STATUTORY INSTRUMENTS

S.I. No. 110 of 2009

EUROPEAN COMMUNITIES (MEDICAL DEVICES) (AMENDMENT) REGULATIONS 2009

(Prn. A9/0441)

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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 93/42/EEC of 14 June 1993 (S.I. No. 252 of 1994) concerning medical devices, hereby make the following Regulations:

1. These following Regulations may be cited as the European Communities (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 (Medical Devices) Regulations, 1994 (Statutory Instrument number 252 of 1994).

"These Regulations" means the European Communities (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/EEC 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.

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

[1]OJ L 247, 21.9.2007, p.21
[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 L 378, 27.12.2006, p.1)
[5]OJ L 390, 31.12.2004, p.24

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

"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. No. 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. No. 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. No. 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. No. 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 "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;'

[6]OJ L 157, 9.6.2006, p.24

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

"device subcategory" means a set of devices having common areas of intended use or common technology;'

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

"generic device group" means a set of devices having the same or similar intended uses or commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics;

(iv) by the insertion after the definition of "relevant notified body identification number" of the following definition:

'single use device" means a device intended to be used once only for a single patient;

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

(i). The definition of "custom made device" is amended by deleting the words:

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

and substituting the words:

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

(ii). The definition of "device" is amended by substituting for the words:

' "device" means a medical device, that is to say an instrument, apparatus, appliance, material or other article, whether used alone or in combination, together with any software necessary for its proper application, which—

(a) is intended by the manufacturer to be used for human beings for the purpose of—

(i) diagnosis, prevention, monitoring, treatment or alleviation of disease,

(ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,

(iii) investigation, replacement or modification of the anatomy or of a physiological process, or

(iv) control of conception; and

(b) does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, even if it is assisted in its function by such means;'

with the words:

' "device" means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, 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—

(i) diagnosis, prevention, monitoring, treatment or alleviation of disease,

(ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,

(iii) investigation, replacement or modification of the anatomy or of a physiological process, or

(iv) control of conception; and

does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, even if it is assisted in its function by such means;

(iii). The definition for "intended for clinical investigation" is deleted and substituted with the following words:

' "intended for clinical investigation" means, in relation to a device, that it is—

(a) intended for use by a registered medical practitioner user when conducting investigations of that device in an adequate human clinical environment; or

(b) for use by any other person who by virtue of his or her professional qualifications is authorised to carry out investigations of that device in an adequate human clinical environment;

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

"(2) Where a 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 Directive 2001/83/EC with regard to the medicinal product.

If, however, such a device is placed on the market in such a way that the device and the medicinal product form a single integral product which is intended exclusively for use in the given combination and which is not reusable, that single product shall be governed by Directive 2001/83/EC. The relevant essential requirements of Schedule 1 to these Regulations shall apply as far as safety and performance-related device features are concerned."

7. Regulation 3 (Application) of the Principal Regulations is amended by deleting Paragraph (3) before paragraph 3(a) 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 deleting Paragraph (3)(*a*) and substituting the following:

"(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 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 all the words in Paragraph (4)(*c*) and substituting the words:

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

10. Regulation 3 (Application) of the Principal Regulations is amended by deleting the words in Paragraph (4)(f) and substituting the words:

"transplants or tissues or cells of human origin nor 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; "

11. Regulation 3 (Application) of the Principal Regulations is amended by deleting Paragraph (4)(h).

12. Regulation 3 (Application) of the Principal Regulations is amended by deleting Paragraph (5) and substituting:

"(5) Where a device is intended by the manufacturer to be used in accordance with both the provisions of personal protective equipment in the European

Communities (Personal Protective Equipment) Regulations (S.I. No. 272 of 1993) and the Principal Regulations, the relevant basic health and safety requirements of S.I. No. 272 of 1993 shall also be fulfilled."

13. Regulation 3 (Application) of the Principal Regulations is amended by adding a new Paragraph (6) as follows:

> "(6) This Directive constitutes a specific Directive within the meaning of Article 1(4) of Directive 2004/108/EC of the European Parliament and of the Council."

14. Regulation 3 (Application) of the Principal Regulations is amended by adding after Paragraph (6) a new Paragraph (7) with the following words:

> "(7) These Regulations shall not affect the application of the Radiological Protection Act 1991 Ionising Radiation order (S.I. No. 125 of 2000) and European Communities (Medical Ionising Radiation Protection) Regulations (S.I. No. 478 of 2002) as amended."

15. Regulation 4 (Classification) of the Principal Regulations is amended by deleting Paragraph (3) and substituting the following words:

"(3) Where the Minister considers that—

(a) the application of the classification rules set out in Schedule 9 requires a decision with regard to the classification of a given device or category of devices; or

(b) a given device or family of devices should be classified by way of derogation from the provisions of Schedule 9 in another class; or

(c) the conformity of a device or family of devices should be established by way of derogation from the provisions of article 7,8, 9 or 10 of Directive 93/42/EEC as amended, by applying solely one of the given procedures chosen from among those referred to in that article; or

(d) a decision is required as to whether a particular product or product group falls within one of the definitions in Regulation 2 (Definitions);

and where the Minister considers that the classification rules set out in Schedule 9 require adaptation in the light of technical progress and any information which becomes available under the information system provided for in Regulation 20, the Minister, may submit a duly substantiated request to the Commission of the European Union and ask it to take the necessary measures for adaptation of the classification rules."

16. Regulation 5 (Essential Requirements) of the Principal Regulations is amended by deleting Paragraph 7 and substituting the following:

"(7) The manufacturer of a custom-made device shall follow the procedure set out in Regulation 5 of the Principal Regulations and Schedule 8; Class IIa, IIb and III devices shall be accompanied by the statement referred to in Schedule 8 which shall be available to the particular patient identified by name, an acronym or a numerical code and the manufacturer should ensure that the statement is supplied with the custom-made device so that it may be made available to the patient on request."

17. Regulation 5 (Essential Requirements for devices) of the Principal Regulations is amended by adding after Paragraph (8) a new Paragraph (9):

"(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."

18. The title of Regulation 11 of the Principal Regulations is amended by deleting the words:

"Procedure for systems and procedure packs"

and substituting the words:

"Particular procedure for systems and procedure packs and procedure for sterilisation"

19. Paragraph 3(a) of Regulation 11 of the Principal Regulations is deleted and the following paragraph substituted:

"(a) Choose to follow one of the procedures referred to in Schedule 2 or 5, the application of which is limited to the aspects of the procedure relating to the obtaining of sterility, until the sterile package is opened or damaged."

20. Paragraph (6) of Regulation 11 of the Principal Regulations is amended by deleting the words:

"The declaration referred to in subarticles (1) and (3)(b) shall be kept available for the Minister or an authorised officer for a period of five years."

and substituting the words:

"The declarations referred to in paragraphs (1) and (3)(b) shall be kept at the disposal of the Competent Authority for a period of five years.";

21. Paragraph 6 of Regulation 12 (General Provisions relating to conformity assessment procedures) of the Principal Regulations is amended by deleting the words:

> "A decision made by a notified body in accordance with Schedule 2 or Schedule 3 shall—"

and substituting the following words:

> "A decision made by a notified body in accordance with Schedules 2, 3, 5 and 6 shall—"

22. Paragraph 8 of Regulation 12 (General Provisions relating to conformity assessment procedures) of the Principal Regulations is amended by deleting the words:

> "Where a period of validity has been extended under subarticle (7), the notified body may, on application made by the manufacturer, grant a further extension of 5 years."

and substituting the following words:

> "Where a period of validity has been extended under paragraph (7), the notified body may, on application made by the manufacturer, grant an extension for further periods of a maximum length of 5 years."

23. Regulation 14 (Registration of persons placing devices on the market) of the Principal Regulations is amended by deleting paragraphs 3, 3(a), 3(b) and 3(c) and inserting the following:

> "(3) A manufacturer who places a device on the market under his or her own name but does not have a registered place of business in the state or another member state of the European Union, shall designate a single authorised representative in the state or another member state of the European Union."

24. Regulation 14 (Registration of persons placing devices on the market) of the Principal Regulations is amended by adding a new paragraph 4 as follows:

> "(4) A person in the State who has been designated as an authorised representative by a manufacturer who does not have a registered place of business in the Community to place on the market a device referred to in subarticle (1) shall inform the Competent Authority of:
>
> (a) his or her registered place of business;
>
> (b) the type of device; and
>
> (c) shall furnish the Competent Authority with sufficient evidence that he or she is the authorised representative of the manufacturer."

25. Regulation 14A of the Principal Regulations is amended by deleting all the words including the title and substituting the following:

"Information relating to Class IIa, IIb and III devices

(14A) The manufacturer or the authorised representative of the manufacturer may supply to the Competent Authority for all medical devices of Class IIa IIb and III data allowing for the identification of such devices together with the label and the instructions for use when such devices are put into service in the State."

26. Regulation 16 (Clinical investigations) of the Principal Regulations is amended by deleting all the paragraphs and substituting the following paragraphs:

"(1) In the case of devices intended for clinical investigations to be conducted in Ireland, the manufacturer or the authorised representative shall follow the procedure referred to in Schedule 8 to these regulations and notify the Competent Authority by means of the statement mentioned in Section 2 of Schedule 8 to these regulations.

(2) In the case of devices falling within Class III and implantable and long-term invasive devices falling within Class IIa or IIb, the manufacturer may commence the relevant clinical investigation at the end of a period of 60 days after notification, unless the Competent Authority have notified the manufacturer within that period of a decision to the contrary based on considerations of public health or public policy.

However manufacturers may be authorised by the Competent Authority to commence the relevant clinical investigations before the expiry of the period of 60 days, in so far as the Ethics Committee has issued a favourable opinion on the programme of investigation, including its review of the clinical investigation plan.

(3) In the case of devices other than those referred to in paragraph 2 of this regulation, manufacturers may be authorised by the Competent Authority to commence clinical investigations immediately after the date of notification, provided that the Ethics Committee mentioned above has issued a favourable opinion on the programme of investigation in question, including its review of the clinical investigation plan.

(4) Clinical investigations shall be conducted in accordance with the provision of Schedule 10 to these regulations.

(5) 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.

(6) 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 16(6) 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 10 to these regulations at the disposal of the Competent Authority and the competent authorities of the other Member States concerned.

(7) The provisions of Regulations 16(1) and 16(2) above do not apply where the clinical investigations are conducted using devices which are authorised in accordance with Regulations 12(1) to (11) of these regulations to bear the CE marking unless the aim of these investigations is to use the devices for a purpose other than that referred to in the relevant conformity assessment procedure. The relevant provisions of Schedule 10 to these regulations remain applicable."

27. Regulation 17 (Notified Bodies) of the Principal Regulations is amended by deleting paragraphs 3, 3(a) and 3(b) and substituting the following:

"(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."

28. Regulation 26 (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."

29. Schedules 1 to 12 of the Principal Regulations amended by Statutory Instrument 444 of 2001 (corresponding to Annex I to XII of Directive 93/42/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 used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their intended use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.

This shall include:

— reducing, as far as possible, the risk of use error due to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and

— consideration of the technical knowledge, experience, education and training and where applicable the medical and physical conditions of intended users (design for lay, professional, disabled or other users).

2. The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art.

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

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

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

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

3. The devices must achieve the performances intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions referred to in Article 1(2)(*a*) of Directive 93/42/EEC as amended, as specified by the manufacturer.

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

5. The devices must be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage taking account of the instructions and information provided by the manufacturer.

6. Any undesirable side-effect must constitute an acceptable risk when weighed against the performances intended.

6a. Demonstration of conformity with the essential requirements must include a clinical evaluation in accordance with Schedule 10.

II. REQUIREMENTS REGARDING DESIGN AND CONSTRUCTION

7. Chemical, physical and biological properties

7.1. The devices must be designed and manufactured in such a way as to guarantee the characteristics and performances referred to in Section I on the 'General requirements'. Particular attention must be paid to:

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

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

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

7.2. The devices must be designed, manufactured and packed in such a way as to minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to the patients, taking account of the intended purpose of the product. Particular attention must be paid to the tissues exposed and to the duration and frequency of exposure.

7.3. The devices must be designed and manufactured in such a way that they can be used safely with the materials, substances and gases with which they enter into contact during their normal use or during routine procedures; if the devices are intended to administer medicinal products they must be designed and manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and restrictions governing these products and that their performance is maintained in accordance with the intended use.

7.4. Where a 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 medical device and taking into account 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 incorporation of the substance into the device as determined by the notified body, in order to ensure that the changes have no negative impact on the established benefit/risk profile of the addition of the substance in the medical device.

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

7.5. The devices must be designed and manufactured in such a way as to reduce to a minimum the risks posed by substances leaking from the device. Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction, in accordance with Annex I to Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances.

If parts of a device (or a device itself) intended to administer and/or remove medicines, body liquids or other substances to or from the body, or devices intended for transport and storage of such body fluids or substances, contain

phthalates which are classified as carcinogenic, mutagenic or toxic to reproduction, of category 1 or 2, in accordance with Annex I to Directive 67/548/EEC, these devices must be labelled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging as a device containing phthalates.

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

7.6. Devices must be designed and manufactured in such a way as to reduce, as much as possible, risks posed by the unintentional ingress of substances into the device taking into account the device and the nature of the environment in which it is intended to be used.

8. Infection and microbial contamination

8.1. The devices and manufacturing processes must be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the patient, user and third parties. The design must allow easy handling and, where necessary, minimize contamination of the device by the patient or vice versa during use.

8.2. Tissues of animal origin must originate from animals that have been subjected to veterinary controls and surveillance adapted to the intended use of the tissues.

Notified bodies shall retain information on the geographical origin of the animals.

Processing, preservation, testing and handling of tissues, cells and substances of animal origin must be carried out so as to provide optimal security. In particular safety with regard to viruses and other transmissible agents must be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process.

8.3. Devices delivered in a sterile state must be designed, manufactured and packed in a non-reusable pack and/or according to appropriate procedures to ensure that they are sterile when placed on the market and remain sterile, under the storage and transport conditions laid down, until the protective packaging is damaged or opened.

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

8.5. Devices intended to be sterilized must be manufactured in appropriately controlled (e. g. environmental) conditions.

8.6. Packaging systems for non-sterile devices must keep the product without deterioration at the level of cleanliness stipulated and, if the devices are to be sterilized prior to use, minimize the risk of microbial contamination; the packaging system must be suitable taking account of the method of sterilization indicated by the manufacturer.

8.7. The packaging and/or label of the device must distinguish between identical or similar products sold in both sterile and non-sterile condition.

9. Construction and environmental properties

9.1. If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system must be safe and must not impair the specified performances of the devices. Any restrictions on use must be indicated on the label or in the instructions for use.

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

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

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

— the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given,

— risks arising where maintenance or calibration are not possible (as with implants), from ageing of materials used or loss of accuracy of any measuring or control mechanism.

9.3. Devices must be designed and manufactured in such a way as to minimize the risks of fire or explosion during normal use and in single fault condition. Particular attention must be paid to devices whose intended use includes exposure to flammable substances or to substances which could cause combustion.

10. Devices with a measuring function

10.1. Devices with a measuring function must be designed and manufactured in such a way as to provide sufficient accuracy and stability within appropriate limits of accuracy and taking account of the intended purpose of the device. The limits of accuracy must be indicated by the manufacturer.

10.2. The measurement, monitoring and display scale must be designed in line with ergonomic principles, taking account of the intended purpose of the device.

10.3. The measurements made by devices with a measuring function must be expressed in legal units conforming to the provisions of Council Directive 80/181/EEC.

11. Protection against radiation

11.1. General

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

11.2. Intended radiation

11.2.1. Where devices are designed to emit hazardous levels of radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent in the emission, it must be possible for the user to control the emissions. Such devices shall be designed and manufactured to ensure reproducibility and tolerance of relevant variable parameters.

11.2.2. Where devices are intended to emit potentially hazardous, visible and/or invisible radiation, they must be fitted, where practicable, with visual displays and/or audible warnings of such emissions.

11.3. Unintended radiation

11.3.1. Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as possible.

11.4. Instructions

11.4.1. The operating instructions for devices emitting radiation must give detailed information as to the nature of the emitted radiation, means of protecting the patient and the user and on ways of avoiding misuse and of eliminating the risks inherent in installation.

11.5. Ionizing radiation

11.5.1. Devices intended to emit ionizing radiation must be designed and manufactured in such a way as to ensure that, where practicable, the quantity, geometry and quality of radiation emitted can be varied and controlled taking into account the intended use.

11.5.2. Devices emitting ionizing radiation intended for diagnostic radiology shall be designed and manufactured in such a way as to achieve appropriate image and/or output quality for the intended medical purpose whilst minimizing radiation exposure of the patient and user.

11.5.3. Devices emitting ionizing radiation, intended for therapeutic radiology shall be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam type and energy and where appropriate the quality of radiation.

12. Requirements for medical devices connected to or equipped with an energy source

12.1. Devices incorporating electronic programmable systems must be designed to ensure the repeatability, reliability and performance of these systems according to the intended use. In the event of a single fault condition (in the system) appropriate means should be adopted to eliminate or reduce as far as possible consequent risks.

12.1a For devices which incorporate software or which are medical software in themselves, the software must be validated according to the state of the art taking into account the principles of development lifecycle, risk management, validation and verification.

12.2. Devices where the safety of the patients depends on an internal power supply must be equipped with a means of determining the state of the power supply.

12.3. Devices where the safety of the patients depends on an external power supply must include an alarm system to signal any power failure.

12.4. Devices intended to monitor one or more clinical parameters of a patient must be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health.

12.5. Devices must be designed and manufactured in such a way as to minimize the risks of creating electromagnetic fields which could impair the operation of other devices or equipment in the usual environment.

12.6. Protection against electrical risks

Devices must be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks during normal use and in single fault condition, provided the devices are installed correctly.

12.7. Protection against mechanical and thermal risks.

12.7.1. Devices must be designed and manufactured in such a way as to protect the patient and user against mechanical risks connected with, for example, resistance, stability and moving parts.

12.7.2. Devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for

limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.

12.7.3. Devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.

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

12.7.5. Accessible parts of the devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings must not attain potentially dangerous temperatures under normal use.

12.8. Protection against the risks posed to the patient by energy supplies or substances

12.8.1. Devices for supplying the patient with energy or substances must be designed and constructed in such a way that the flow-rate can be set and maintained accurately enough to guarantee the safety of the patient and of the user.

12.8.2. Devices must be fitted with the means of preventing and/or indicating any inadequacies in the flow-rate which could pose a danger.Devices must incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy from an energy and/or substance source.

12.9. The function of the controls and indicators must be clearly specified on the devices.

Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information must be understandable to the user and, as appropriate, the patient.

13. Information supplied by the manufacturer

13.1. Each device must be accompanied by the information needed to use it safely and properly, taking account of the training and knowledge of the potential users, and to identify the manufacturer. This information comprises the details on the label and the data in the instructions for use.

As far as practicable and appropriate, the information needed to use the device safely must be set out on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging. If individual packaging of each unit is not practicable, the information must be set out in the leaflet supplied with one or more devices. Instructions for use must be included in the packaging for every device. By way of exception, no such instructions for use are needed for devices in Class I or IIa if they can be used safely without any such instructions.

13.2. Where appropriate, this information should take the form of symbols. Any symbol or identification colour used must conform to the harmonized standards. In areas for which no standards exist, the symbols and colours must be described in the documentation supplied with the device.

13.3. The label must bear the following particulars:

(*a*) the name or trade name and address of the manufacturer. For devices imported into the Community, in view of their distribution in the Community, the label, or the outer packaging, or instructions for use, shall contain in addition the name and address of the authorised representative where the manufacturer does not have a registered place of business in the Community;

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

(*c*) where appropriate, the word 'STERILE';

(*d*) where appropriate, the batch code, preceded by the word 'LOT', or the serial number;

(*e*) where appropriate, an indication of the date by which the device should be used, in safety, expressed as the year and month;

(*f*) where appropriate, an indication that the device is for single use. A manufacturer's indication of single use must be consistent across the Community;

(*g*) if the device is custom-made, the words 'custom-made device';

(*h*) if the device is intended for clinical investigations, the words 'exclusively for clinical investigations';

(*i*) any special storage and/or handling conditions;

(*j*) any special operating instructions;

(*k*) any warnings and/or precautions to take;

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

(*m*) where applicable, method of sterilization;

(*n*) in the case of a device within the meaning of Article 1(4a) of Directive 93/42/EEC as amended, an indication that the device contains a human blood derivative.

13.4. If the intended purpose of the device is not obvious to the user, the manufacturer must clearly state it on the label and in the instructions for use.

13.5. Wherever reasonable and practicable, the devices and detachable components must be identified, where appropriate in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices and detachable components.

13.6. Where appropriate, the instructions for use must contain the following particulars:

(*a*) the details referred to in Section 13.3, with the exception of (*d*) and (*e*);

(*b*) the performances referred to in Section 3 and any undesirable side effects;

(*c*) if the device must be installed with or connected to other medical devices or equipment in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct devices or equipment to use in order to obtain a safe combination;

(*d*) all the information needed to verify whether the device is properly installed and can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the devices operate properly and safely at all times;

(*e*) where appropriate, information to avoid certain risks in connection with implantation of the device;

(*f*) information regarding the risks of reciprocal interference posed by the presence of the device during specific investigations or treatment;

(*g*) the necessary instructions in the event of damage to the sterile packaging and, where appropriate, details of appropriate methods of resterilization;

(*h*) if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of sterilization of the device to be resterilized, and any restriction on the number of reuses.

Where devices are supplied with the intention that they be sterilized before use, the instructions for cleaning and sterilization must be such that, if correctly followed, the device will still comply with the requirements in Section I.

If the device bears an indication that the device is for single use, information on known characteristics and technical factors known to the manufacturer that could pose a risk if the device were to be reused. If in accordance with Section 13.1 no instructions for use are needed, the information must be made available to the user upon request;

(*i*) details of any further treatment or handling needed before the device can be used (for example, sterilization, final assembly, etc.);

(*j*) in the case of devices emitting radiation for medical purposes, details of the nature, type, intensity and distribution of this radiation.

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

(*k*) precautions to be taken in the event of changes in the performance of the device;

(*l*) precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources, etc.;

(*m*) adequate information regarding the medicinal product or products which the device in question is designed to administer, including any limitations in the choice of substances to be delivered;

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

(*o*) medicinal substances, or human blood derivatives incorporated into the device as an integral part in accordance with Section 7.4;

(*p*) degree of accuracy claimed for devices with a measuring function;

(*q*) date of issue or the latest revision of the instructions for use.

SCHEDULE 2

EC DECLARATION OF CONFORMITY

(Full quality assurance system)

1. The manufacturer must ensure application of the quality system approved for the design, manufacture and final inspection of the products concerned, as specified in Section 3 and is subject to audit as laid down in Sections 3.3 and 4 and to Community surveillance as specified in Section 5.

2. The EC declaration of conformity is the procedure whereby the manufacturer who fulfils the obligations imposed by Section 1 ensures and declares that the products concerned meet the provisions of Directive 93/42/EEC as amended which apply to them.

The manufacturer must affix the CE marking in accordance with Article 17 of Directive 93/42/EEC as amended and draw up a written declaration of conformity. This declaration must cover one or more medical devices manufactured, clearly identified by means of product name, product code or other unambiguous reference and must be kept by the manufacturer.

3. Quality system

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

The application must include:

— the name and address of the manufacturer and any additional manufacturing site covered by the quality system,

— all the relevant information on the product or product category covered by the procedure,

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

— the documentation on the quality system,

— an undertaking by the manufacturer to fulfil the obligations imposed by the quality system approved,

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

— an undertaking by the manufacturer to institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase, including the provisions referred to in Schedule 10 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:

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

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

3.2. Application of the quality system must ensure that the products conform to the provisions of Directive 93/42/EEC as amended which apply to them at every stage, from design to final inspection. All the elements, requirements and provisions adopted by the manufacturer for his or her quality system must be documented in a systematic and orderly manner in the form of written policies and procedures such as quality programmes, quality plans, quality manuals and quality records.

It 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 design and of product, including control of products which fail to conform,

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

(*c*) the procedures for monitoring and verifying the design of the products, including the corresponding documentation, and in particular:

— a general description of the product, including any variants planned, and its intended use(s),

— the design specifications, including the standards which will be applied and the results of the risk analysis, and also a description of the solutions adopted to fulfil the essential requirements which apply to the products if the standards referred to in Article 5 of Directive 93/42/EEC as amended are not applied in full,

— the techniques used to control and verify the design and the processes and systematic measures which will be used when the products are being designed,

— if the device is to be connected to other device(s) in order to operate as intended, proof must be provided that it conforms to the essential requirements when connected to any such device(s) having the characteristics specified by the manufacturer,

— a statement indicating whether or not the device incorporates, as an integral part, a substance or a human blood derivative referred to in section 7.4 of 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,

— a statement indicating whether or not the device is manufactured utilising tissues of animal origin as referred to in Commission Directive 2003/32/EC,

— the solutions adopted as referred to in Schedule 1, Chapter I, Section 2,

— the pre-clinical evaluation,

— the clinical evaluation referred to in Schedule 10,

— the draft label and, where appropriate, instructions for use.

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

— the processes and procedures which will be used, particularly as regards sterilization, purchasing and the relevant documents,

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

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

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

The assessment team must include at least one member with past experience of assessments of the technology concerned. The assessment procedure must include an assessment, on a representative basis, of the documentation of the design of the product(s) concerned, an inspection on the manufacturer's premises and, in duly substantiated cases, on the premises of the manufacturer's suppliers and/or subcontractors to inspect the manufacturing processes. The decision is notified to the manufacturer. It must contain the conclusions of the inspection and a reasoned assessment.

3.4. The manufacturer must inform the notified body which approved the quality system of any plan for substantial changes to the quality system or the product-range covered. The notified body must assess the changes proposed and verify whether after these changes the quality system still meets the requirements referred to in Section 3.2. It must notify the manufacturer of its decision. This decision must contain the conclusions of the inspection and a reasoned assessment.

4. Examination of the design of the product

4.1. In addition to the obligations imposed by Section 3, the manufacturer must lodge with the notified body an application for examination of the design dossier relating to the product which he plans to manufacture and which falls into the category referred to in Section 3.1.

4.2. The application must describe the design, manufacture and performances of the product in question. It must include the documents needed to assess whether the product conforms to the requirements of Directive 93/42/EEC as amended, as referred to in Section 3.2(*c*).

4.3. The notified body must examine the application and, if the product conforms to the relevant provisions of Directive 93/42/EEC as amended, issue the application with an EC design-examination certificate. The notified body may require the application to be completed by further tests or proof to allow assessment of conformity with the requirements of the Directive. The certificate must contain the conclusions of the examination, the conditions of validity, the data needed for identification of the approved design, where appropriate, a description of the intended purpose of the product.

In the case of devices referred to in Schedule 1, Section 7.4, 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 must 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 7.4, third paragraph, the scientific opinion of the EMEA must be included in the documentation concerning the device. The opinion of the EMEA must 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.

In the case of devices manufactured utilising tissues of animal origin as referred to in Directive 2003/32/EC, the notified body must follow the procedures referred to in that Directive.

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

5. Surveillance

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

5.2. The manufacturer must authorize the notified body to carry out all the necessary inspections and supply it with all relevant information, in particular:

— the documentation on the quality system,

— the data stipulated in the part of the quality system relating to design, such as the results of analyses, calculations, tests, the solutions adopted as referred to in Schedule 1, Chapter I, Section 2, 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 inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.

5.3. The notified body must periodically carry out appropriate inspections and assessments to make sure that the manufacturer applies the approved quality system and must supply the manufacturer with an assessment report.

5.4. In addition, the notified body may pay unannounced visits to the manufacturer. At the time of such visits, the notified body may, where necessary, carry out or ask for tests in order to check that the quality system is working properly. It must provide the manufacturer with an inspection report and, if a test has been carried out, with a test report.

6. Administrative provisions

6.1. The manufacturer or his or her authorised representative must, for a period ending at least five years, and in the case of implantable devices at least 15 years, after the last product has been manufactured, keep at the disposal of the national authorities:

— the declaration of conformity,

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

— the changes referred to in Section 3.4,

— the documentation referred to in Section 4.2, and

— the decisions and reports from the notified body as referred to in Sections 3.3, 4.3, 4.4, 5.3 and 5.4.

7. Application to devices in Classes IIa and IIb.

7.1. In line with Article 11(2) and (3) of Directive 93/42/EEC as amended, this Schedule may apply to products in Classes IIa and IIb. Section 4, however, does not apply.

7.2. For devices in Class IIa the notified body shall assess, as part of the assessment in Section 3.3, the technical documentation as described in Section 3.2(*c*) for at least one representative sample for each device subcategory for compliance with the provisions of Directive 93/42/EEC as amended

7.3. For devices in Class IIb the notified body shall assess, as part of the assessment in Section 3.3, the technical documentation as described in Section 3.2(*c*) for at least one representative sample for each generic device group for compliance with the provisions of Directive 93/42/EEC as amended

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

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

8. Application to the devices referred to Article 1(4a) of Directive 93/42/EEC as amended.Upon completing the manufacture of each batch of devices referred to in Article 1(4a) of Directive 93/42/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 ascertains and certifies that a representative sample of the production covered fulfils the relevant provisions of Directive 93/42/EEC as amended.

2. The application includes:

— the name and address of the manufacturer and the name and address of the authorized representative if the application is lodged by the representative,

— the documentation described in Section 3 needed to assess the conformity of the representative sample of the production in question, hereinafter referred to as the 'type', with the requirements of Directive 93/42/EEC as amended. The applicant must make a 'type' available to the notified body. The notified body may request other samples as necessary,

— a written declaration that no application has been lodged with any other notified body for the same type.

3. The documentation must allow an understanding of the design, the manufacture and the performances of the product and must contain the following 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 sterilisation, and diagrams of components, sub-assemblies, circuits, etc.,

— the descriptions and explanations necessary to understand the above mentioned drawings and diagrams and the operation of the product,

— a list of the standards referred to in Article 5 of Directive 93/42/EEC as amended, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements if the standards referred to in Article 5 of Directive 93/42/EEC as amended have not been applied in full,

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

— a statement indicating whether or not the device incorporates, as an integral part, a substance, or human blood derivative, referred to in Section 7.4 of Schedule 1, and 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,

— a statement indicating whether or not the device is manufactured utilising tissues of animal origin as referred to in Directive 2003/32/EC,

— the solutions adopted as referred to in Schedule 1, Chapter I, Section 2,

— the pre-clinical evaluation,

— the clinical evaluation referred to in Schedule 10,

— the draft label and, where appropriate, instructions for use.

4. The notified body must:

4.1. examine and assess the documentation and verify that the type has been manufactured in conformity with that documentation; it must also record the items designed in conformity with the applicable provisions of the standards referred to in Article 5 of Directive 93/42/EEC as amended, as well as the items not designed on the basis of the relevant provisions of the abovementioned standards;

4.2. carry out or arrange for the appropriate inspections and the tests necessary to verify whether the solutions adopted by the manufacturer meet the essential requirements of Directive 93/42/EEC as amended if the standards referred to in Article 5 of Directive 93/42/EEC as amended have not been applied; if the device is to be connected to other device(*s*) in order to operate as intended, proof must be provided that it conforms to the essential requirements when connected to any such device(*s*) having the characteristics specified by the manufacturer;

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

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

5. If the type conforms to the provisions of Directive 93/42/EEC as amended, the notified body issues the applicant with an EC type-examination certificate. The certificate must contain the name and address of the manufacturer, the conclusions of the inspection, the conditions of validity and the data needed for identification of the type approved. The relevant parts of the documentation must be annexed to the certificate and a copy kept by the notified body.

In the case of devices referred to in Schedule 1, Section 7.4, second paragraph, the notified body shall, as regards the aspects referred to in that section, consult one of the 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 must 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 7.4, third paragraph, the scientific opinion of the EMEA must be included in the documentation concerning the device. The opinion of the EMEA must 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. In the case of devices manufactured utilising tissues of animal origin as referred to in Directive 2003/32/EC, the notified body must follow the procedures referred to in that Directive.

6. The applicant must inform the notified body which issued the EC type examination certificate of any significant change made to the approved product. Changes to the approved product must receive further approval from the notified body which issued the EC type-examination certificate wherever the changes may affect conformity with the essential requirements or with the conditions prescribed for use of the product. This new approval must, where appropriate, take the form of a supplement to the initial EC type examination certificate.

7. Administrative provisions

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 or her authorised 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. In the case of implantable devices, the period shall be at least 15 years after the last product has been manufactured.

SCHEDULE 4

EC VERIFICATION

1. EC verification is the procedure whereby the manufacturer or his or her authorized representative ensures and declares that the products which have been subject to the procedure set out in Section 4 conform to the type described in the EC type-examination certificate and meet the requirements of Directive 93/42/EEC which apply to them.

2. The manufacturer must take all the measures necessary to ensure that the manufacturing process produces products which conform to the type described in the EC type-examination certificate and to the requirements of the Directive which apply to them. Before the start of manufacture, the manufacturer must prepare documents defining the manufacturing process, in particular as regards sterilization where necessary, together with all the routine, pre-established provisions to be implemented to ensure homogeneous production and, where appropriate, conformity of the products with the type described in the EC type-examination certificate and with the requirements of Directive 93/42/EEC as amended which apply to them. The manufacturer must affix the CE marking in accordance with Article 17 of Directive 93/42/EEC as amended and draw up a declaration of conformity. In addition, for products placed on the market in sterile condition, and only for those aspects of the manufacturing process designed to secure and maintain sterility, the manufacturer must apply the provisions of Schedule 5, Sections 3 and 4.

3. The manufacturer must undertake to institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase, including the provisions referred to in Schedule 10, 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:

(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 subparagraph (i) leading to systematic recall of devices of the same type by the manufacturer.

4. The notified body must carry out the appropriate examinations and tests in order to verify the conformity of the product with the requirements of the Directive either by examining and testing every product as specified in Section 5 or by examining and testing products on a statistical basis as specified in Section 6, as the manufacturer decides. The aforementioned checks do not apply to those aspects of the manufacturing process designed to secure sterility.

5. Verification by examination and testing of every product

5.1. Every product is examined individually and the appropriate tests defined in the relevant standard(s) referred to in Article 5 of Directive 93/42/EEC as amended or equivalent tests must be carried out in order to verify, where appropriate, the conformity of the products with the EC type described in the type-examination certificate and with the requirements of the Directive which apply to them.

5.2. The notified body must affix, or have affixed its identification number to each approved product and must draw up a written certificate of conformity relating to the tests carried out.

6. Statistical verification

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

6.2. A random sample is taken from each batch. The products which make up the sample are examined individually and the appropriate tests defined in the relevant standard(s) referred to in Article 5 of Directive 93/42/EEC as amended or equivalent tests must be carried out to verify, where appropriate, the conformity of the products with the type described in the EC type-examination certificate and with the requirements of the Directive which apply to them in order to determine whether to accept or reject the batch.

6.3. Statistical control of products will be based on attributes and/or variables, entailing sampling schemes with operational characteristics which ensure a high level of safety and performance according to the state of the art. The sampling schemes will be established by the harmonised standards referred to in Article 5 of Directive 93/42/EEC as amended, taking account of the specific nature of the product categories in question.

6.4. If the batch is accepted, the notified body affixes or has affixed its identification number to each product and draws up a written certificate of conformity relating to the tests carried out. All products in the batch may be put on the market except any in the sample which failed to conform. If a batch is rejected, the competent notified body must take appropriate measures to prevent the batch from being placed on the market. In the event of frequent rejection of batches, the notified body may suspend the statistical verification. The manufacturer may, on the responsibility of the notified body, affix the notified body's identification number during the manufacturing process.

7. Administrative provisions

The manufacturer or his or her authorised representative must, for a period ending at least five years, and in the case of implantable devices at least 15 years, after the last product has been manufactured, make available to the national authorities:

— the declaration of conformity,

— the documentation referred to in Section 2,

— the certificates referred to in Sections 5.2 and 6.4,

— where appropriate, the type-examination certificate referred to in Schedule 3.

8. Application to devices in Class IIa In line with Article 11 (2) of Directive 93/42/EEC as amended, this Schedule may apply to products in Class IIa, subject to the following:

8.1. in derogation from Sections 1 and 2, by virtue of the declaration of conformity the manufacturer ensures and declares that the products in Class IIa are manufactured in conformity with the technical documentation referred to in Section 3 of Schedule 7 and meet the requirements of Directive 93/42/EEC as amended which apply to them;

8.2. in derogation from Sections 1, 2, 5 and 6, the verifications conducted by the notified body are intended to confirm the conformity of the products in Class IIa with the technical documentation referred to in Section 3 of Schedule 7.

9. Application to devices referred to in Article 1(4a) of Directive 93/42/EEC as amended.

In the case of section 5, upon completing the manufacture of each batch of devices referred to in Article 1(4a) of Directive 93/42/EEC as amended, and in the case of verification under section 6, the manufacturer shall inform the notified body of the release of this batch of devices and send to it the official certificate concerning the release of the batch of human blood derivative used in the device issued by 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

(Production quality assurance)

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

2. The EC declaration of conformity is the part of the procedure whereby the manufacturer who fulfils the obligations imposed by Section 1 ensures and declares that the products concerned conform to the type described in the EC type-examination certificate and meet the provisions of Directive 93/42/EEC as amended which apply to them. The manufacturer must affix the CE marking in accordance with Article 17 of Directive 93/42/EEC as amended and draw up a written declaration of conformity. This declaration must cover one or more medical devices manufactured, clearly identified by means of product name, product code or other unambiguous reference, and must be kept by the manufacturer.

3. Quality system

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

The application must include:

— the name and address of the manufacturer,

— all the relevant information on the product or product category covered by the procedure,

— a written declaration that no application has been lodged with any other notified body for the same products,

— the documentation on the quality system,

— an undertaking to fulfil the obligations imposed by the quality system is approved,

— an undertaking to maintain the practicability and effectiveness of the approved quality system,

— where appropriate, the technical documentation on the types approved and a copy of the EC type-examination certificates,

— an undertaking by the manufacturer to institute and keep up to date a systematic procedure to review experience gained from devices in the post- production phase, including the provisions referred to in Schedule 10, 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:

(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 subparagraph (i) above leading to a systematic recall of devices of the same type by the manufacturer.

3.2. Application of the quality system must ensure that the products conform to the type described in the EC type-examination certificate. All the elements, requirements and provisions adopted by the manufacturer for his quality system must be documented in a systematic and orderly manner in the form of written policy statements and procedures. This quality system documentation must permit uniform interpretation of the quality policy and procedures such as quality programmes, plans, manuals and records. It must include in particular an adequate description of:

(*a*) the manufacturer's quality objectives;

(*b*) the organization of the business 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 product, including control of products which fail to 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 inspection and quality assurance techniques at the manufacturing stage and in particular:

— the processes and procedures which will be used, particularly as regards sterilization, purchasing and the relevant documents,

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

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

3.3. The notified body must audit the quality system to determine whether it meets the requirements referred to in Section 3.2. It must presume that quality systems which implement the relevant harmonized standards conform to these requirements. The assessment team must include at least one member with past experience of assessments of the technology concerned. The assessment procedure must include an inspection on the manufacturer's premises and, in duly substantiated cases, on the premises of the manufacturer's suppliers to inspect the manufacturing processes. The decision must be notified to the manufacturer after the final inspection and contain the conclusions of the inspection and a reasoned assessment.

3.4. The manufacturer must inform the notified body which approved the quality system of any plan for substantial changes to the quality system. The notified body must assess the changes proposed and verify whether after these changes the quality system still meets the requirements referred to in Section 3.2. After the abovementioned information has been received the decision is notified to the manufacturer. It must contain the conclusions of the inspection and a reasoned assessment.

4. Surveillance

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

4.2. The manufacturer authorizes the notified body to carry out all the necessary inspections and must supply it with all relevant information, in particular:

— the documentation on the quality system,

— the technical documentation,

— the data stipulated in the part of the quality system relating to manufacture, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.

4.3. The notified body must periodically carry out appropriate inspections and assessments to make sure that the manufacturer applies the approved quality system and supply the manufacturer with an assessment report.

4.4. In addition, the notified body may pay unannounced visits to the manufacturer. At the time of such visits, the notified body may, where necessary, carry out or ask for tests in order to check that the quality system is working properly. It must provide the manufacturer with an inspection report and, if a test has been carried out, with a test report.

5. Administrative provisions

5.1. The manufacturer or his or her authorised representative must, for a period ending at least five years, and in the case of implantable devices at least fifteen years, after the last product has been manufactured, make available to the national authorities:

— the declaration of conformity,

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

— the changes referred to in Section 3.4,

— the documentation referred to in the seventh indent of Section 3.1,

— the decisions and reports from the notified body as referred to in Sections 4.3 and 4.4,

— where appropriate, the type-examination certificate referred to in Schedule 3.

6. Application to devices in Class IIa

In line with Article 11(2) of Directive 93/42/EEC as amended, this Schedule may apply to products in Class IIa, subject to the following:

6.1. By way of derogation from Sections 2, 3.1 and 3.2, by virtue of the declaration of conformity the manufacturer ensures and declares that the products in Class IIa are manufactured in conformity with the technical documentation referred to in Section 3 of Schedule 7 and meet the requirements of Directive 93/42/EEC as amended which apply to them.

6.2. For devices in Class IIa the notified body shall assess, as part of the assessment in Section 3.3, the technical documentation as described in Section 3 of Schedule 7 for at least one representative sample for each device subcategory for compliance with the provisions of Directive 93/42/EEC as amended.

6.3. In choosing representative sample(s) the notified body shall take into account the novelty of the technology, similarities in design, technology, manufacturing and sterilisation methods, the intended use and the results of any previous relevant assessments (e.g. with regard to physical, chemical or biological properties) that have been carried out in accordance with Directive 93/42/EEC as amended. The notified body shall document and keep available to the competent authority its rationale for the sample(s) taken.

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

7. Application to devices referred to in Article 1(4a) of Directive 93/42/EEC as amended.

Upon completing the manufacture of each batch of devices referred to in Article 1(4a) of Directive 93/42/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

EC DECLARATION OF CONFORMITY
(Product quality assurance)

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

In addition, for products placed on the market in sterile condition, and only for those aspects of the manufacturing process designed to secure and maintain sterility, the manufacturer must apply the provisions of Schedule 5, Sections 3 and 4.

2. The EC declaration of conformity is the part of the procedure whereby the manufacturer who fulfils the obligations imposed by Section 1 ensures and declares that the products concerned conform to the type described in the

EC type-examination certificate and meet the provisions of Directive 93/42/EEC as amended which apply to them. The manufacturer affixes the CE marking in accordance with Article 17 of Directive 93/42/EEC as amended and draws up a written declaration of conformity. This declaration must cover one or more medical devices manufactured, clearly identified by means of product name, product code or other unambiguous reference, and be kept by the manufacturer. The CE marking must be accompanied by the identification number of the notified body which performs the tasks referred to in this Schedule.

3. Quality system

3.1. The manufacturer lodges an application for assessment of his or her quality system with a notified body.

The application must include:

— the name and address of the manufacturer,

— all the relevant information on the product or product category covered by the procedure,

— a written declaration specifying that no application has been lodged with any other notified body for the same products,

— the documentation on the quality system,

— an undertaking by the manufacturer to fulfil the obligations imposed by the quality system approved,

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

— where appropriate, the technical documentation on the types approved and a copy of the EC type-examination certificates,

— an undertaking by the manufacturer to institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase, including the provisions referred to in Schedule 10, 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:

(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 the performance of a device for the reasons referred to in subparagraph (i) leading to a systematic recall of devices of the same type by the manufacturer.

3.2. Under the quality system, each product or a representative sample of each batch is examined and the appropriate tests defined in the relevant standard(s) referred to in Article 5 of Directive 93/42/EEC as amended or equivalent tests are carried out to ensure that the products conform to the type described in the EC type-examination certificate and fulfil the provisions of Directive 93/42/EEC as amended which apply to them. All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner in the form of written measures, procedures and instructions. This quality system documentation

must permit uniform interpretation of the quality programmes, quality plans, quality manuals and quality records.

It must include in particular an adequate description of:

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

— the examinations and tests that will be carried out after manufacture; it must be possible to trace back the calibration of the test equipment adequately,

— the methods of monitoring the efficient operation of the quality system,

— the quality records, such as reports concerning inspections, tests, calibration and the qualifications of the staff concerned, etc.,

— where the final inspection and testing of the products, or elements 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. The aforementioned checks do not apply to those aspects of the manufacturing process designed to secure sterility.

3.3. The notified body audits the quality system to determine whether it meets the requirements referred to in section 3.2. It must presume that quality systems which implement the relevant harmonized standards conform to these requirements. The assessment team must include at least one member with past experience of assessments of the technology concerned. The assessment procedure must include an inspection on the manufacturer's premises and, in duly substantiated cases, on the premises of the manufacturer's suppliers to inspect the manufacturing processes. The decision must be notified to the manufacturer. It must contain the conclusions of the inspection and a reasoned assessment.

3.4. The manufacturer must inform the notified body which approved the quality system of any plan for substantial changes to the quality system. The notified body must assess the changes proposed and verify whether after these changes the quality system will still meet the requirements referred to in Section 3.2. After receiving the abovementioned information it must notify the manufacturer of its decision. This decision must contain the conclusions of the inspection and a reasoned assessment.

4. Surveillance

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

4.2. The manufacturer must allow the notified body access for inspection purposes to the inspection, testing and storage locations and supply it with all relevant information, in particular:

— the documentation on the quality system,

— the technical documentation,

— the quality records, such as inspection reports, test data, calibration data, qualification reports of the staff concerned, etc.

4.3. The notified body must periodically carry out appropriate inspections and assessments to make sure that the manufacturer applies the quality system and must supply the manufacturer with an assessment report.

4.4. In addition, the notified body may pay unannounced visits to the manufacturer. At the time of such visits, the notified body may, where necessary, carry out or ask for tests in order to check that the quality system is working properly and that the production conforms to the requirements of the Directive which apply to it. To this end, an adequate sample of the final products, taken on site by the notified body, must be examined and the appropriate tests defined in the relevant standard(s) referred to in Article 5 of Directive 93/42/EEC as amended or equivalent tests must be carried out. Where one or more of the samples fails to conform, the notified body must take the appropriate measures. It must provide the manufacturer with an inspection report and, if a test has been carried out, with a test report.

5. Administrative provisions

5.1. The manufacturer or his or her authorised representative must, for a period ending at least five years, and in the case of implantable devices at least fifteen years, after the last product has been manufactured, make available to the national authorities:

— the declaration of conformity,

— the documentation referred to in the seventh indent of Section 3.1,

— the changes referred to in Section 3.4,

— the decisions and reports from the notified body as referred to in the final indent of Section 3.4 and in Sections 4.3 and 4.4,

— where appropriate, the certificate of conformity referred to in Schedule 3.

6. Application to devices in Class IIa

In line with Article 11(2) of Directive 93/42/EEC as amended, this Schedule may apply to products in Class IIa, subject to the following:

6.1. By way of derogation from Sections 2, 3.1 and 3.2, by virtue of the declaration of conformity the manufacturer ensures and declares that the products in Class IIa are manufactured in conformity with the technical documentation referred to in Section 3 of Schedule 7 and meet the requirements of Directive 93/42/EEC as amended which apply to them.

6.2. For devices in Class IIa the notified body shall assess, as part of the assessment in Section 3.3, the technical documentation as described in Section 3 of Schedule 7 for at least one representative sample for each device subcategory for compliance with the provisions of Directive 93/42/EEC as amended.

6.3. In choosing representative sample(s) the notified body shall take into account the novelty of the technology, similarities in design, technology, manufacturing and sterilisation methods, the intended use and the results of any previous relevant assessments (e.g. with regard to physical, chemical or biological properties) that have been carried out in accordance with Directive 93/42/EEC as amended. The notified body shall document and keep available to the competent authority its rationale for the sample(s) taken.

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

SCHEDULE 7

EC DECLARATION OF CONFORMITY

1. The EC declaration of conformity is the procedure whereby the manufacturer or his or her authorised representative who fulfils the obligations imposed by Section 2 and, in the case of products placed on the market in a sterile condition and devices with a measuring function, the obligations imposed by Section 5 ensures and declares that the products concerned meet the provisions of Directive 93/42/EEC as amended which apply to them.

2. The manufacturer must prepare the technical documentation described in Section 3. The manufacturer or his or her authorised representative must make this documentation, including the declaration of conformity, available to the national authorities for inspection purposes for a period ending at least five years after the last product has been manufactured. In the case of implantable devices the period shall be at least 15 years after the last product has been manufactured.

3. The technical documentation must allow assessment of the conformity of the product with the requirements of the Directive. It must include in particular:

— a general description of the product, including any variants planned and its intended use(s),

— design drawings, methods of manufacture envisaged and diagrams of components, sub-assemblies, circuits, etc.,

— the descriptions and explanations necessary to understand the abovementioned drawings and diagrams and the operations of the product,

— the results of the risk analysis and a list of the standards referred to in Article 5 of Directive 93/42/EEC as amended, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the Directive if the standards referred to in Article 5 of Directive 93/42/EEC as amended have not been applied in full,

— in the case of products placed on the market in a sterile condition, description of the methods used and the validation report,

— the results of the design calculations and of the inspections carried out, etc.; if the device is to be connected to other device(s) in order to operate as intended, proof must be provided that it conforms to the essential requirements when connected to any such device(s) having the characteristics specified by the manufacturer,

— the solutions adopted as referred to in Schedule 1, Chapter I, Section 2,

— the pre-clinical evaluation,

— the clinical evaluation in accordance with Schedule 10,

— the label and instructions for use.

4. The manufacturer shall institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase, including the provisions referred to in Schedule 10, and to implement appropriate means to apply any necessary corrective actions, taking account of the nature and risks in relation to the product. He or she shall notify the competent authorities of the following incidents immediately on learning of them:

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

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

5. With products placed on the market in sterile condition and Class I devices with a measuring function, the manufacturer must observe not only the provisions laid down in this Schedule but also one of the procedures referred to in Schedule 2, 4, 5 or 6. Application of the abovementioned Schedules and the intervention by the notified body is limited to:

— in the case of products placed on the market in sterile condition, only the aspects of manufacture concerned with securing and maintaining sterile conditions,

— in the case of devices with a measuring function, only the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Section 6.1. of this Schedule is applicable.

6. Application to devices in Class IIa

In line with Article 11 (2) of Directive 93/42/EEC as amended, this Schedule may apply to products in Class IIa, subject to the following derogation:

6.1. Where this Schedule is applied in conjunction with the procedure referred to in Schedule 4, 5 or 6, the declaration of conformity referred to in the abovementioned Schedules forms a single declaration. As regards the declaration based on this Schedule, the manufacturer must ensure and declare that the product design meets the provisions of Directive 93/42/EEC as amended which apply to it.

SCHEDULE 8

STATEMENT CONCERNING DEVICES FOR SPECIAL PURPOSES

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

2. The statement must contain the following information:

2.1. for custom-made devices:

— the name and address of the manufacturer,

— data allowing identification of the device in question,

— a statement that the device is intended for exclusive use by a particular patient, together with the name of the patient,

— the name of the medical practitioner or other authorized person who made out the prescription and, where applicable, the name of the clinic concerned,

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

— a statement that the device in question conforms to the essential requirements set out in Schedule 1 and, where applicable, indicating which essential requirements have not been fully met, together with the grounds;

2.2. for devices intended for the clinical investigations covered by Schedule 10:

— data allowing identification of the device in question,

— 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 7.4 of Schedule 1,

— a statement indicating whether or not the device is manufactured utilising tissues of animal origin as referred to in Directive 2003/32/EC,

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

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

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

— a statement that the device in question conforms to the essential requirements apart from the aspects covered by the investigations and that, with regard to these aspects, every precaution has been taken to protect the health and safety of the patient.

3. The manufacturer must also undertake to keep available for the competent national authorities:

3.1. For custom-made devices, documentation, indicating manufacturing site(s) and allowing an understanding of the design, manufacture and performances of the product, including the expected performances, so as to allow assessment of conformity with the requirements of Directive 93/42/EEC as amended. The manufacturer must take all the measures necessary to ensure that the manufacturing process produces products which are manufactured in accordance with the documentation mentioned in the first paragraph;

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

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

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

— the descriptions and explanations necessary to understand the abovementioned drawings and diagrams and the operation of the product,

— the results of the risk analysis and a list of the standards referred to in Article 5 of Directive 93/42/EEC as amended, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of Directive 93/42/EEC as amended if the standards referred to in Article 5 of Directive 93/42/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 7.4 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,

— if the device is manufactured utilising tissues of animal origin as referred to in Directive 2003/32/EC, the risk management measures in this connection which have been applied to reduce the risk of infection,

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

The manufacturer must take all the measures necessary to ensure that the manufacturing process produces products which are manufactured in accordance with the documentation referred to in the first paragraph of this Section. The manufacturer must authorise the assessment, or audit where necessary, of the effectiveness of these measures.

4. The information contained in the declarations concerned by this Schedule shall be kept for a period of time of at least five years. In the case of implantable devices the period shall be at least 15 years.

5. For custom-made devices, the manufacturer must undertake to review and document experience gained in the post-production phase, including the provisions referred to in Schedule 10, 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 subparagraph (i) leading to systematic recall of devices of the same type by the manufacturer.

SCHEDULE 9

CLASSIFICATION CRITERIA

I. DEFINITIONS

1. Definitions for the classification rules

1.1. Duration

Transient

Normally intended for continuous use for less than 60 minutes.

Short term

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

Long term

Normally intended for continuous use for more than 30 days.

1.2. Invasive devices

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

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

Surgically invasive device
An invasive device which penetrates inside the body through the surface of the body, with the aid or in the context of a surgical operation. For the purposes of Directive 93/42/EEC as amended devices other than those referred to in the previous subparagraph and which produce penetration other than through an established body orifice, shall be treated as surgically invasive devices.

Implantable device

Any device which is intended:

— to be totally introduced into the human body or,

— to replace an epithelial surface or the surface of the eye, by surgical intervention which is intended to remain in place after the procedure. Any device intended to be partially introduced into the human body through surgical intervention and intended to remain in place after the procedure for at least 30 days is also considered an implantable device.

1.3. Reusable surgical instrument

Instrument intended for surgical use by cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar procedures, without connection to any active medical device and which can be reused after appropriate procedures have been carried out.

1.4. Active medical device

Any medical device operation of which depends on a source of electrical energy or any source of power other than that directly generated by the human body or gravity and which acts by converting this energy. Medical devices intended to transmit energy, substances or other elements between an active medical device and the patient, without any significant change, are not considered to be active medical devices. Stand alone software is considered to be an active medical device.

1.5. Active therapeutical device

Any active medical device, whether used alone or in combination with other medical devices, to support, modify, replace or restore biological functions or structures with a view to treatment or alleviation of an illness, injury or handicap.

1.6. Active device for diagnosis

Any active medical device, whether used alone or in combination with other medical devices, to supply information for detecting, diagnosing, monitoring or treating physiological conditions, states of health, illnesses or congenital deformities.

1.7. Central circulatory system

For the purposes of Directive 93/42/EEC as amended, 'central circulatory system' means the following vessels:
arteriae pulmonales, aorta ascendens, arcus aorta, aorta descendens to the bifurcatio aortae, arteriae coronariae, arteria carotis communis, arteria carotis externa, arteria carotis interna, arteriae cerebrales, truncus brachiocephalicus, venae cordis, venae pulmonales, vena cava superior, vena cava inferior.

1.8. Central nervous system

For the purposes of Directive 93/42/EEC as amended, 'central nervous system' means brain, meninges and spinal cord.

II. IMPLEMENTING RULES

2. Implementing rules

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

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

2.3. Software, which drives a device or influences the use of a device, falls automatically in the same class.

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

2.5. If several rules apply to the same device, based on the performance specified for the device by the manufacturer, the strictest rules resulting in the higher classification shall apply.

2.6. In calculating the duration referred to in Section 1.1 of Chapter I, continuous use means 'an uninterrupted actual use of the device for the intended purpose'. However where usage of a device is discontinued in order for the device to be replaced immediately by the same or an identical device this shall be considered an extension of the continuous use of the device.

III. CLASSIFICATION

1. Non-invasive devices

1.1. Rule 1

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

1.2. Rule 2

All non-invasive devices intended for channelling or storing blood, body liquids or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the body are in Class IIa:

— if they may be connected to an active medical device in Class IIa or a higher class,

— if they are intended for use for storing or channelling blood or other body liquids or for storing organs, parts of organs or body tissues, in all other cases they are in Class I.

1.3. Rule 3

All non-invasive devices intended for modifying the biological or chemical composition of blood, other body liquids or other liquids intended for infusion into the body are in Class IIb, unless the treatment consists of filtration, centrifugation or exchanges of gas, heat, in which case they are in Class IIa.

1.4. Rule 4

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

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

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

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

2. Invasive devices

2.1. Rule 5

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

— are in Class I if they are intended for transient use,

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

— are in Class IIb if they are intended for long-term use, except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in a nasal cavity and are not liable to be absorbed by the mucous membrane, in which case they are in Class IIa. All invasive devices with respect to body orifices, other than surgically invasive devices, intended for connection to an active medical device in Class IIa or a higher class, are in Class IIa.

2.2. Rule 6

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

— intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class III,

— reusable surgical instruments, in which case they are in Class I,

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

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

— intended to have a biological effect or to be wholly or mainly absorbed in which case they are in Class IIb,

— intended to administer medicines by means of a delivery system, if this is done in a manner that is potentially hazardous taking account of the mode of application, in which case they are in Class IIb.

2.3. Rule 7

All surgically invasive devices intended for short-term use are in Class IIa unless they are intended:

— either specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class III,

— or specifically for use in direct contact with the central nervous system, in which case they are in Class III,

— or to supply energy in the form of ionizing radiation in which case they are in Class IIb,

— or to have a biological effect or to be wholly or mainly absorbed in which case they are in Class III,

— or to undergo chemical change in the body, except if the devices are placed in the teeth, or to administer medicines, in which case they are in Class IIb.

2.4. Rule 8

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

— to be placed in the teeth, in which case they are in Class IIa,

— to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in Class III,

— to have a biological effect or to be wholly or mainly absorbed, in which case they are in Class III,

— or to undergo chemical change in the body, except if the devices are placed in the teeth, or to administer medicines, in which case they are in Class III.

3. Additional rules applicable to active devices

3.1. Rule 9

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

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

3.2. Rule 10

Active devices intended for diagnosis are in Class IIa:

— if they are intended to supply energy which will be absorbed by the human body, except for devices used to illuminate the patient's body, in the visible spectrum,

— if they are intended to image in vivo distribution of radiopharmaceuticals,

— if they are intended to allow direct diagnosis or monitoring of vital physiological processes, unless they are specifically intended for monitoring of vital physiological parameters, where the nature of variations is such that it could result in immediate danger to the patient, for instance variations in cardiac performance, respiration, activity of CNS in which case they are in Class IIb.

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

Rule 11

All active devices intended to administer and/or remove medicines, body liquids or other substances to or from the body are in Class IIa, unless this is done in a manner:

— that is potentially hazardous, taking account of the nature of the substances involved, of the part of the body concerned and of the mode of application in which case they are in Class IIb.

3.3. Rule 12

All other active devices are in Class I.

4. Special Rules

4.1. Rule 13

All devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, as defined in Article 1 of Directive 2001/83/EC, and which is liable to act on the human body with action ancillary to that of the devices, are in Class III. All devices incorporating, as an integral part, a human blood derivative are in Class III.

4.2. Rule 14

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

4.3. Rule 15

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

All devices intended specifically to be used for disinfecting medical devices are in Class IIa. Unless they are specifically to be used for disinfecting invasive devices in which case they are in Class IIb.

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

4.4. Rule 16

Devices specifically intended for recording of X-ray diagnostic images are in Class IIa.

4.5. Rule 17

All devices manufactured utilizing animal tissues or derivatives rendered nonviable are Class III except where such devices are intended to come into contact with intact skin only.

5. Rule 18

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

SCHEDULE 10

CLINICAL EVALUATION

1. General provisions

1.1. As a general rule, confirmation of conformity with the requirements concerning the characteristics and performances referred to in Sections 1 and 3 of 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 6 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 clinical investigations made.

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

1.1a In the case of implantable devices and devices in Class III clinical investigations shall be performed unless it is duly justified to rely on existing clinical data.

1.1b The clinical evaluation and its outcome shall be documented. This documentation shall be included and/or fully referenced in the technical documentation of the device.

1.1c The clinical evaluation and its documentation must be actively updated with data obtained from the post-market surveillance. Where post-market clinical follow-up as part of the post-market surveillance plan for the device is not deemed necessary, this must be duly justified and documented.

1.1d Where demonstration of conformity with essential requirements based on clinical data is not deemed appropriate, adequate justification for any such exclusion has to be given based on risk management output and under consideration of the specifics of the device/body interaction, the clinical performances intended and the claims of the manufacturer.

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

1.2. All the data must remain confidential, in accordance with the provisions of Article 20 of Directive 93/42/EEC as amended.

2. Clinical investigations

2.1. Objectives

The objectives of clinical investigation are:

— to verify that, under normal conditions of use, the performance of the devices conform to those referred to in Section 3 of Schedule 1, and

— to determine any undesirable side-effects, under normal conditions of use, and assess whether they constitute risks when weighed against the intended performance of the device.

2.2. Ethical considerations

Clinical investigations must be carried out in accordance with the Helsinki Declaration adopted by the 18th World Medical Assembly in Helsinki, Finland, in 1964, as last amended by the World Medical Assembly. It is mandatory that all measures relating to the protection of human subjects are carried out in the spirit of the Helsinki Declaration. This includes every step in the clinical investigation from first consideration of the need and justification of the study to publication of the results.

2.3. Methods

2.3.1. Clinical investigations must be performed on the basis of an appropriate plan of investigation reflecting the latest scientific and technical knowledge and defined in such a way as to confirm or refute the manufacturer's claims for the device; these investigations must include an adequate number of observations to guarantee the scientific validity of the conclusions.

2.3.2. The procedures used to perform the investigations must be appropriate to the device under examination.

2.3.3. Clinical investigations must be performed in circumstances similar to the normal conditions of use of the device.

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

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

2.3.6. The investigations must be performed under the responsibility of a medical practitioner or another authorized qualified person in an appropriate environment. The medical practitioner or other authorized person must have access to the technical and clinical data regarding the device.

2.3.7. The written report, signed by the medical practitioner or other authorized person responsible, must contain a critical evaluation of all the data collected during the clinical investigation.

SCHEDULE 11

CRITERIA TO BE MET FOR THE DESIGNATION OF NOTIFIED BODIES

1. The notified body, its Director and the assessment and verification staff shall not be the designer, manufacturer, supplier, installer or user of the devices which they inspect, nor the authorized representative of any of these persons. They may not be directly involved in the design, construction, marketing or maintenance of the devices, nor represent the parties engaged in these activities. This in no way precludes the possibility of exchanges of technical information between the manufacturer and the body.

2. The notified body and its staff must carry out the assessment and verification operations with the highest degree of professional integrity and the requisite competence in the field of medical devices and must be free from all pressures and inducements, particularly financial, which might influence their judgment or the results of the inspection, especially from persons or groups of persons with an interest in the results of the verifications. Should the notified body subcontract specific tasks connected with the establishment and verification of the facts, it must first ensure that the subcontractor meets the provisions of Directive 93/42/EEC as amended and, in particular, of this Schedule.

The notified body shall keep at the disposal of the national authorities the relevant documents assessing the subcontractor's qualifications and the work carried out by the subcontractor under Directive 93/42/EEC as amended.

3. The notified body must be able to carry out all the tasks assigned to such bodies by one of Schedules 2 to 6 and for which it has been notified, whether these tasks are carried out by the body itself or on its responsibility. In particular, it must have the necessary staff and possess the facilities needed to perform properly the technical and administrative tasks entailed in assessment and verification. This presupposes the availability of sufficient scientific staff within the organisation who possess experience and knowledge sufficient to assess the medical functionality and performance of devices for which it has been notified, having regard to the requirements of Directive 93/42/EEC as amended and, in particular, those set out in Schedule 1. It must also have access to the equipment necessary for the verifications required.

4. The notified body must have:

— sound vocational training covering all the assessment and verification operations for which the body has been designated,

— satisfactory knowledge of the rules on the inspections which they carry out and adequate experience of such inspections,

— the ability required to draw up the certificates, records and reports to demonstrate that the inspections have been carried out.

5. The impartiality of the notified body must be guaranteed. Their remuneration must not depend on the number of inspections carried out, nor on the results of the inspections.

6. The body must take out civil liability insurance, unless liability is assumed by the State under domestic legislation or the Member State itself carries out the inspections directly.

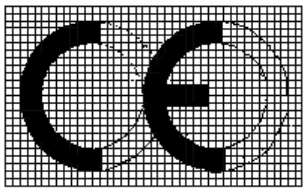
7. The staff of the notified body are bound to observe professional secrecy with regard to all information gained in the course of their duties (except vis-à-vis the competent administrative authorities of the State in which their activities are carried out) pursuant to Directive 93/42/EEC as amended or any provision of national law putting it into effect.

SCHEDULE 12

CE MARKING OF CONFORMITY

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

—



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

— the various components of the CE marking must have substantially the same vertical dimension, which may not be less than 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 (Medical Devices) Regulations, 1994 (S.I. No. 252 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.

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TEACH SUN ALLIANCE, SRÁID THEACH LAIGHEAN, BAILE ÁTHA CLIATH 2,
nó tríd an bpost ó
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