



COMMISSION OF THE EUROPEAN COMMUNITIES

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Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

**amending Council Directives 90/385/EEC and 93/42/EEC and Directive 98/8/EC of the
European Parliament and the Council as regards the review of the medical device
directives**

{SEC(2005)1742}

(presented by the Commission)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

- Grounds for and objectives of the proposal

Since its adoption in 1993, a great deal of experience has been gained on the implementation of the Directive 93/42/EEC concerning medical devices. Whilst overall the experience has been extremely positive, some experience reveals that the Directive requires improved implementation by all parties concerned. Furthermore, to support this improved implementation, legislative modification is necessary both to clarify certain existing requirements and to provide a legal basis for planned initiatives. The proposal amends Directive 93/42/EEC in this regard and also, in order to align the text of the framework Directives on medical devices, it amends Directive 90/385/EEC relating to active implantable medical devices.

- General context

Directive 93/42/EEC itself requests the Commission to submit a report to the Council, no later than five years from the date of implementation of the Directive, concerning certain aspects of the functioning of the Directive. It was the view of various Member States that the review called for under Article 11 (4) should be extended to cover not only those aspects referred to in the Article, but also to cover all elements of the Directive that have given rise to concern or where improvements can be made.

Arising from this review process, a Report on the functioning of the Medical Devices Directives was published in June of 2002. The conclusions of this Report were brought forward by the Commission in its Communication COM (2003)386 which was welcomed by the Council in its Conclusions of December 2003 and was received favourably at Parliament.

The Communication highlighted that whilst the Devices Directives provide in themselves an appropriate legal framework, there is room for improvement. The most important areas where improvement should be made concern:

conformity assessment - where questions arose as to the absence of clear rules on design examination by notified bodies,

the sufficiency and adequacy of clinical data for all classes of devices,

post market surveillance - where better coordination of activities in the area of post market surveillance are needed,

Notified Bodies - in relation to their competence for the tasks for which they are designated, differences in interpretation between Notified Bodies and lack of transparency in the performance, and control, of their activities,

and increased transparency to the general public in relation to the approval of devices.

modification of Directive 90/385/EEC relating to active implantable medical devices in order to align it with the other framework Directives on medical devices.

- Existing provisions in the area of the proposal

This proposal aims at amending the already existing Directives 93/42/EEC on medical devices and 90/385/EEC on active implantable medical devices.

2. CONSULTATION OF INTERESTED PARTIES AND IMPACT ASSESSMENT

- Consultation of interested parties

Consultation methods, main sectors targeted and general profile of respondents

Beginning in 2003, the primary method of consultation was through the Commission services' Medical Device Experts Group, comprising the Commission, Member States, Notified Bodies, European standards bodies and industry. The bulk of all comments arose from national authorities and industry.

Summary of responses and how they have been taken into account

Authorities, sought clarification on certain areas, such as the appropriate design documentation and design review for particular groups of medical devices, and text to aid better implementation on certain aspects of the Directives, such as clinical evaluation. All substantial comments from authorities were considered and have resulted in either proposed legislative or non-legislative measures.

Industry, criticised the apparent un-harmonised interpretation and implementation of the Directives by Member States, and welcomed any initiative, either legislative or non legislative, that brings clarification and consistency to interpretation and implementation. They also highlighted: clarification of the role of a national authority or the European Medicines Agency (EMA) when consulted for devices containing a medicinal product or human blood derivative, the provision of electronic labelling and the inclusion of reproprocessors of 'single use' devices in the definition of 'manufacturer'.

Here text has been proposed in all areas except reprocessing. In examining the reprocessing issue in detail, including bilateral meetings involving the relevant trade federations, it became clear that it goes far beyond this Directive, and a simple expansion of the definition of 'manufacturer', and raises questions that would require further reflection by the Commission services, in consultation with a wider group of stakeholders, to explore possible development of appropriate legislation in this area.

An open consultation was conducted over the internet from 11/05/2005 to 25/06/2005. The Commission received 80 response(s). The results are available on the sectors website: http://europa.eu.int/comm/enterprise/medical_devices/index_en.htm.

- Impact assessment

In order to reach the objective of improved coherence and effectiveness of legislation, action was considered in key areas of the Directive namely: Simplification, Better Implementation, Better Conformity Assessment, Legal Certainty (More Binding Rules) in the Directive and Improved Market Surveillance.

As the Directive is already in existence, two basic options are open in order to achieve the objective, either 'legislative', requiring modification of the current legislation, or 'non-legislative', including co-ordination of national competencies to create transparency and foster harmonised implementation.

Since the proposal is more regulatory clarification rather than regulatory change, there are no significant economic impacts expected. Similarly there were no environmental impacts identified by the current proposal. However, three principal impacts, health, economic and social impacts, can be singled out which arise not from any specific option chosen, but from the proposal in its entirety:

- Increased clarity will continue to support a high level of public health protection.
- The proposal will provide more transparency and increase the certainty for all market players and, in particular, the public.
- For enterprises and citizens alike, the improved regulatory framework will continue to support fast technical progress to benefit citizens under better clarified conditions for guaranteeing safety and increased trust.

While, certainly, the regulatory clarification will lead to 'de facto' changes in implementation, for those manufacturers who are correctly implementing the Directive there will be no economic effect.

3. LEGAL ELEMENTS OF THE PROPOSAL

- Summary of the proposed action

This proposal amends Directive 93/42/EEC on medical devices by modifying current provisions, to bring about clarity, or by introducing new provisions, seen as necessary to continue to support the protection of human health. Also, the proposal updates Directive 90/385/EEC on active implantable medical devices to make it coherent with the other Directives on medical devices. Finally, Directive 98/8/EC on biocides is amended to exclude in vitro diagnostic medical devices from its scope, this removes the legal ambiguity that exists, in certain cases, as to which Directive should apply.

- Legal basis

The legal basis for the proposal is Article 95 EC Treaty (formerly Article 100A) upon which Directive 93/42/EEC is based.

In order to achieve the objective of abolishing technical barriers to trade and clarification of existing provisions in Directives 93/42/EEC and 90/385/EEC, it is necessary and appropriate to harmonise the laws, regulations and administrative provisions in the Member States on certain aspects concerning the placing on the market or putting into service of medical devices.

- Subsidiarity principle

The subsidiarity principle applies insofar as the proposal does not fall under the exclusive competence of the Community.

The objectives of the proposal cannot be sufficiently achieved by the Member States for the following reason(s).

The proposal aims at amending existing Community legislation that harmonized the legal framework for medical devices on Community level in the light of experiences gained by national authorities in its implementation over the past number of years.

Any Member State legislative action would endanger the harmonized framework and present a potential breach of Directives 93/42/EEC and 90/385/EEC.

Community action will better achieve the objectives of the proposal for the following reason(s).

Such amendments to an existing harmonized framework can best be achieved on Community level.

National authorities, through the Medical Device Expert Group Report of June 2002 into the functioning of the medical device Directives, have called for the Commission to propose necessary changes to the Directives on medical devices.

The proposal relates to harmonised legislation for the placing on the market and putting into service of medical devices within the Community and thus cannot be achieved by Member States alone.

The proposal therefore complies with the subsidiarity principle.

- Proportionality principle

The proposal complies with the proportionality principle for the following reason(s).

The proposal is based on experiences gained with the existing framework, it concentrates on changes only where they were perceived by Member States and stakeholders to be necessary for its proper functioning.

The proposal has been subject to an impact assessment and whilst, certainly, the regulatory clarification will lead to 'de facto' changes in implementation, for those manufacturers who are correctly implementing the Directive there will be no economic effect.

- Choice of instruments

Proposed instruments: directive.

Other means would not be adequate for the following reason(s).

Given that the existing framework that is intended to be updated here has been adopted in the form of Directives, a Directive is the most appropriate instrument here that will allow Member States to incorporate the amendments into their existing transposing laws of Directive 93/42/EEC and 90/385/EEC.

4. BUDGETARY IMPLICATION

The proposal has no implication for the Community budget.

5. ADDITIONAL INFORMATION

- Simulation, pilot phase and transitory period

There was or there will be a transitory period for the proposal.

- Simplification

The proposal provides for simplification of legislation.

The proposal adapts the existing legislation in areas where the Commission, Member States and stakeholders saw a need to clarify the legislation to ensure better implementation.

- Correlation table

The Member States are required to communicate to the Commission the text of national provisions transposing the Directive as well as a correlation table between those provisions and this Directive.

- European Economic Area

The proposed act concerns an EEA matter and should therefore extend to the European Economic Area.

- Detailed explanation of the proposal

The proposed legislative modification, developed to reflect the regulatory changes called for in the Commission Communication and subsequently welcomed by Council and Parliament, brings forth either additional or replacement text regarding, in particular:

Conformity assessment modules

Here it has been further clarified that, for the conformity assessment of class IIa and class IIb devices under Annex II notified bodies are required to assess, on a representative basis, the design documentation for the device concerned.

Clinical data and evaluation

In order to clarify and enhance the provisions on clinical evaluation, significant modification was required of Annex X concerning clinical data and its evaluation and to various references to clinical data within the provisions of the Directive, including the definition of clinical evaluation and provision for the possibility to centralise data on clinical investigations in the European databank.

Legal certainty regarding scope

To provide a method to make binding decisions on issues arising at national level, in relation to the misinterpretation of a product as being or not being a medical device, a procedure, based on comitology, has been added to Article 13.

Also, in order to clarify that it is possible for both the Directive on medical devices and the Directive on personal protective equipment to simultaneously apply to a product, such as a surgical glove, it is necessary to delete the reference in Article 1 to the Directive on personal protective equipment to allow both apply.

Measures to increase transparency

Article 20 on confidentiality, which previously maintained all information available under the Directive as being confidential, has been relaxed, to allow certain information on all devices to be publicly available and to allow, by comitology, a method of making other information non-confidential, such as summary information on the approval of high risk devices.

Legal basis for better coordination and communication of market surveillance activities

The market for medical devices is a global market, with a significant number of devices being imported into the European Union. This has led to an increasing need to coordinate activities of national authorities when applied to issues related to the directive taking place across a number of Member States and/or third countries. Thus it is necessary to introduce a new provision, Article 20a, on cooperation to provide a legal basis for this coordination and international activities.

Clarification regarding medicinal products/medical device provisions

Devices that incorporate as an integral part a medicinal product or blood plasma derivative are required to be reviewed by a notified body in consultation with a national authority for medicines or the European Medicines Agency (EMA) as appropriate. These provisions, which are currently contained in Annex I Section 7.4 of the Directive needed modification to reflect the experience gained over the years in their implementation, clarifying both the role of the notified body and the relevant authority.

Devices with an ancillary human tissue engineered product

Provisions are made to include devices with an ancillary human tissue engineered product in the scope. This mirrors the proposed Community legislation on Advanced Therapies and fills a potential regulatory gap.

Custom-made devices

In order to better evidence the compliance of custom made device manufacturers there is now an explicit requirement for a post market vigilance system reporting to authorities, as already in place for other devices. In order to enhance patient information a requirement is introduced that the 'Statement' under Annex VIII should be also given to the patient and that it must contain the name of the manufacturer.

Amendment of other Directives:

Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices - Alignment of text on certain aspects across all three medical device directives.

The Directive 90/385/EEC on active implantable medical devices, adopted in 1990, was the first in the series of directives on medical devices, however, it has not benefited to the same extent from the market experiences and developments as the Directive 93/42/EEC concerning medical devices and the Directive 98/79/EC on in vitro diagnostic medical devices, which were adopted in later years.

To ensure consistency of interpretation and implementation of the medical device Directives and to update the Directive 90/385/EEC on active implantable medical devices in terms of health protection measures, certain aspects, such as authorised representative, the European Databank, health protection measures, and the application of the Directive 2000/70/EC on medical devices incorporating stable derivatives of human blood or human plasma have to be added to Directive 90/385/EC. The latter alignment, on human blood or plasma, results in a significant body of text being inserted into the Directive.

Directive 98/8/EC concerning the placing of biocidal products on the market

Under this regulatory reform, the Directive on biocides needs to be modified in order to clarify that, alongside the active implantable medical devices and medical devices, also in vitro diagnostic medical devices, now subject of a specific Directive, will be excluded from the scope of the biocides Directive.

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Council Directives 90/385/EEC and 93/42/EEC and Directive 98/8/EC of the European Parliament and the Council as regards the review of the medical device directives

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission¹,

Having regard to the opinion of the European Economic and Social Committee²,

Acting in accordance with the procedure laid down in Article 251 of the Treaty³,

Whereas:

- (1) Council Directive 93/42/EEC of 14 June 1993 concerning medical devices⁴ requests the Commission to submit a report to the Council, no later than five years from the date of implementation of that Directive, concerning: (i) information on incidents occurring following the placing of devices on the market, (ii) clinical investigation carried out in accordance with the procedure set out in Annex VIII to Directive 93/42/EEC, and (iii) design examination and EC type examination of medical devices that incorporate, as an integral part, a substance which, if used separately, may be considered to be a medicinal product as defined in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use⁵ and which is liable to act upon the body with action ancillary to that of the device.
- (2) The Commission brought forward the conclusions of this report in its Communication to the Council and the European Parliament on medical devices⁶ which, upon request

¹ OJ C [...], [...], p. [...].

² OJ C [...], [...], p. [...].

³ OJ C [...], [...], p. [...].

⁴ OJ L 169, 12.7.1993, p. 1, Directive as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

⁵ OJ L 311, 28.11.2001, p. 67 – 128, Directive as last amended by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use (OJ L 136, 30.4.2004, p. 34 – 57)

⁶ COM (2003) 386 final, 02.07.2003, OJ C 96, 21.4.2004, p. 5.

of the Member States, was expanded to cover all aspects of the Community regulatory framework for medical devices.

- (3) This Communication was welcomed by the Council in its Conclusions on medical devices of 2 December 2003⁷. It was also discussed by the European Parliament which adopted a resolution on health implications of Directive 93/42/EEC.⁸
- (4) Following from the conclusions drawn in that Communication it is necessary and appropriate to amend Directive 93/42/EEC, Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices⁹ and Council Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market¹⁰.
- (5) To ensure consistency of interpretation and implementation between Directives 93/42/EEC and 90/385/EEC the legal framework related to issues such as authorised representative, the European databank, health protection measures, and the application of Directive 93/42/EEC as regards medical devices incorporating stable derivatives of human blood or human plasma¹¹ should be extended to Directive 90/385/EEC. The application of the provisions on medical devices incorporating stable derivatives of human blood or human plasma includes application of Directive 2002/98/EC of the European Parliament and of the Council setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC¹².
- (6) It is necessary to clarify that consideration of a product having a medical purpose is intrinsic to the definition of a medical device and that software in its own right can be defined as a medical device.
- (7) In the light of technical innovation and the development of initiatives at the international level it is necessary to enhance the provisions on clinical evaluation, including clarification that clinical data is generally required for all devices regardless of classification and the possibility to centralise data on clinical investigations in the European databank.
- (8) In the light of the development of a Community framework on human tissue engineered products it is necessary to address medical devices that are combined with human tissue engineered products where they have a function ancillary to that of the device under Directives 93/42/EEC and 90/385/EEC.

⁷ Council Conclusions on 2 December 2003 on Medical Devices (2004/C 20/01), OJ C 20, 24.1.2004, p. 1.

⁸ European Parliament resolution on the health implications of Council Directive 93/42/EEC concerning medical devices (2001/2270(INI)).

⁹ OJ L 189 , 20.7.1990, p. 17 – 36, Directive as last amended by Regulation (EC) No 1882/2003.

¹⁰ OJ L 123 , 24.4.1998, p. 1 – 63, Directive as last amended by Regulation (EC) No 1882/2003.

¹¹ as introduced by Directive 2000/70/EC of the European Parliament and of the Council of 16 November 2000 amending Council Directive 93/42/EEC as regards medical devices incorporating stable derivatives of human blood or human plasma, OJ L 313 , 13.12.2000, p. 22 – 24.

¹² OJ L 33, 8.2.2003, p. 30 – 40.

- (9) In order to better evidence the compliance of custom-made device manufacturers an explicit requirement for a post market production review system reporting to authorities should be introduced, as is already in place for other devices and to enhance patient information a requirement should be introduced that the 'Statement' under Annex VIII to Directive 93/42/EEC is also to be given to the patient and that it must contain the name of the manufacturer.
- (10) In the light of technical progress in information technology and medical devices, a process should be provided to allow information supplied by the manufacturer to be available by other means.
- (11) Manufacturers of Class I sterile and/or measuring medical devices should be given the option of using the full quality assurance conformity assessment module in order to provide them with more flexibility in the choice of compliance modules.
- (12) In order to support market surveillance activities by Member States it is necessary and appropriate to link the retention of documents for administrative purposes to the lifetime of the product as defined by the manufacturer.
- (13) For the appropriate and efficient functioning of Directive 93/42/EEC as regards regulatory advice on classification issues arising at national level, in particular on whether or not a product falls under the definition of a medical device, it is in the interest of national market surveillance and the health and safety of humans to establish a procedure for decisions on whether or not a products falls under the medical device definition.
- (14) To ensure that, where a manufacturer does not have a registered place of business in the Community, authorities have a single individual person authorized by the manufacturer whom they can address in matters relating to the compliance of the devices with the Directives it is necessary to introduce an obligation for such manufacturers to designate an authorized representative for all classes of devices.
- (15) To further ensure public health and safety it is necessary to provide for a more consistent application of the provisions on health protection measures.
- (16) In support of transparency in Community legislation, certain information related to medical devices and their conformity with Directive 93/42/EEC, in particular information on registration, on vigilance reports and on certificates, should be available to any interested party and the general public.
- (17) To better coordinate the application and efficiency of national resources when applied to issues related to Directive 93/42/EEC the Member States should cooperate with each other and at international level.
- (18) As design for patient safety initiatives play an increasing role in public health policy it is necessary to expressively set out the need to consider ergonomic design in the essential requirements. In addition the level of training and knowledge of the user, such as in the case of a lay user, is further emphasised within the essential requirements.

- (19) In the light of experience gained regarding activities of both, the notified body and the authorities, in the assessment of devices which require intervention of the appropriate authorities for medicines and human blood derivatives their duties and tasks should be clarified.
- (20) Taking account of the growing importance of software in the field of medical devices, be it as stand alone or as software incorporated in a device, validation of software in accordance with the state of the art should be an essential requirement.
- (21) In the light of the increased use of third parties to carry out the design and manufacture of devices on behalf of the manufacturer, it is important that the manufacturer demonstrates that he applies adequate controls to the third party to continue to ensure the efficient operating of the quality system.
- (22) The classification rules are based on the vulnerability of the human body taking account of the potential risks associated with the technical design and manufacture of the devices. For class III devices explicit prior authorization with regard to conformity, including an assessment of the design documentation, is required for them to be placed on the market. In performing its duties under the quality assurance and verification conformity assessment modules for all other classes of devices it is essential and necessary for a notified body, in order to be assured of the compliance of the manufacturer with Directive 93/42/EEC, to review the design documentation for the medical device. The depth and extent of this review should be commensurate with the classification of the device, the novelty of the intended treatment, the degree of intervention, the novelty of the technology or construction materials, and the complexity of the design and/or technology. This review can be achieved by taking a representative example of design documentation of one or more type(s) of devices from those being manufactured. Further review(s), and in particular the assessment of changes to the design that could affect conformity with the essential requirements, should be part of the surveillance activities of the notified body.
- (23) It is necessary to remove the incoherence in the classification rules that meant that invasive devices with respect to body orifices intended for connection to an active class I medical device were not classified.
- (24) It should be clarified that alongside Directives 90/385/EEC and 93/42/EEC, also *in vitro* diagnostic medical devices, which are the subject of Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices¹³ should be excluded from the scope of Directive 98/8/EC.
- (25) Directives 90/385/EEC, 93/42/EEC and 98/8/EC should therefore be amended accordingly,

¹³ OJ L 331, 7.12.1998, p. 1. Directive as last amended by Regulation (EC) No 1882/2003.

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Directive 90/385/EEC is amended as follows:

(1) Article 1 is amended as follows:

(a) Paragraph 2 is amended as follows:

(i) point (a) shall be replaced by:

“(a) ‘medical device’ means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software necessary for its proper application intended by the manufacturer to be used for medical purposes for human beings for the purpose of:

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

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

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

— control of conception,

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

(ii) in paragraph 2 points (d), (e) and (f) are replaced by the following:

“(d) ‘custom-made device’ means any device specifically made in accordance with a duly qualified medical practitioner's written prescription which gives, under his responsibility, specific design characteristics and is intended for the sole use of a particular patient.

The abovementioned prescription may also be made out by any other person authorized by virtue of his professional qualifications to do so.

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

(e) ‘device intended for clinical investigation’ means any device intended for use by a duly qualified medical practitioner when conducting investigations as referred to in Section 2.1 of Annex 7 in an adequate human clinical environment.

For the purpose of conducting clinical investigation, any other person who, by virtue of his professional qualifications, is authorized to carry out such investigation shall be accepted as equivalent to a duly qualified medical practitioner;

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

(iii) the following point (j) is added:

“(j) ‘authorised representative’ means any natural or legal person established in the Community who, explicitly designated by the manufacturer, acts and may be addressed by authorities and bodies in the Community instead of the manufacturer with regard to the latter's obligations under this Directive;”

(b) Paragraph 3 is replaced by the following:

“3. Where an active implantable medical device is intended to administer a substance defined as a medicinal product within the meaning of Council Directive 2001/83/EC of the European Parliament and of the Council (*), that substance shall be subject to the system of marketing authorization provided for in that Directive.

(*) OJ L 311, 27.11.2001, p.67.”

(c) In paragraph 4 the reference ‘65/65/EEC’ is replaced by ‘2001/83/EC’.

(d) The following paragraphs 4a and 4b are inserted:

“4a. Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product constituent or a medicinal product derived from human blood or human plasma within the meaning of Article 1 of Directive 2001/83/EC and which is liable to act upon the human body with action that is ancillary to that of the device, hereinafter referred to as a “human blood derivative”, that device must be assessed and authorised in accordance with this Directive.

4b. Where a devices incorporates, as an integral part, a substance, which, if used separately, may be considered to be a human tissue engineered product within the meaning of [Article 2 (2) of the Regulation (EC) No [...] of the European Parliament and of the Council (**) [on advanced Therapies and amending Regulation (EC) No 726/2004]] and which is liable to act upon the body with action that is ancillary to that of the device, that device must be assessed and authorized in accordance with this Directive.

(**) [OJ L of ..., p...]”

(e) Paragraph 5 is replaced by the following:

“5. 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 (***)

(***) OJ L 390, 31.12.2004, p. 24.”

(f) The following paragraph 6 is added:

“6. This Directive shall not apply to human blood, blood products, plasma or blood cells of human origin, or to human tissue engineered products or to devices which incorporate at the time of placing on the market such blood products, plasma or cells, or human tissue engineered products with the exception of devices referred to in paragraphs 4a and 4b.”

(2) Article 6 is amended as follows:

(a) Paragraph 2 is amended as follows:

(i) the second subparagraph is deleted.

(ii) In the third subparagraph the words ‘Articles 3 and 7’ are replaced by ‘Articles 5 and 7’.

(b) The following paragraph 3 is added:

“3. The Committee may examine any question connected with the implementation of this Directive.”

(3) The following Articles 10a, 10b and 10c are inserted:

“Article 10a

1. Any manufacturer who, under his own name, places devices on the market in accordance with the procedures referred to in Article 9 (2) and Article 10 (1) shall inform the competent authorities of the Member State in which he has his registered place of business of the address of the registered place of business and the description of the devices concerned.

2. Where a manufacturer who places devices on the market under his own name does not have a registered place of business in a Member State, he shall designate a single authorized representative established in the Community.

For devices referred to in paragraph 1 the authorized representative shall inform the competent authorities of the Member State in which he has his registered place of business of the address of the registered place of business and the category of devices concerned.

3. The Member States shall on request inform the other Member States and the Commission of the details referred to in paragraphs 1 and 2.

Article 10b

1. Regulatory data in accordance with this Directive shall be stored in a European databank accessible to the competent authorities to enable them to carry out their tasks relating to this Directive on a well-informed basis.

The databank shall contain the following:

(a) data relating to the registration of manufacturers and devices in accordance with Article 10a;

(b) data relating to certificates issued, modified, supplemented, suspended, withdrawn or refused according to the procedures, as laid down in Annexes 2 to 5;

(c) data obtained in accordance with the vigilance procedure as defined in Article 8;

(d) data related to clinical investigations referred to in Article 10;

2. Data shall be forwarded in a standardised format.

3. The Commission shall, in accordance with the procedure laid down in Article 6 (2), adopt the measures for the implementation of paragraph 1 and 2 of this Article and in particular the scope of the required data related to clinical investigations.

Article 10c

Where a Member State considers in relation to a given product or group of products, that, in order to ensure protection of health and safety and/or to ensure that public health requirements are observed, such products should be withdrawn from the market, or their placing on the market and putting into service should be prohibited or restricted, it may take any justified transitional measures.

The Member State shall then inform the Commission and all other Member States of the transitional measures giving the reasons for its decision.

The Commission shall, whenever possible, consult the interested parties and the Member States.

Where the national measures are justified, the Commission shall adopt the necessary Community measures in accordance with the procedure referred to in Article 6(2). In case the national measures are unjustified, the Commission shall inform all Member States and the consulted interested parties.”

(4) In Article 11 the following paragraphs 5, 6 and 7 are added:

“5. The notified body shall inform the other notified bodies and its competent authority about all certificates refused, suspended or withdrawn and, on request, about certificates issued. It shall also make available, on request, all additional relevant information.

6. Where a notified body finds that pertinent requirements of this Directive have not been met or are no longer met by the manufacturer or that a certificate should not have been issued, it shall, taking account of the principle of proportionality, suspend or withdraw the certificate issued or place any restrictions on it unless compliance with such requirements is ensured by the implementation of appropriate corrective measures by the manufacturer.

In the case of suspension or withdrawal of the certificate or of any restriction placed on it or in cases where an intervention of the competent authority may become necessary, the notified body shall inform its competent authority thereof.

The Member State shall inform the other Member States and the Commission.

7. The notified body shall, on request, supply all relevant information and documents, including budgetary documents, required to enable the Member State to verify compliance with the requirements laid down in Annex 8.”

(5) Annexes 1 to 5 are amended in accordance with Annex I to this Directive.

Article 2

Directive 93/42/EEC is amended as follows:

(1) Article 1 is amended as follows:

(a) Paragraph 2 is amended as follows:

(i) in point (a) the introductory phrase is replaced by the following:

“‘medical device’ means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for medical purposes for human beings for the purpose of:”

(ii) the following point (k) is added:

“(k) ‘clinical data’ means the safety and/or performance data that is generated from the clinical use of a device and must include data obtained from any of the following:

— 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 data on clinical experience of either the device in question or a similar device for which equivalence to the device in question can be demonstrated; or

— any combination of the above.”

(b) Paragraph 3 is replaced by the following:

“3. Where a device is intended to administer a medicinal product within the meaning of Article 1 of Directive 2001/83/EC of the European Parliament and of the Council(*), that device shall be governed by this Directive, 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 Annex I to this Directive shall apply as far as safety and performance related device features are concerned.

(*) OJ L 311, 28.11.2001, p. 67.”

(c) In paragraph 4 the reference ‘65/65/EEC’ is replaced by ‘2001/83/EC’.

(d) In paragraph 4a the reference ‘89/381/EEC’ is replaced by ‘2001/83/EC’.

(e) The following paragraph 4b is inserted:

“4b. Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a human tissue engineered product within the meaning of [Article 2 (2)] of Regulation (EC) No [...] of the European Parliament and of the Council(**)[Regulation on Advanced Therapies and amending Regulation (EC) No 726/2004] and which is liable to act upon the body with action that is ancillary to that of the device, that device must be assessed and authorized in accordance with this Directive.”

(**) [OJ L of ..., p...]”

(f) Paragraph 5 is amended as follows:

(i) point (c) is replaced by the following:

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

(ii) point (f) is replaced by the following:

“(f) 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 4b.”

(g) Paragraph 6 is deleted.

(h) Paragraphs 7 and 8 are replaced by the following:

“7. This Directive is a specific Directive within the meaning of Article 1(4) of Directive 2004/108/EC of the European Parliament and of the Council (***)

8. This Directive does not affect the application of Council Directive 96/29/Euratom(****), nor of Council Directive 97/43/Euratom(*****).

(***) OJ L 390, 31.12.2004, p. 24

(****) OJ L 159, 29.6.1996, p. 1

(*****) OJ L 180, 9.7.1987, p. 22”

(2) The second indent of Article 4 (2) is replaced by the following:

“— custom-made devices being placed on the market and put into service if they meet the conditions laid down in Article 11 in combination with Annex VIII; Class IIa, IIb and III devices shall be accompanied by the statement referred to in Annex VIII, which shall be provided to the named patient.”

(3) In Article 9 paragraph (3) is replaced by the following:

“3 Where a Member State considers that the classification rules set out in Annex IX require adaptation in the light of technical progress and any information which becomes available under the information system provided for in Article 10, it shall submit a duly substantiated request to the Commission and ask it to take the necessary measures. The Commission shall adopt these measures in accordance with the procedure referred to in Article 7 (2).”

(4) Article 11 is amended as follows:

(a) In paragraph 11, the words ‘Annexes II and III’ are replaced by ‘Annexes II, III, V and VI’.

(b) The following paragraph is added:

“14. The Commission may, in accordance with the procedure referred to in Article 7 (2), adopt measures allowing instructions for use to be provided by other means.”

(5) Article 12 is amended as follows:

(a) In paragraph 3, the words “Annex IV, V or VI” are replaced by “Annex II, IV, V or VI”.

(b) in paragraph 4, the third sentence is replaced by the following:

“The declarations referred to in paragraphs 2 and 3 shall be kept at the disposal of the competent authorities for a period of time at least equivalent to the lifetime of the

device as defined by the manufacturer but not less than five years from the date of manufacture.”

(6) In Article 13(1) the following point (d) is inserted:

”or

(d) application of the classification rules set out in Annex IX requires a decision as to whether a product falls within one of the definitions in Article 1 paragraph 2, points (a) to (e),”;

(7) Article 14 (2) is replaced by the following:

“2. Where a manufacturer who places devices on the market under his own name does not have a registered place of business in a Member State, he shall designate a single authorised representative.

For devices referred to in the first sentence of paragraph 1, the authorised representative shall notify the competent authorities of the Member State in which he has his registered place of business of all details as referred to in paragraph 1.”

(8) Article 14a is amended as follows:

(a) The second subparagraph of paragraph 1 is amended as follows:

(i) point (a) is replaced by the following

“(a) data relating to the registration of manufacturers and authorised representatives and devices in accordance with Article 14;”

(ii) the following point (d) is added:

“(d) data related to clinical investigations referred to in Article 15;”

(b) Paragraph 3 is replaced by the following:

“3. The Commission shall, in accordance with the procedure referred to in Article 7 (2), adopt measures for the implementation of paragraphs 1 and 2 of this Article and in particular the scope of the required data related to clinical investigations.”

(9) Article 14b is replaced by the following:

“Article 14b

Health Protection Measures

Where a Member State considers, in relation to a given product or group of products, that, in order to ensure protection of health and safety and/or to ensure that public health requirements are observed, such products should be withdrawn from the market, or their placing on the market and putting into service should be prohibited or restricted, it may take any necessary and justified transitional measures.

The Member State shall then inform the Commission and all other Member States giving the reasons for its decision.

The Commission shall, whenever possible, consult the interested parties and the Member States.

Where the national measures are justified, the Commission shall adopt the necessary Community measures in accordance with the procedure referred to in Article 7(2). If the national measures are unjustified, the Commission shall inform all Member States and the consulted interested parties.”

(10) Article 15(2) and (3) are replaced by the following:

“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 authorities have notified him within that period of a decision to the contrary based on considerations of public health or public policy. Such decisions shall be communicated by the competent authority to the other Member States.

Member States may however authorize manufacturers to commence the relevant clinical investigations before the expiry of the period of 60 days, in so far as the relevant ethics committee has issued a favourable opinion on the programme of investigation in question, including the reviewed clinical investigation plan.

3. In the case of devices other than those referred to in paragraph 2, Member States may authorize manufacturers to commence clinical investigations immediately after the date of notification, provided that the ethics committee concerned has delivered a favourable opinion with regard to the reviewed clinical investigation plan.”

(11) Article 16 (5) is replaced by the following:

“5. The notified body shall inform the other notified bodies and its competent authority about all certificates refused, suspended or withdrawn and, on request, about certificates issued. The notified body shall also make available, on request, all additional relevant information.”

(12) In Article 18 (b) the word ‘Article 8’ is replaced by ‘Article 8(3)’.

(13) Article 20 is replaced by the following:

“Article 20

Confidentiality

1. Without prejudice to the existing national provisions and practices on medical confidentiality, Member States shall ensure that all the parties involved in the application of this Directive are bound to observe confidentiality with regard to all information obtained in carrying out their tasks.

This does not affect the obligation of Member States and notified bodies with regard to mutual information and the dissemination of warnings, nor the obligations of the persons concerned to provide information under criminal law.

2. The following information shall not be treated as confidential:

(a) information on the registration of persons responsible for placing devices on the market in accordance with Article 14;

(b) competent authority vigilance reports in accordance with Article 10(3);

(c) data relating to certificates issued, modified, supplemented, suspended, withdrawn or refused.

3. The Commission may, in accordance with the procedure referred to in Article 7 (2), determine the conditions under which other information may be made publicly available, and in particular for Class IIb and Class III devices an obligation for manufacturers to prepare and make available a summary of the information and data related to the device.”

(14) The following Article 20a is inserted:

“Article 20a

Cooperation

Member States shall take appropriate measures in order to encourage the authorities responsible for implementing this Directive to cooperate and provide each other and the Commission with information in order to assist the functioning of this Directive.

Without prejudice to the provisions of this Directive, implementation may be part of initiatives developed at an international level.”

(15) Annexes I to X are amended in accordance with Annex II to this Directive.

Article 3

In Article 1 (2) of Directive 98/8/EC the following point (s) is added:

“(s) Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices (*).

(*) OJ L 331, 7.12.1998, p. 1.”

Article 4

1. Member States shall adopt and publish by [12 months after publication] the laws, regulations and administrative provisions necessary to comply with this Directive. They shall

forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

They shall apply those provisions from [12 months from the transposition].

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 5

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 6

This Directive is addressed to the Member States.

Done at Brussels,

For the European Parliament
The President

For the Council
The President

ANNEX I

Annexes 1 to 5 to Directive 90/385/EEC are amended as follows:

(1) Annex 1 is amended as follows:

(a) In Section 9, seventh indent, the following phrase is added:

“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.”

(b) Section 10 is replaced by the following:

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

For a substance which:

— has already been granted, as a medicinal product, a Community marketing authorisation in accordance with Council Regulation (EEC) No 2309/93 (*) or Regulation (EC) No 726/2004; or

— falls within the scope of the Annex to Regulation (EC) No 726/2004;

or

— is a human blood derivative;

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 the European Medicines Agency (EMA) on the quality and safety of the substance. When issuing its opinion, the EMA shall take into account the manufacturing process and the data related to the incorporation of the substance into the device.

For other substances, 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 in accordance with Directive 2001/83/EC, on the quality and safety of the substance. When issuing its opinion, the concerned competent authority shall take into account the manufacturing process and the data related to the incorporation of the substance into the device.

Where changes are made to an ancillary substance incorporated in a medical device, in particular related to its manufacturing process, they shall be assessed by analogy with the procedures for the evaluation of variations to medicinal products laid down in Commission Regulations (EC) No. 1084/2003 (**) and EC No. 1085/2003 (***).

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, and 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.

(*) OJ L 214, 24.8.1993, p. 1.

(**) OJ L 159, 27.6.2003 p. 1.

(***) OJ L 159, 27.6.2003 p. 24.”

(c) The following Section 10a is inserted:

“10a. Where a device incorporates, as an integral part, a product which, if used separately, may be considered to be a human tissue engineered product within the meaning of [Article 2 (2) of the Regulation on Advanced Therapies and amending Regulation (EC) No 726/2004] and which is liable to act upon the body with action that is ancillary to that of the device, the quality, safety and usefulness of the product must be verified by analogy with the methods specified in Regulation EC No. [...] [on Advanced Therapies and amending Regulation (EC) No 726/2004].

The notified body shall, having verified the usefulness of the product as part of the medical device and taking account of the intended purpose of the device, seek a scientific opinion from the [Committee of Advanced Therapies] on the quality and safety of the product. When issuing its opinion, the [Committee of Advanced Therapies] shall take into account the manufacturing process and the data related to the incorporation of the product into the device.”

(d) The following indent is added to Section 14.2.:

“— in the case of a device within the meaning of Article 1(4a), an indication that the device contains a human blood derivative or a human tissue engineered product.”

(2) Annex 2 is amended as follows:

(a) The following indent is added to Section 3.2(c):

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

(b) In Section 4.2 the first paragraph is replaced by the following:

“The application shall describe the design, manufacture, and performances of the product in question and it must include the documents needed to assess whether the product conforms to the requirements of this Directive, and in particular Annex 2, Section 3.2, third paragraph, points (c) and (d).”

(c) In Section 4.3 the following subparagraphs are added:

“In the case of devices referred to in Annex 1, Section 10 third paragraph, the notified body shall, as regards the aspects referred to in that section, consult one of the competent bodies designated by the Member States in accordance with Directive 2001/83/EC before taking a decision. 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 Annex 1, Section 10a, second subparagraph, the scientific opinion of the EMEA must be included in the documentation concerning the device. 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 referred to in Annex 1, Section 10a, the scientific opinion of the [Committee of Advanced Therapies] must be included in the documentation concerning the device. The notified body will give due consideration to the opinion of the [Committee of Advanced Therapies] when making its decision. The notified body may not deliver the certificate if the [Committee of Advanced Therapies] scientific opinion is unfavourable. It will convey its final decision to the [Committee of Advanced Therapies].”

(d) The following Section 7 is added:

“7. Application to the devices referred to in Article 1(4a):

Upon completing the manufacture of each batch of devices referred to in Article 1(4a), 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.”

(3) Annex 3 is amended as follows:

(a) The sixth indent of Section 3 is replaced by the following:

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

(b) The following subparagraphs are added to Section 5:

“In the case of devices referred to in Annex 1, Section 10 third paragraph, the notified body shall, as regards the aspects referred to in that section, consult one of the competent bodies designated by the Member States in accordance with Directive 2001/83/EC before taking a decision. 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 Annex 1, Section 10 second paragraph, the scientific opinion of the EMEA must be included in the documentation concerning the device. 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 referred to in Annex 1, Section 10a, the scientific opinion of the [Committee of Advanced Therapies] must be included in the documentation concerning the device. The notified body will give due consideration to the opinion of the [Committee of Advanced Therapies] when making its decision. The notified body may not deliver the certificate if the [Committee of Advanced Therapies] scientific opinion is unfavourable. It will convey its final decision to the [Committee of Advanced Therapies].”

(4) The following Section 7 is added to Annex 4:

“7. Application to the devices referred to in Article 1(4a):

Upon completing the manufacture of each batch of devices referred to in Article 1(4a), 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.”

(5) The following Section 6 is added to Annex 5:

“6. Application to the devices referred to in Article 1(4a):

Upon completing the manufacture of each batch of devices referred to in Article 1(4a), 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.”

ANNEX II

Annexes I to X to Directive 93/42/EEC are amended as follows:

(1) Annex I is amended as follows:

(a) Section 1. is replaced by the following:

“1. The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended and, where applicable, by virtue of the technical knowledge, experience, education or training of intended users, 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, risks posed by user error due to the ergonomic features of the device and its intended user environment.”

(b) Section 7.4. is replaced by the following:

“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 Directive 2001/83/EC.

For a substance which:

— has already been granted, as a medicinal product, a Community marketing authorisation in accordance with Council Regulation (EEC) No 2309/93 (*) or Regulation (EC) No 726/2004;

or

— falls within the scope of the Annex to Regulation (EC) No 726/2004;

or

— is a human blood derivative;

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 the European Medicines Agency (EMA) on the quality and safety of the substance. When issuing its opinion, the EMA shall take into account the manufacturing process and the data related to the incorporation of the substance into the device.

For other substances, 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 in accordance with Directive 2001/83/EC, on the quality and

safety of the substance. When issuing its opinion, the concerned competent authority shall take into account the manufacturing process and the data related to the incorporation of the substance into the device.

Where changes are made to an ancillary substance incorporated in a medical device, in particular related to its manufacturing process, they shall be assessed by analogy with the procedures for the evaluation of variations to medicinal products laid down in Commission Regulations (EC) No. 1084/2003 (**) and EC No.1085/2003 (***). 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, and 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.

(*) OJ L214, 24.8.1993, p. 1.

(**) OJ L 159, 27.6.2003, p. 1.

(***) OJ L 159, 27.6.2003, p. 24.”

(c) The following Section 7.4a is inserted:

“7.4a. Where a device incorporates, as an integral part, a product which, if used separately, may be considered to be a human tissue engineered product within the meaning of [Article 2 (2) of the Regulation on Advanced Therapies and amending Regulation (EC) No 726/2004] and which is liable to act upon the body with action that is ancillary to that of the device, the quality, safety and usefulness of the product must be verified by analogy with the methods specified in Regulation EC No. [...] [on Advanced Therapies and amending Regulation (EC) No 726/2004].

The notified body shall, having verified the usefulness of the product as part of the medical device and taking account of the intended purpose of the device, seek a scientific opinion from the [Committee of Advanced Therapies] on the quality and safety of the product. When issuing its opinion, the [Committee of Advanced Therapies] shall take into account the manufacturing process and the data related to the incorporation of the product into the device.”

(d) In Section 8.2. the word ‘transferable’ is replaced by the word ‘transmissible’;

(e) The following Section 12.1a is inserted:

“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.”

(f) In Section 13.1. the first paragraph is replaced by the following:

“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.”

(g) Section 13.3 is amended as follows:

(i) point (a) is replaced by the following:

“(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 authorized representative where the manufacturer does not have a registered place of business in the Community;”

(ii) point (b) is replaced by the following:

“(b) the details strictly necessary for the user to identify the device and the contents of the packaging including the respective code of an internationally recognized generic medical device nomenclature;”

(iii) at the end of point (n) the following phrase is added:

“and in case of devices within the meaning of Article 1(4b) an indication that the device contains a human tissue engineered product”

(h) Section 13.6 is amended as follows:

(i) point (o) is replaced by the following:

“(o) medicinal substances, human blood derivatives or human tissue engineered products incorporated into the device as an integral part in accordance with Sections 7.4a and 7.4b;”

(i) Section 14 is deleted.

(2) Annex II is amended as follows:

(a) In Section 3.1, second paragraph, the first subparagraph of the seventh indent is replaced by the following:

“— 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 Annex X, 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:”

(b) Section 3.2. is amended as follows:

(i) the following paragraph is inserted after the first paragraph:

“It shall include in particular the corresponding documentation, data and records arising from the procedures referred to in Section 3.2(c).”

(ii) in point (b) the following indent is added:

“— 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;”

(iii) point (c) is replaced by the following:

“(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 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, a human blood derivative or a human tissue engineered product referred to in sections 7.4 and 7.4a of Annex I and the data on the tests conducted in this connection required to assess the safety, quality and usefulness of that substance, human blood derivative or human tissue engineered product, 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 Annex I Section I (2),

— the preclinical evaluation,

- the clinical evaluation referred to in Annex X,
- the draft label and, where appropriate, instructions for use;

(* OJ L 105, 26.4.2003, p. 18.”

(c) the second paragraph of Section 3.3. is replaced by the following:

“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.”

(d) In Section 4.3. the second and third paragraphs are replaced by the following:

“In the case of devices referred to in Annex I, Section 7.4a, second paragraph, the scientific opinion of the EMEA must be included in the documentation concerning the device. 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 referred to in Annex I, Section 7.4a, third paragraph, the notified body shall, as regards the aspects referred to in that section, consult one of the competent bodies designated by the Member States in accordance with Directive 2001/83/EC before taking a decision. 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 Annex I, Section 7.4a, the scientific opinion of the [Committee of Advanced Therapies] must be included in the documentation concerning the device. The notified body will give due consideration to the opinion of the [Committee of Advanced Therapies] when making its decision. The notified body may not deliver the certificate if the [Committee of Advanced Therapies] scientific opinion is unfavourable. It will convey its final decision to the [Committee of Advanced Therapies].

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. The notified body shall give due consideration to any comments received when making its decision.”

(e) In Section 5.2, the second indent is replaced by the following:

“ — the data stipulated in the part of the quality system relating to design, such as the results of analyses, calculation tests, the solutions adopted as referred to in Annex I Section I (2), preclinical and clinical evaluation, post-market clinical follow-up plan and the results of the post-market clinical follow-up, if applicable etc.,”

(f) In Section 6.1 is amended as follows:

(i) the first sentence is replaced by the following:

“The manufacturer must, for a period at least equivalent to the intended lifetime of the product as defined by the manufacturer but not less than five years from the date of manufacture, keep at the disposal of the national authorities:”

(ii) in the second indent the following phrase is added:

“and in particular the documentation, data and records referred to in the second paragraph of Section 3.2.”;

(g) Section 6.3 is deleted;

(h) In Section 8 the words “Article 4 (3) of Directive 89/381EEC” are replaced by the words “Article 114(2) of Directive 2001/83/EC”.

(3) Annex III is amended as follows:

(a) Section 3 is replaced by the following:

“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 sterilization, 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,

— a list of the standards referred to in Article 5, 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 have not been applied in full,

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

— a declaration stating whether or not the device incorporates, as an integral part, a substance, human blood derivative or a human tissue engineered product, referred to in Sections 7.4 and 7.4a of Annex I, and the data on the tests conducted in this connection which are required to assess the safety, quality and usefulness of that substance, human blood derivative or human tissue engineered product, 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 Annex I, Section I(2),
- the preclinical evaluation,
- the clinical evaluation referred to in Annex X,
- the draft label and, where appropriate, instructions for use.”

(b) In Section 5 the second and third paragraphs are replaced by the following:

“In the case of devices referred to in Annex I, Section 7.4, second paragraph, the scientific opinion of the EMEA must be included in the documentation concerning the device. 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 referred to in Annex I, Section 7.4a, third paragraph, the notified body shall, as regards the aspects referred to in that section, consult one of the competent bodies designated by the Member States in accordance with Directive 2001/83/EC before taking a decision. 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 Annex I, Section 7.4a, the scientific opinion of the [Committee of Advanced Therapies] must be included in the documentation concerning the device. The notified body will give due consideration to the opinion of the [Committee of Advanced Therapies] when making its decision. The notified body may not deliver the certificate if the [Committee of Advanced Therapies] scientific opinion is unfavourable. It will convey its final decision to the [Committee of Advanced Therapies].

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. The notified body shall give due consideration to any comments received when making its decision.”

(c) Section 7.3 is replaced by the following:

“7.3. The manufacturer or his authorized representative must keep with the technical documentation copies of EC type-examination certificates and their additions for a period at least equivalent to the intended lifetime of the product as defined by the manufacturer but not less than five years from the date of manufacture.”

(d) Section 7.4 is deleted.

(4) Annex IV is amended as follows:

(a) In Section 3 the first paragraph is replaced by the following:

“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 Annex X, 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:”

(b) Section 6.3 is replaced by the following:

“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, taking account of the specific nature of the product categories in question.”

(c) In Section 7 the first paragraph is replaced by the following:

“The manufacturer or his authorized representative must, for a period at least equivalent to the intended lifetime of the product as defined by the manufacturer but not less than five years from the date of manufacture, make available to the national authorities:”

(d) In the first paragraph of Section 8 the word ‘exemptions’ is deleted.

(e) In Section 9 the words ‘Article 4(3) of Directive 89/381EEC’ are replaced by ‘Article 114(2) of Directive 2001/83/EC’.

(5) Annex V is amended as follows:

(a) In Section 3.1. the eighth indent is replaced by the following:

“— 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 Annex X, 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:”

(b) In Section 3.2.(b) the following indent is added:

“— 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) In Section 4.2, the following indent is inserted after the first indent:

“— the technical documentation,”

(d) In Section 5.1 the first sentence is replaced by the following:

“The manufacturer must, for a period at least equivalent to the intended lifetime of the product as defined by the manufacturer but not less than five years from the date of manufacture, make available to the national authorities:”

(e) In Section 6, first paragraph, the word ‘exemptions’ is deleted.

(f) In Section 7 the words ‘Article 4(3) of Directive 89/381EEC’ are replaced by ‘Article 114(2) of Directive 2001/83/EC’.

(6) Annex VI is amended as follows:

(a) In the eight indent of Section 3.1 the first paragraph is replaced by the following:

“— 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 Annex X, 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:”

(b) In Section 3.2. the following indent is added:

“— 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;”

(c) In Section 5.1. the first sentence is replaced by the following:

“The manufacturer must, for a period at least equivalent to the intended lifetime of the product as defined by the manufacturer but not less than five years from the date of manufacture, make available to the national authorities:”

(7) Annex VII is amended as follows:

(a) Section 2 is replaced by the following:

“2. The manufacturer must prepare the technical documentation described in Section 3. The manufacturer or his authorized representative established in the Community must make this documentation, including the declaration of conformity, available to the national authorities for inspection purposes for a period at least equivalent to the intended lifetime of the product as defined by the manufacturer but not less than five years from the date of manufacture.”

(b) Section 3 is amended as follows:

(i) the first indent is replaced by the following:

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

(ii) the seventh indent is replaced by the following indent:

“ — the test reports,”

(iii) the following indent is inserted after the seventh indent:

“— the clinical evaluation in accordance with Annex X,”

(c) In Section 4 the first paragraph is replaced by the following:

“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 Annex X, and to implement appropriate means to apply any necessary corrective actions, taking account of the nature and risks in relation to the product. He shall notify the competent authorities of the following incidents immediately on learning of them:”

(d) In Section 5 and Section 6.1. the words ‘Annex IV, V or VI’ are replaced by ‘Annex II, IV, V or VI’.

(8) Annex VIII is amended as follows:

(a) In Section 2.1. the following indent is inserted after the introductory phrase:

“— the name and address of the manufacturer and any additional manufacturing site,”

(b) Section 2.2. is amended as follows:

(i) the second indent is replaced by the following:

“— the clinical investigation plan,”

(ii) the following indents are inserted as third, fourth and fifth indents:

“— the investigator’s brochure,

— the confirmation of insurance of subjects,

— the documents used to obtain informed consent,”

(c) Section 3.2. is replaced by the following:

“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 sterilization, 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, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of this Directive if the standards referred to in Article 5 have not been applied,

— a declaration stating whether or not the device incorporates, as an integral part, a substance, human blood derivative or human tissue engineered product, referred to in sections 7.4 and 7.4a of Annex I, 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 and 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 authorize the assessment, or audit where necessary, of the effectiveness of these measures.”

(d) Section 4 is replaced by the following:

“4. The information contained in the declarations concerned by this Annex should be kept for a period at least equivalent to the intended lifetime of the product as defined by the manufacturer but not less than five years from the date of manufacture.”

(e) The following Section 5 is added:

“5. For custom-made devices, 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 Annex X, 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 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.”

(9) Annex IX is amended as follows:

(a) Chapter I is amended as follows:

(i) in Section 1.4. the following sentence is added:

“Stand alone software is considered to be an active medical device.”

(ii) Section 1.7. is replaced by the following:

“1.7 Central circulatory system

For the purposes of this Directive, ‘central circulatory system’ means the following vessels:

arteriae pulmonales, aorta ascendens, aorta arcus, 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.”

(b) In Chapter II, Section 2 the following Section 2.6 is added:

“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.”

(c) Chapter III is amended as follows:

(i) the introductory phrase of the first sentence of Section 2.1 is replaced by the following:

“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:”

(ii) Section 2.2 is replaced by the following:

“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 ionizing 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.”

(iii) in Section 2.3 the first indent is replaced by the following:

“— 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,”

(iv) in Section 4.1., first paragraph, the reference ‘65/65/EEC’ is replaced by the reference ‘2001/83/EC’.

(v) in Section 4.1. the second paragraph is replaced by the following:

“All devices incorporating, as an integral part, a human blood derivative or a human tissue engineered product, are in Class III.”

(vi) in Section 4.3. second paragraph the following phrase is added:

“unless they are specifically to be used for disinfecting invasive devices in which case they are in Class IIb.”

(vii) in Section 4.4. the words ‘Non active devices’ are replaced by the word ‘Devices’

(10) Annex X is amended as follows:

(a) Section 1.1 is replaced by the following:

“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 Annex I, 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 Annex I, must be based on clinical data. The evaluation of this data, hereafter referred to as clinical evaluation, where appropriate taking account of any relevant harmonized 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 .”

(b) The following Sections 1.1a, 1.1b, 1.1c and 1.1d are inserted:

“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 have to be actively updated. Where post market clinical follow up as part of the postmarket 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 preclinical evaluation alone has to be duly substantiated.”

(c) In Section 2.2. the words ‘41st World Medical Assembly in Hong Kong in 1989’ are replaced by the words ‘World Medical Assembly.’;

(d) Section 2.3.5 is replaced by the following:

“2.3.5. All serious adverse events, whether device related or not, must be fully recorded and immediately notified to the competent authority of the Member State in which the event occurred.

A summary of the events referred to in the first paragraph, shall be provided, on a periodic basis, to all competent authorities of the Member States in which the clinical investigation is being performed.”