurance)

1. The manufacturer shall apply the quality system approved for the manufacture and shall conduct the final inspection of the products concerned as specified in Section 3, and he shall be subject to the surveillance referred to in Section 4.
2. This declaration of conformity is the procedural element whereby the manufacturer who satisfies the obligations of Section 1 guarantees and declares that the products concerned conform to the type described in the EC type-examination certificate and meet the provisions of this decision which apply to them.

The manufacturer or his authorized representative established in the European Economic Area shall affix the CE marking in accordance with § 17 of the Medical Devices Decree and shall draw up a written declaration of conformity. This declaration shall cover one or more identified specimens of the product and shall be kept by the manufacturer. The CE marking shall be accompanied by the identification number of the notified body responsible for the tasks of this Annex.

### 3. Quality system

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

The application shall include:

- a) all appropriate information concerning the products which it is intended to manufacture;
- b) the quality-system documentation;
- c) an undertaking to fulfil the obligations arising from the quality system as approved;
- d) an undertaking to maintain the approved quality system in such a way that it remains adequate and efficacious;
- e) where appropriate, the technical documentation relating to the approved type and a copy of the EC type-examination certificate; and
- f) an undertaking by the manufacturer to institute and keep up-dated a post-marketing surveillance system. The undertaking shall include an obligation for the manufacturer to notify the National Agency for Medicines of the following incidents

immediately on learning of them:

- I) any deterioration in the characteristics or performances, and any inaccuracies in the instruction leaflet for a device which might lead to or have led to the death of a patient or a deterioration in his state of health; and
- II) any technical or medical reason resulting in withdrawal of a 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. This quality-system documentation must make possible a uniform interpretation of the quality policies and procedures such as quality programmes, quality plans, quality manuals and quality records.

It shall 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 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 the design and of the products, including control of products which do not conform;
- c) the techniques of control and of quality assurance at the manufacturing stage and in particular the processes and procedures which will be used, particularly as regards 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; and
- d) the appropriate tests and trials which will be effected before, during and after production, the frequency with which they will take place, and the test equipment used.

3.3. The notified body shall effect an audit of the quality system to determine whether it meets the requirements referred to in 3.2. It shall presume conformity with these requirements for the quality systems which use the corresponding harmonized standards.

The team entrusted with the evaluation shall 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. It shall 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 that 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 3.2; it shall notify the manufacturer of its decision. This decision shall contain the conclusions of the control 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 all necessary inspections and shall supply it with all appropriate information, in particular 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 concerned.
- 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 shall communicate to the other notified bodies all relevant information concerning approvals of quality systems issued, refused or withdrawn.

## Annex 6

## STATEMENT CONCERNING DEVICES INTENDED FOR SPECIAL PURPOSES

1. The manufacturer or his authorized representative established within the European Economic Area shall draw up for custom-made devices or for devices intended for clinical investigations the statement comprising the elements stipulated in Section 2.
2. The statement shall comprise the following information:
  - 2.1. for custom-made devices:
    - a) data allowing the device in question to be identified;
    - b) a statement affirming that the device is intended for exclusive use by a particular patient, together with his name;
    - c) the name of the doctor who drew up the prescription and, if applicable, the name of the hospital concerned;
    - d) the particular features of the device as described by the medical prescription concerned;
    - e) a statement affirming that the device complies with the essential requirements given in Annex 1 and, where applicable, indicating which essential requirements have not been wholly met, together with the grounds.
  - 2.2. for devices intended for clinical investigations:
    - a) data allowing the devices in question to be identified;
    - b) an investigation plan giving in particular the purpose, scope and number of the devices concerned;
    - c) the name of the doctor and of the institution responsible for the investigations;
    - d) the place, date of commencement and duration scheduled for the investigations;
    - e) a statement affirming that the device in question complies with the essential requirements apart from the aspects constituting the object of 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 shall undertake to keep available for the National Agency for Medicines:
  - 3.1. for custom-made devices, documentation enabling the design, manufacture and performances of the product, including the expected performances, to be understood, so

as to allow conformity with the requirement of this directive to be assessed. The manufacturer shall take all necessary measures to see that the manufacturing process ensures that the products manufactured conform to the documentation.

- 3.2. for devices intended for clinical investigations, the documentation shall also contain:
- a) a general description of the product;
  - b) design drawings, manufacturing methods, in particular as regards sterilization, and diagrams of parts, sub-assemblies, circuits;
  - c) the descriptions and explanations necessary for the understanding of the said drawings and diagrams and of the operation of the product;
  - d) a list of the standards laid down in Subsection 1 of § 8 of the Medical Devices Decree, applied in full or in part, and a description of the solutions adopted to satisfy the essential requirements of Annex 1 where the standards in Subsection 1 of § 8 of the Medical Devices Decree have not been applied;
  - e) the results of the design calculations, checks and technical tests carried out.

The manufacturer shall take all necessary measures to see that the manufacturing process ensures that the products manufactured conform to the documentation referred to in 3.1 and in the first paragraph of this Section.

The manufacturer may authorize the evaluation, by audit where necessary, of the effectiveness of these measures.

*Annex 7*

## CLINICAL EVALUATION

1. Adequacy of the clinical data presented, as referred to in Section 4.2 of Annex 2, and in Section 3 of Annex 3, shall be based, account being taken as appropriate of the relevant harmonized standards, on either a collation of currently available relevant scientific literature covering the intended use of the device and the techniques therefor, as well as, if appropriate, a written report making a critical assessment of this collation; or the results of all clinical investigations made, including those carried out in accordance with this decision.  
All data must remain confidential unless it is deemed essential that they be divulged.
2. The purpose of clinical investigation is to verify that, under normal conditions of use, the performances of the device comply with those indicated in Section 2 of Annex 1, determine any undesirable side effects, under normal conditions of use, and assess whether they are acceptable risks having regard to the intended performance of the device.  
Ethical consideration clinical investigations shall be made in accordance with the Declaration of Helsinki approved by the 18th World Medical Assembly in Helsinki, Finland, in 1964, and amended by the 29th World Medical Assembly in Tokyo, Japan, in 1975 and the 35th World Medical Assembly in Venice, Italy, in 1983. It is mandatory that all measures relating to the protection of human subjects are carried out in the spirit of the Declaration of Helsinki. This includes every step in the clinical investigation from first consideration of need and justification of the study to publication of results.
3. Clinical investigations shall be performed according to an appropriate state of the art plan of investigation defined in such a way as to confirm or refute the manufacturer's claims for the device; the investigations shall include an adequate number of observations to guarantee the scientific validity of the conclusions. The procedures utilized to perform the investigations shall be appropriate to the device under examination. Clinical investigations shall be performed in circumstances equivalent to those which would be found in normal conditions of use of the device. All appropriate features, including those involving the safety and performances of the device, and its effects on the patients, shall be examined. All adverse events shall be fully recorded.

4. The investigations shall be performed under the responsibility of an appropriately qualified medical specialist, in an appropriate environment. The medical specialist shall have access to the technical data regarding the device. The written report, signed by the responsible medical specialist, shall comprise a critical evaluation of all the data collected during the clinical investigation.

*Annex 8*

## REQUIREMENTS CONCERNING NOTIFIED BODIES

1. The notified body, its director and the staff responsible for carrying out the evaluation and verification operations shall not be the designer, manufacturer, supplier or installer of devices which they control, nor the authorized representative of any of those parties. They may not become directly involved in the design, construction, marketing or maintenance of the devices, nor represent the parties engaged in these activities. This does not preclude 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 evaluation and verification operations with the highest degree of professional integrity and technical competence and must be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of the inspection, especially from persons or groups of persons with an interest in the results of verifications.
3. The notified body as defined in this decision, must be able to carry out all the tasks in one of Annexes 2 to 5 assigned to such a body and for which it has been notified, whether those tasks are carried out by the body itself or under its responsibility. In particular, it must have at its disposal the necessary staff and possess the necessary facilities to enable it to perform properly the technical and administrative tasks connected with evaluation and verification. It must also have access to the equipment necessary for the verifications required.
- 3.2. The staff responsible for control operations must have:
  - sound vocational training covering all the evaluation and verification operations for which the body has been designated;
  - satisfactory knowledge of the requirements of the controls they carry out and adequate experience of such operations;
  - the ability required to draw up the certificates, records and reports to demonstrate that the controls have been carried out.
- 3.3. The impartiality of inspection staff must be guaranteed. Their remuneration must not depend on the number of controls carried out, nor on the results of such controls.
4. The notified body must according to § 14 of the Medical Devices Decree taking

account the extent and nature of its functions take out an adequate liability insurance unless liability is assumed by the state.

5. The staff of the notified body are bound to observe professional secrecy with regard to all information gained in carrying out their tasks as defined in this decision except the giving of information as defined in the Medical Devices Act and this decision, to the Ministry of Social Affairs and Health, the National Agency for Medicines and other notified bodies.