STATUTORY INSTRUMENTS

S.I. No. 109 of 2009

EUROPEAN COMMUNITIES (ACTIVE IMPLANTABLE MEDICAL DEVICES) (AMENDMENT) REGULATIONS 2009

(Prn. A9/0440)

S.I. No. 109 of 2009

EUROPEAN COMMUNITIES (ACTIVE IMPLANTABLE MEDICAL DEVICES) (AMENDMENT) REGULATIONS 2009

I, MARY HARNEY, Minister for Health and Children, in exercise of the powers conferred on me by section 3 of the European Communities Act, 1972, (No. 27 of 1972) and for the purpose of giving full effect to Council Directive 2007/47/EC of 5 September 2007 amending Council Directive 90/385/EEC of 20 July 1990 (S.I. No. 253 of 1994) concerning active implantable medical devices, hereby make the following Regulations:

1. These following Regulations may be cited as the European Communities (Active Implantable Medical Devices) (Amendment) Regulations 2009. These Regulations shall come into force on 21 March 2010.

2. In these Regulations:

"The Principal Regulations" means the European Communities (Active Implantable Medical Devices) Regulations, 1994 (Statutory Instrument number 253 of 1994).

"These Regulations" means the European Communities Active Implantable Medical Devices (Amendment) Regulations 2009 amending the Principal Regulations.

"The Directive" means the Directive 2007/47/EC[1] of the European Parliament and Council of 5 September 2007 amending Directive 90/385/EEC relating to Active Implantable Medical Devices, 93/42/EC relating to medical devices and 98/8/EEC relating to placing of biocidal products on the market.

"Directive 90/385/EEC" means Directive 90/385/EEC[2] of the European Parliament and Council of 20 June 1990 concerning Active Implantable Medical Devices.

"Directive 93/42/EEC" means Directive 93/42/EEC[3] of the European Parliament and Council of 14 June 1993 concerning Medical Devices.

"Directive 2001/83/EC" means Directive 2001/83/EC[4] of the European Parliament and Council of 6 November 2001 concerning the Community code relating to Medicinal Products for Human Use.

[1]OJ L 247 21.9.2007 p21
[2]OJ L 189 20.7.1990 p.17
[3]OJ L 169 12.7.1993 p.1
[4]OJ L 311 28.11.2001 p.67. Directive as last amended by Regulation (EC) No. 1901/2006 (OJ L378 27.12.2006, p1)

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 3*rd April*, 2009.

"Directive 2004/108/EC" means Directive 2004/108/EC[5] of the European Parliament and Council of 15 December 2004 concerning electromagnetic compatibility.

"Directive 2006/42/EC" means Directive 2006/42/EC[6] of the European Parliament and of the Council of 17 May 2006 on machinery.

"European Communities (Medical Ionising Radiation Protection) Regulations (S.I. 478 of 2002)" means the European Communities (Medical Ionising Radiation Protection) Regulations of 15 October 2002 (Statutory Instrument number 478 of 2002).

"European Communities (Personal Protective Equipment) Regulations (S.I. 272 of 1993)" means European Communities (Personal Protective Equipment) Regulations of 22 September 1993 (Statutory Instrument number 272 of 1993).

"Medicinal Products (Control of Placing on the Market) Regulations (S.I. 540 of 2007)" means Medicinal Products (Control of Placing on the Market) Regulations of 20 July 2007 (Statutory Instrument number 540 of 2007).

"Radiological Protection Act 1991 Ionising Radiation order (S.I. 125 of 2000)" means Radiological Protection Act 1991 Ionising Radiation order of 13 May 2000 (Statutory Instrument number 125 of 2000).

3. A reference in these Regulations to a Regulation is to a Regulation of these Regulations, unless it is indicated that reference to some other Regulations is intended.

A reference in these Regulations to a paragraph or subparagraph is to the paragraph or subparagraph of the provision in which the reference occurs, unless it is indicated that reference to some other provision is intended.

A reference in these Regulations to a Schedule is to a Schedule to these Regulations, unless it is indicated that reference to some other Regulations is intended.

4. Regulation 2 (Definitions) of the Principal Regulations is amended:

(i) by the insertion after the definition of "accessory" of the following two definitions:

' "active medical device" means any medical device relying for its functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity;'

' "active implantable medical device" means any medical device 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 after the procedure;'

[5]OJ L 390 31.12.2004 p.24
[6]OJ L 157 9.6.2006 p.24

(ii) by the insertion after the definition of "CE marking" of the following definition:

‘ "clinical data" means the safety and/or performance information that is generated from the use of a device. Clinical data are sourced from:

— clinical investigation(s) of the device concerned; or

— clinical investigation(s) or other studies reported in the scientific literature, of a similar device for which equivalence to the device in question can be demonstrated; or

— published and/or unpublished reports on other clinical experience of either the device in question or a similar device for which equivalence to the device in question can be demonstrated;’

(iii) by the insertion after the definition of "manufacturer" of the following definition:

‘ "medical device" means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

— diagnosis, prevention, monitoring, treatment or alleviation of disease,

— diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,

— investigation, replacement or modification of the anatomy or of a physiological process,

— control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;’

5. Regulation 2 (Definitions) of the Principal Regulations is amended by the following changes in the definitions:

(i) The definition of "authorised representative" is amended by deleting the words:

"means an authorised representative established within the European Community;"

and substituting the words:

"means any natural or legal person established in the European Community who, explicitly designated by the manufacturer, acts and may be addressed by authorities and bodies in the European Community instead of the manufacturer with regard to the latter's obligations under this Directive;"

(ii) The definition of custom-made device is amended by deleting the words

' "custom-made" means, in relation to a device—

(a) that it is manufactured specifically in accordance with a written prescription of a registered medical practitioner or a professional user which gives, under his responsibility, specific characteristics as to its design; and

(b) that it is intended to be used only for a particular named patient;

but does not include a mass-produced product which needs to be adapted to meet the specific requirements of the registered practitioner or professional user;'

and substituting the words:

' "custom-made device" means any device specifically made in accordance with a registered medical practitioner's written prescription which gives, under his or her responsibility, specific design characteristics and is intended for the sole use of a particular patient.

Mass-produced devices which need to be adapted to meet the specific requirements of the medical practitioner or any other professional user shall not be considered to be custom-made devices;'

(iii) The definition "intended for clinical investigation" is amended by deleting the words:

"means in relation to a device, that it is intended for use by a registered medical practitioner when conducting clinical investigations of that device;"

and substituting the following words:

" means in relation to a device;

(a) that it is intended for use by a registered medical practitioner user when conducting investigations of that device as referred to in Section 2.1 of Schedule 7 in an adequate human clinical environment; or

(b) that it is for use by any other person who by virtue of his or her professional qualifications is authorised to carry out investigations of that device as referred to in Section 2.1 of Schedule 7 in an adequate human clinical environment."

(iv) The definition of "intended purpose" is amended by deleting the words:

‘ “intended purpose” means the use for which the device is intended and for which it is designed, according to the data supplied by the manufacturer in the instructions relating to it;’

and substituting the words:

‘ “intended purpose” means the use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions and/or in promotional material;’

6. Regulation 3 (Application) of the Principal Regulations is amended by deleting Paragraph (2) and substituting the following words:

> “(2) Where an active implantable medical device is intended to administer a medicinal product within the meaning of Article 1 of Directive 2001/83/EC, that device shall be governed by these Regulations, without prejudice to the provisions of Article 1 of Directive 2001/83/EC with regard to the medicinal product.”

7. Regulation 3 (Application) of the Principal Regulations is amended by deleting Paragraph (3) and substituting the words:

> “(3) 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 and which is liable to act upon the body with action ancillary to that of the device, that device shall be assessed and authorised in accordance with these Regulations.”

8. Regulation 3 (Application) of the Principal Regulations is amended by adding a new sub paragraph 3(a) after Paragraph 3 with the words:

> “3 (a) Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product constituent or a medicinal product derived from human blood or human plasma within the meaning of Article 1 of Directive 2001/83/EC and which is liable to act upon the human body with action that is ancillary to that of the device, hereinafter referred to as a “human blood derivative”, that device shall be assessed and authorised in accordance with these Regulations;”

9. Regulation 3 (Application) of the Principal Regulations is amended by deleting the words in Paragraph (4):

“The Directive constitutes a specific Directive within the meaning of Article 2 (2) of Council Directive 89/336/EC.”

and substituting the words:

"This Directive constitutes a specific Directive within the meaning of Article 1 (4) of Directive 2004/108/EC."

10. Regulation 3 (Application) of the Principal Regulations is amended by adding a new Paragraph (5):

"These regulations shall not apply to:

(a) medicinal products covered by Directive 2001/83/EC. In deciding whether a product falls under that Directive or this Directive, particular account shall be taken of the principal mode of action of the product;"

(b) human blood, blood products, plasma or blood cells of human origin or to devices which incorporate at the time of placing on the market such blood products, plasma or cells with the exception of devices referred to in paragraph 3(a) of Regulation 3 of these Regulations;

(c) transplants or tissues or cells of human origin or to products incorporating or derived from tissues or cells of human origin, with the exception of devices referred to in paragraph 3(a) of Regulation 3 of these Regulations;

(d) transplants or tissues or cells of animal origin, unless a device is manufactured utilising animal tissue which is rendered non-viable, or non-viable products derived from animal tissue;"

11. Regulation 4 (Essential Requirements for devices) of the Principal Regulations is amended by adding after Paragraph (8) a new Paragraph (9) as follows:

"(9) Where a relevant hazard exists, devices which are also machinery within the meaning of Article 2(a) of Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery shall also meet the essential health and safety requirements set out in Annex I to that Directive to the extent to which those essential health and safety requirements are more specific than the essential requirements set out in Schedule 1 of these Regulations."

12. "Regulation 7 (General Provisions relating to conformity assessment procedures) of the Principal Regulations is amended by deleting the words in Paragraph (4):

"(4) Decisions taken by the notified bodies following the procedures set out in Schedules 2 and 3 shall be valid for a maximum of five years and may be extended on application made at a time agreed in the contract signed by both parties for further periods of five years."

and substituting the words:

"(4) Decisions taken by the notified bodies following the procedures set out in Schedules 2, 3 and 5 shall be valid for a maximum of five years and may be

extended on application made at a time agreed in the contract signed by both parties for further periods of a maximum length of five years."

13. The Principal Regulations are amended by inserting after Regulation 8 the following:

"8A Registration of persons placing devices on the Market

(1) Any manufacturer who, under his or her own name, places devices on the market in accordance with the procedure referred to in Article 9 (2) of Directive 90/385/EEC shall inform the Competent Authority of the address of the registered place of business and the description of the devices concerned.

The Competent Authority may request to be informed of all data allowing for the devices to be identified together with the label and the instructions for use when the devices are put into service in the state.

(2) Where a manufacturer who places a device on the market under his or her own name does not have a registered place of business in the state, he or she shall designate a single authorised representative in the state or another member state of the European Union.

For devices referred to in the first sub-paragraph of Paragraph (1) the authorised representative shall inform the Competent Authority of all details referred to in Paragraph (1)."

14. Regulation 10 (Clinical Investigations) of the Principal Regulations is amended by deleting paragraphs 1 to 5 and substituting the following:

"(1) Before devices intended for clinical investigation are made available to a medical specialist for the purpose of a clinical investigation to take place within the State, their manufacturer or the authorised representative shall give at least 60 days notice in writing to the Competent Authority of the making available of the devices for the intended investigation, in the form of the statement referred to in Sections 1 and 2.2 of Schedule 6 and the undertaking by the manufacturer mentioned in Section 3 of that Schedule.

(2) If, within 60 days of the giving of that notice, the Competent Authority gives written notice to the manufacturer or his or her authorised representative, that on the grounds relating to the health and safety of patients, users or others, devices should not be made available for the purposes of those investigations, devices may not be made available. Manufacturers may commence the relevant clinical investigation at the end of a period of 60 days after notification unless the Competent Authority has notified the manufacturer within that period of a decision to the contrary.

(3) The Competent Authority may, however, authorise a manufacturer to commence the relevant clinical investigations in question before the expiry of the 60 days period, provided that the Ethics Committee concerned, has delivered a favourable opinion with respect to the investigation programme in question, including the review of the relevant clinical investigation plan.

(4) The manufacturer of a device intended for clinical investigation shall take all the necessary measures to ensure that the manufacturing process ensures that a device manufactured according to that process conforms to the documentation referred to in Section 3.2 of Schedule 6 and may authorise the evaluation, by audit where necessary, of the effectiveness of the measures he or she takes pursuant to Schedule 6.

(5) Clinical investigations shall be conducted in accordance with the provisions of Schedule 7 to these regulations.

(6) Where a clinical investigation is refused or halted, the Competent Authority shall communicate such decision and the grounds thereof to all Member States and the Commission. Where a significant modification or temporary interruption of a clinical investigation has been called, the Competent Authority shall inform the Member States concerned about such actions and the grounds for the actions taken.

(7) The manufacturer or his or her authorised representative shall notify the Competent Authority and the competent authorities of the other Member States concerned of the end of the clinical investigation, with a justification in case of early termination.

(a) In the case of early termination of the clinical investigation on safety grounds, the notification referred to in regulation 10(7) above shall be communicated by the Competent Authority to all Member States and the Commission.

(b) The manufacturer or the authorised representative of the manufacturer shall keep the report referred to in Section 2.3.7 of Schedule 7 to these Regulations at the disposal of the Competent Authority and the competent authorities of the other member states concerned."

15. Regulation 11 of the Principal Regulations is amended by adding after paragraph (2) the following paragraphs:

"(3) The Notified Body shall inform the Competent Authority about all CE marking approvals issued, modified, supplemented, suspended, withdrawn or refused and the other notified bodies within the scope of the Directive about CE marking approvals suspended, withdrawn or refused and, on request, about CE marking approvals issued. The notified body shall also make available, on request, all additional relevant information.

(4) Where a notified body finds that the requirements of these regulations have not been met or are no longer met by the manufacturer or that a certificate should not have been issued, the notified body may suspend or withdraw the certificate issued or place any restrictions on it unless compliance with such requirements is ensured by the implementation of appropriate corrective measures by the manufacturer.

(5) In the case of suspension or withdrawal or of any restriction or where the intervention of the Competent Authority may become necessary the notified body shall inform the Competent Authority thereof.

(6) The notified body shall, on request by the Competent Authority supply all relevant information and documents including budgetary documents required to enable the Competent Authority to verify compliance with the criteria laid down in Schedule 8.

16. Regulation 20 (Offences) of the Principal Regulations is amended by deleting paragraph 5 and substituting the following words:

"(5) Proceedings for an offence under these Regulations may be instituted at any time within two years from the date on which the offence was committed."

17. Schedules 1 to 9 of the Principal Regulations (corresponding to Annex I to IX of Directive 90/385/EEC) are deleted and substituted with the following:

"SCHEDULE 1

ESSENTIAL REQUIREMENTS

I. 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 Article 1(2)(a) of Directive 90/385/EEC as amended as specified by him or her.

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 (temperature, humidity, etc.).

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

5a. Demonstration of conformity with the essential requirements must include a clinical evaluation in accordance with Schedule 7.

II. REQUIREMENTS REGARDING DESIGN AND CONSTRUCTION

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

7. Implantable 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:

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

— risks connected with the use of energy sources with particular reference, where electricity is used, to insulation, leakage currents and overheating of the devices,

— risks connected with reasonably foreseeable environmental conditions such as magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure and acceleration,

— risks connected with medical treatment, in particular those resulting from the use of defibrillators or high-frequency surgical equipment,

— risks connected with ionising radiation from radioactive substances included in the device, in compliance with the protection requirements laid down in Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation (1)and Council Directive 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionising radiation in relation to medical exposure,

— 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 I. 'General requirements', with particular attention being paid to:

— the choice of materials used, particularly as regards toxicity aspects,

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

— compatibility of the devices with the substances they are intended to administer,

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

— the reliability of the source of energy,

— if appropriate, that they are leakproof,

— proper functioning of the programming and control systems, including software.

For devices which incorporate software or which are medical software in themselves, the software must be validated according to the state of the art taking into account the principles of development lifecycle, risk management, validation and verification.

10. Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product as defined in Article 1 of Directive 2001/83/EC, and which is liable to act upon the body with action ancillary to that of the device, the quality, safety and usefulness of the substance must be verified by analogy with the methods specified in Annex I to Directive 2001/83/EC.

For the substances referred to in the first paragraph, the notified body shall, having verified the usefulness of the substance as part of the medical device and taking account of the intended purpose of the device, seek a scientific opinion from one of the competent authorities designated by the Member States or the European Medicines Agency (EMEA) acting particularly through its committee in accordance with Regulation (EC) No 726/2004 on the quality and safety of the substance including the clinical benefit/risk profile of the incorporation of the substance into the device. When issuing its opinion, the competent authority or the EMEA shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the notified body.

Where a device incorporates, as an integral part, a human blood derivative, the notified body shall, having verified the usefulness of the substance as part of the device and taking account of the intended purpose of the device, seek a scientific opinion from the EMEA, acting particularly through its committee, on the quality and safety of the substance, including the clinical benefit/risk profile of the incorporation of the human blood derivative into the device. When issuing its opinion, the EMEA shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the notified body. Where changes are made to an ancillary substance incorporated in a device, in particular related to its manufacturing process, the notified body shall be informed of the changes and shall consult the relevant medicines competent authority (i.e. the one involved in the initial consultation), in order to confirm that the quality and safety of the ancillary substance are maintained. The competent authority shall take into account the

data related to the usefulness of the incorporation of the substance into the device as determined by the notified body, in order to ensure that the changes have no negative impact on the established benefit/risk profile of the addition of the substance in the device.

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

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 (particularly with regard to 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:

— the method of sterilization,

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

— the name and address of the manufacturer,

— a description of the device,

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

— if the device is custom-made, the words ‘custom-made device’,

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

— the month and year of manufacture,

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

14.2. On the sales packaging:

— the name and address of the manufacturer and the name and address of the authorised representative, where the manufacturer does not have a registered place of business in the Community,

— a description of the device,

— the purpose of the device,

— the relevant characteristics for its use,

— if the device is intended for clinical investigations, the words: 'exclusively for clinical investigations',

— if the device is custom-made, the words: 'custom-made device',

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

— the month and year of manufacture,

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

— the conditions for transporting and storing the device,

— in the case of a device within the meaning of Article 1(4a) of Directive 90/385/EEC as amended, an indication that the device contains a human blood derivative.

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

— the year of authorization to affix the CE mark,

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

— the performances referred to in section 2 and any undesirable side effects,

— information allowing the physician to select a suitable device and the corresponding software and accessories,

— 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,

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

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

— the necessary instructions in the event of the sterile pack being damaged and, where appropriate, details of appropriate methods of resterilization,

— 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:

— information allowing the lifetime of the energy source to be established,

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

— 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, etc.,

— adequate information regarding the medicinal products which the device in question is designed to administer,

— date of issue or the latest revision of the instructions for use.

16. Confirmation that the device satisfies the requirements in respect of characteristics and performances, as referred to in I. 'General requirements', in normal conditions of use, and the evaluation of the side effects or undesirable effects must be based on clinical data established in accordance with Schedule 7.

SCHEDULE 2

EC DECLARATION OF CONFORMITY

(Complete 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 EC 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 Directive 90/385/EEC as amended which apply to them.

The manufacturer or his or her authorized representative established within the Community shall affix the CE marking in accordance with Article 12 of Directive 90/385/EEC as amended and shall draw up a written declaration of conformity.

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

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

3. Quality system

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

The application shall include:

— all the appropriate items of information for the category of products manufacture of which is envisaged,

— the quality-system documentation,

— an undertaking to fulfil the obligations arising from the quality system as approved,

— an undertaking to maintain the approved quality system in such a way that it remains adequate and efficacious,

—an undertaking by the manufacturer to institute and keep updated a post-marketing surveillance system including the provisions referred to in Schedule 7. The undertaking shall include an obligation for the manufacturer to notify the competent authorities of the following incidents immediately on learning of them:

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

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

3.2. The application of the quality system must ensure that the products conform to the provisions of Directive 90/385/EEC as amended which apply to them at every stage, from design to final controls.

All the elements, requirements and provisions adopted by the manufacturer for his or her 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 the corresponding documentation, data and records arising from the procedures referred to in point (c).

It shall include in particular an adequate description of:

(a) the 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,

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

(c) the procedures for monitoring and verifying the design of the products 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 Article 5 of Directive 90/385/EEC as amended 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,

— a statement indicating whether or not the device incorporates, as an integral part, a substance or a human blood derivative referred to in Section 10 of Schedule 1 and the data on the tests conducted in this connection required to assess the safety, quality and usefulness of that substance or human blood derivative, taking account of the intended purpose of the device,

— the pre-clinical evaluation,

— the clinical evaluation referred to in Schedule 7;

(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;

(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. Without prejudice to Article 13 of of Directive 90/385/EEC as amended, 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 and, in duly substantiated cases, on the premises of the manufacturer's suppliers and/or subcontractors to inspect the manufacturing processes. The decision shall be notified to the manufacturer after the final inspection. 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 or her under section 3, the manufacturer shall make an application for examination of the design dossier relating to the product which he or she 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 it must include the documents needed to assess whether the product conforms to the requirements of this Directive, and in particular Schedule 2, Section 3.2, third paragraph, points (c) and (d).

It shall include inter alia:

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

— the necessary proof of their appropriations, in particular where the standards referred to in Article 5 of Directive 90/385/EEC as amended 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 or her responsibility,

— a statement as to whether or not the device incorporates, as an integral part, a substance as referred to in section 10 of Schedule 1, whose action in combination with the device may result in its bioavailability, together with data on the relevant trials conducted,

— the clinical evaluation referred to in Schedule 7,

— the draft instruction leaflet.

4.3. The notified body shall examine the application and, where the product complies with the relevant provisions of this Directive, 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.

In the case of devices referred to in Schedule 1, Section 10, second paragraph, the notified body shall, as regards the aspects referred to in that section, consult one of the competent authorities designated by

the Member States in accordance with Directive 2001/83/EC or the EMEA before taking a decision. The opinion of the competent national authority or the EMEA shall be drawn up within 210 days after receipt of valid documentation. The scientific opinion of the competent national authority or the EMEA must be included in the documentation concerning the device. The notified body will give due consideration to the views expressed in this consultation when making its decision. It will convey its final decision to the competent body concerned.

In the case of devices referred to in Schedule 1, Section 10, third paragraph, the scientific opinion of the EMEA must be included in the documentation concerning the device. The opinion shall be drawn up within 210 days after receipt of valid documentation. The notified body will give due consideration to the opinion of the EMEA when making its decision. The notified body may not deliver the certificate if the EMEA's scientific opinion is unfavourable. It will convey its final decision to the EMEA.

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 Directive 90/385/EEC as amended or the conditions prescribed for the use of the product. This supplementary approval shall be given in the form of an addendum to the EC 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, tests, pre-clinical and clinical evaluation, post-market clinical follow-up plan and the results of the post-market clinical follow-up, if applicable, etc.,

— the data stipulated in the part of the quality system relating to manufacture, such as reports concerning inspections, tests,

standardizations/calibrations and the qualifications of the staff concerned, etc.

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

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

6. Administrative provisions

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

— the declaration of conformity,

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

— the amendments referred to in Section 3.4,

— the documentation referred to in Section 4.2,

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

6.2. On request, the notified body shall make available to the other notified bodies and the competent authority all relevant information on approvals of quality systems issued, refused or withdrawn.

7. Application to the devices referred to in Article 1(4a) of Directive 90/385/EEC as amended:

Upon completing the manufacture of each batch of devices referred to in Article 1(4a) of Directive 90/385/EEC as amended, the manufacturer shall inform the notified body of the release of the batch of devices and send to it the official certificate concerning the release of the batch of human blood derivative used in the device, issued by a State laboratory or a laboratory designated for that purpose by a Member State in accordance with Article 114(2) of Directive 2001/83/EC.

SCHEDULE 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 Directive.

2. The application for EC type-examination shall be made by the manufacturer, or by his or her authorized representative established in the Community, 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 Directive. 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 general description of the type, including any variants planned, and its intended use(s),

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

— the descriptions and explanations necessary for the understanding of the abovementioned drawings and diagrams and of the operation of the product,

— a list of the standards referred to in Article 5 of Directive 90/385/EEC as amended, applied in full or in part, and a description of the solutions adopted to satisfy the essential requirements where the standards referred to in Article 5 of Directive 90/385/EEC as amended have not been applied,

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

— a declaration stating whether or not the device incorporates, as an integral part, a substance or a human blood derivative as referred to in Section 10 of Annex 1 and the data on the tests conducted in this connection required to assess the safety, quality and usefulness of that substance or human blood derivative, taking account of the intended purpose of the device,

— the pre-clinical evaluation,

— the clinical evaluation referred to in Schedule 7,

— the draft instruction leaflet.

4. The notified body shall:

4.1. 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 Article 5 of Directive 90/385/EEC as amended, as well as the items for which the design is not based on the relevant provisions of the said standards;

4.2. 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 Directive 90/385/EEC as amended where the standards referred to in Article 5 of Directive 90/385/EEC as amended have not been applied;

4.3. 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;

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

5. Where the type meets the provisions of this Directive, the notified body shall issue an EC type-examination certificate to the applicant. The certificate shall contain the name and address of the manufacturer, the conclusions of the control, the conditions under which the certificate is valid and the information necessary for identification of the type approved.

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

In the case of devices referred to in Schedule 1, Section 10, second paragraph, the notified body shall, as regards the aspects referred to in that section, consult one of the competent authorities designated by the Member States in accordance with Directive 2001/83/EC or the

EMEA before taking a decision. The opinion of the competent national authority or the EMEA shall be drawn up within 210 days after receipt of valid documentation. The scientific opinion of the competent national authority or the EMEA must be included in the documentation concerning the device. The notified body will give due consideration to the views expressed in this consultation when making its decision. It will convey its final decision to the competent body concerned.

In the case of devices referred to in Schedule 1, Section 10, third paragraph, the scientific opinion of the EMEA must be included in the documentation concerning the device. The opinion shall be drawn up within 210 days after receipt of valid documentation. The notified body will give due consideration to the opinion of the EMEA when making its decision. The notified body may not deliver the certificate if the EMEA's scientific opinion is unfavourable. It will convey its final decision to the EMEA.

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

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

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

SCHEDULE 4

EC VERIFICATION

1. EC verification is the procedure whereby the manufacturer or his or her authorized representative established within the Community ensures and declares that the products subject to the provisions of section 3 are in conformity with the type as described in the EC type-examination certification and satisfy the requirements of Directive 90/385/EEC as amended that apply to them.

2. The manufacturer or his or her authorized representative established within the Community shall take all measures necessary in order that the manufacturing process ensures conformity of the products to the type as described in the EC type-examination certification and to the requirements of Directive 90/385/EEC as amended that apply to them. The manufacturer or his or her authorized representative established within the Community shall affix the CE marking to each product and draw up a written declaration of conformity.

3. The manufacturer shall, before the start of manufacture, prepare documents defining the manufacturing processes, in particular as regards sterilization, together with all the routine, pre-established provisions to be implemented to ensure uniformity of production and conformity of the products with the type as described in the EC type examination certificate as well as with the relevant requirements of this Directive 90/385/EEC as amended.

4. The manufacturer shall undertake to institute and keep updated a post-marketing surveillance system including the provisions referred to in Schedule 7. This undertaking shall include the obligation on the part of the manufacturer to notify the competent authorities of the following events immediately on learning of them:

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

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

5. The notified body shall carry out the appropriate examinations and tests in order to check the conformity of the product to the requirements of Directive 90/385/EEC as amended 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. Manufacturers shall present the products manufactured in the form of uniform batches and shall take all necessary measures in order that the manufacturing process ensures the uniformity of each batch produced.

6.2. A random sample shall be taken from each batch. Products in a sample shall be individually examined and appropriate tests, as set out in the standard(s) referred to in Article 5 of Directive 90/385/EEC as amended, or equivalent tests shall be carried out to verify their conformity to the type as described in the EC type-examination certificate and thereby determine whether a batch is to be accepted or rejected.

6.3. Statistical control of products will be based on attributes and/or variables, entailing sampling schemes with operational characteristics which ensure a high level of safety and performance according to the state of the art. The sampling schemes will be established by the harmonised standards referred to in Article 5 of Directive 90/385/EEC as amended, taking account of the specific nature of the product categories in question.

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

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

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

7. Application to the devices referred to in Article 1(4a) of Directive 90/385/EEC as amended:

Upon completing the manufacture of each batch of devices referred to in Article 1(4a) of Directive 90/385/EEC as amended, the manufacturer shall inform the notified body of the release of the batch of devices and send to it the official certificate concerning the release of the batch of human blood derivative used in the device, issued by a State laboratory or a laboratory designated for that purpose by a Member State in accordance with Article 114(2) of Directive 2001/83/EC.

SCHEDULE 5

EC DECLARATION OF CONFORMITY TO TYPE

(Assurance of production quality)

1. The manufacturer shall apply the quality system approved for the manufacture and shall conduct the final inspection of the products concerned as specified in 3; he or she 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 the Directive which apply to them.

The manufacturer or his or her authorized representative established within the Community shall affix the CE marking in accordance with Article 12 of Directive 90/385/EEC as amended and draw up a written declaration of conformity. This declaration shall cover one or more devices manufactured, clearly identified by means of product name, product code or other unambiguous reference and must be kept by the manufacturer. The CE marking shall be accompanied by the identification number of the notified body responsible.

3. Quality system

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

The application shall include:

— all appropriate information concerning the products which it is intended to manufacture,

— the quality-system documentation,

— an undertaking to fulfil the obligations arising from the quality system as approved,

— an undertaking to maintain the approved quality system in such a way that it remains adequate and efficacious,

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

— an undertaking by the manufacturer to institute and keep updated a post-marketing surveillance system including the provisions referred to in Schedule 7. The undertaking shall

include an obligation for the manufacturer to notify the competent authorities of the following incidents immediately on learning of them:

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

(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 or her 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 products, including control of products which do not conform,

— where the manufacture and/or final inspection and testing of the products, or elements thereof, are carried out by a third party, the methods of monitoring the efficient operation of the quality system and in particular the type and extent of control applied to the third party;

(c) the 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;

(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. Without prejudice to Article 13 of Directive 90/385/EEC as amended, 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 technical 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, etc.

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

4.4. In addition, the notified body may make unannounced visits to the manufacturer, and shall supply him or her 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.

6. Application to the devices referred to in Article 1(4a) of Directive 90/385/EEC as amended:

Upon completing the manufacture of each batch of devices referred to in Article 1(4a) of Directive 90/385/EEC as amended, the manufacturer shall inform the notified body of the release of the batch of devices and send to it the official certificate concerning the release of the batch of human blood derivative used in the device, issued by a State laboratory or a laboratory designated for that purpose by a Member State in accordance with Article 114(2) of Directive 2001/83/EC.

SCHEDULE 6

STATEMENT CONCERNING DEVICES INTENDED FOR SPECIAL PURPOSES

1. The manufacturer or his or her authorized representative established within the Community 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:

— the name and address of the manufacturer,

— the information necessary for the identification of the product in question,

— a statement affirming that the device is intended for exclusive use by a particular patient, together with his or her name,

— the name of the registered medical practitioner who drew up the prescription and, if applicable, the name of the clinic concerned,

— the specific characteristics of the product revealed by the prescription,

— a statement affirming that the device complies with the essential requirements given in Schedule 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 covered in Schedule 7:

— data allowing the devices in question to be identified,

— the clinical investigation plan,

— the investigator's brochure,

— the confirmation of insurance of subjects,

— the documents used to obtain informed consent,

— a statement indicating whether or not the device incorporates, as an integral part, a substance or human blood derivative referred to in Section 10 of Schedule 1,

— the opinion of the ethics committee concerned and details of the aspects covered by its opinion,

— the name of the registered medical practitioner or other authorised person and of the institution responsible for the investigations,

— the place, date of commencement and duration scheduled for the investigations,

— 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 competent national authorities:

3.1. For custom-made devices, documentation, indicating manufacturing site(s) and enabling the design, manufacture and performances of the product, including the expected performances, to be understood, so as to allow conformity with the requirements of Directive 90/385/EEC as amended 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 referred to in the first paragraph.

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

— a general description of the product and its intended use,

— design drawings, manufacturing methods, in particular as regards sterilization, and diagrams of parts, sub-assemblies, circuits, etc.,

— the descriptions and explanations necessary for the understanding of the said drawings and diagrams and of the operation of the product,

— the results of the risk analysis and a list of the standards laid down in Article 5 of Directive 90/385/EEC as amended, applied in full or in part, and a description of the solutions adopted to satisfy the essential requirements of the Directive where the standards in Article 5 of Directive 90/385/EEC as amended have not been applied,

— if the device incorporates, as an integral part, a substance or human blood derivative referred to in Section 10 of Schedule 1, the data on the tests conducted in this connection which are required to assess the safety, quality and usefulness of that substance, or human blood derivative, taking account of the intended purpose of the device,

— the results of the design calculations, checks and technical tests carried out, etc.

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.

4. The information included in the declarations covered by this Schedule shall be kept for a period of at least 15 years from the date of manufacture of the last product.

5. For custom-made devices, the manufacturer must undertake to review and to document experience gained in the post-production phase, including the provisions referred to in Schedule 7, and to implement appropriate means to apply any necessary corrective action. This undertaking must include an obligation for the manufacturer to notify the competent authorities of the following incidents immediately on learning of them and the relevant corrective actions:

(i) any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labelling or the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his or her state of health;

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

SCHEDULE 7

CLINICAL EVALUATION

1. General provisions

1.1. As a general rule, confirmation of conformity with the requirements concerning the characteristics and performances referred to in Sections 1 and 2 of Schedule 1 under the normal conditions of use of the device and the evaluation of the side-effects and of the acceptability of the benefit/risk ratio referred to in Section 5 of Schedule 1, must be based on clinical data. The evaluation of this data (hereinafter referred to as clinical evaluation), where appropriate taking account of any relevant harmonised standards, must follow a defined and methodologically sound procedure based on:

1.1.1. Either a critical evaluation of the relevant scientific literature currently available relating to the safety, performance, design characteristics and intended purpose of the device where:

— there is demonstration of equivalence of the device to the device to which the data relates and,

— the data adequately demonstrate compliance with the relevant essential requirements.

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

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

1.2. Clinical investigations shall be performed unless it is duly justified to rely on existing clinical data.

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

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

1.5. Where demonstration of conformity with essential requirements based on clinical data is not deemed appropriate, adequate justification for any such exclusion has to be given based on risk management output and under consideration of the specifics of the device/body interaction, the clinical performances intended and the claims of the manufacturer. Adequacy of demonstration of conformity

with the essential requirements by performance evaluation, bench testing and pre-clinical evaluation alone has to be duly substantiated.

1.6. All data must remain confidential unless it is deemed essential that they be divulged.

2. Clinical investigation

2.1. *Purpose*

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 Schedule 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.

2.2. 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.

2.3. Methods

2.3.1. 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.

2.3.2. The procedures utilized to perform the investigations shall be appropriate to the device under examination.

2.3.3. Clinical investigations shall be performed in circumstances equivalent to those which would be found in normal conditions of use of the device.

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

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

2.3.6. The investigations shall be performed under the responsibility of a registered medical practitioner or authorised person, in an appropriate environment. The medical specialist shall have access to the technical data regarding the device.

2.3.7. The written report, signed by the responsible medical specialist, shall comprise a critical evaluation of all the data collected during the clinical investigation.

SCHEDULE 8

MINIMUM CRITERIA TO BE MET WHEN DESIGNATING INSPECTION BODIES TO BE NOTIFIED

1. The 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 body.

2. The 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 body must be able to carry out all the tasks in one of Schedules 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.

4. 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.

5. 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.

6. The body must take out liability insurance unless liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for controls.

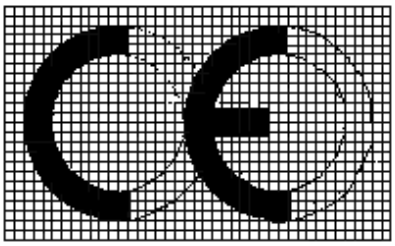
7. The staff of the body are bound to observe professional secrecy with regard to all information gained in carrying out their tasks (except vis-à-vis the competent administrative authorities of the State in which their activities are carried out) under Directive 90/385/EEC as amended or any provision of national law giving effect to it.

SCHEDULE 9

CE CONFORMITY MARKING

— The CE conformity marking shall consist of the initials 'CE' taking the following form:

—



— if the marking is reduced or enlarged the proportions given in the above graduated drawing must be respected.

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

GIVEN under the Official Seal of the Minister for Health and Children,
30 March 2009

MARY HARNEY.
Minister for Health and Children.

EXPLANATORY NOTE

(This note is not part of the Instrument and does not purport to be a legal interpretation)

These regulations amend the European Communities (Active Implantable Medical Devices) Regulations, 1994 (S.I. No. 253 of 1994) to give effect to Commission Directive 2007/47/EC of 5 September 2007, which brought in a number of amendments to the earlier Directive with regard to the definitions conformity assessment and general reporting procedures.

BAILE ÁTHA CLIATH
ARNA FHOILSIÚ AG OIFIG AN tSOLÁTHAIR
Le ceannach díreach ón
OIFIG DHÍOLTA FOILSEACHÁN RIALTAIS,
TEACH SUN ALLIANCE, SRÁID THEACH LAIGHEAN, BAILE ÁTHA CLIATH 2,
nó tríd an bpost ó
FOILSEACHÁIN RIALTAIS, AN RANNÓG POST-TRÁCHTA,
AONAD 20 PÁIRC MIONDÍOLA COIS LOCHA, CLÁR CHLAINNE MHUIRIS,
CONTAE MHAIGH EO,
(Teil: 01 - 6476834 nó 1890 213434; Fax: 094 - 9378964 nó 01 - 6476843)
nó trí aon díoltóir leabhar.

———————

DUBLIN
PUBLISHED BY THE STATIONERY OFFICE
To be purchased directly from the
GOVERNMENT PUBLICATIONS SALE OFFICE
SUN ALLIANCE HOUSE, MOLESWORTH STREET, DUBLIN 2,
or by mail order from
GOVERNMENT PUBLICATIONS, POSTAL TRADE SECTION,
UNIT 20 LAKESIDE RETAIL PARK, CLAREMORRIS, CO. MAYO,
(Tel: 01 - 6476834 or 1890 213434; Fax: 094 - 9378964 or 01 - 6476843)
or through any bookseller.

———————

ISBN 978-1-4064-4490-2

€8.89

9 781406 444902

Wt. (B26657). 285. 4/09. Cahill. Gr. 30-15.