COUNCIL OF THE EUROPEAN UNION

Brussels, 26 January 2007

16009/1/06 REV 1

LIMITE

ECO 187
SAN 257
CODEC 1438

Interinstitutional File: 2005/0263 (COD)

NOTE

from :	Presidency
to :	Working Party on Pharmaceuticals and Medical Devices
No. Cion prop. :	5072/06 ECO 1 SAN 1 CODEC 6
Subject :	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

Delegations will find in the Annex to this Note a consolidated version of Directive 90/385/EEC prepared by the Presidency. This document is based on Working Document MD-64. In this document the "standard" text conventions from earlier documents is used, i.e.

underlined text = Commission proposal for new text of the Directive,
text with ~~strikethrough~~ = Commission proposal for deletion of previous text of the Directive;
text in **bold and underlined** = Presidency proposal for amendments to the text;
text in **~~bold and strikethrough~~** = Presidency proposal for deletions of text.

In addition, the German Presidency has put frames around elements of the text where it sees a need for further clarification.

COUNCIL DIRECTIVE 90/385/EEC

of 20 June 1990

concerning active implantable medical devices

Article 1

1. This Directive shall apply to active implantable medical devices.

2. For the purposes of this Directive, the following definitions shall apply:

[1](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 ~~or~~ software **intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and** necessary for its proper ~~functioning~~ application, intended by the manufacturer to be used ~~for medical purposes~~ for human beings ~~in the~~ for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease ~~or injury~~,
- 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, ~~chemical~~, immunological or metabolic means, but which may be assisted in its function by such means;

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

[1] See Parliament amendment 15

(c) 'active implantable medical device' means any active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure;

(d) 'custom-made device' means any ~~active implantable medical~~ device specifically made in accordance with a duly qualified medical ~~specialist's~~ practitioner's written prescription which gives, under his responsibility, specific design characteristics and is intended ~~to be used only for an individual named patient~~ 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~~[2].

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

(e) 'device intended for clinical investigation' means any ~~active implantable medical~~ device intended for use by a ~~specialist doctor~~ 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 ~~medical~~ device is intended ~~and for which it is suited~~ according to the data supplied by the manufacturer on the labelling, in the instructions and/or in promotional materials;

[2] This requirement makes sence for general MD like in case of eyeclasses or hearing aids, but not for an AIMD, the change of the wording would possibly give a wrong message to the public

(g) 'putting into service' means **making available to the medical profession for implantation**~~, the stage at which a device has been made available to the final user as being ready for use on the Community market for the first time for its intended purpose~~[3]**;**

(h) 'placing on the market' means the first making available in return for payment or free of charge of a device other than a device intended for clinical investigation, with a view to distribution and/or use on the Community market, regardless of whether it is new or fully refurbished;

(i) 'manufacturer' means the natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party. The obligations of this Directive **to** ~~that shall~~ be met by manufacturers also apply to the natural or legal person who assembles, packages, processes, fully refurbishes and/or labels one or more ready-made products and/or assigns to them their intended purpose as a device with a view to their being placed on the market under his own name. This subparagraph **does** ~~shall~~ not apply to the person who, while not a manufacturer within the meaning of the first subparagraph, assembles or adapts devices already on the market to their intended purpose for an individual patient~~.~~;[4]

(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**;**

[3] There are good historical and technical reasons corroberated by experience to define the putting into service of an AIMD differently from the putting into service of a general MD. For instance, an AIMD often contains a battery. The lifetime of such a battery is of crucial importance for the safety and performance of such an AIMD. The directive requires the safety of an AIMD when placed on the market or put into service. As a consequence of the proposed change we could in theory in the future have AIMDs which were safely placed on the market and put into service (e.g. at the storage of a hospital) but which are unsafe at the time of implantation because the battery is already depleted.

[4] No need to change the definition of a manufacturer.

3. Where an active implantable medical device is intended to administer a substance defined as a medicinal product within the meaning of **~~Council Directive~~** ~~65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products, as last amended by Directive 87/21/EEC~~ **Article 1 of** Directive 2001/83/EC **~~of the European Parliament and of the Council~~**, **with regard to the medicinal product,** that substance shall be subject to the system of marketing authorization provided for in that Directive.

4. Where an active implantable medical device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product within the meaning of Article 1 of Directive ~~65/65/EEC~~ 2001/83/EC, that device **~~must~~ shall** be evaluated and authorised in accordance with the provisions of this Directive.

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~~ shall** be assessed and authorised in accordance with this Directive.

~~[5]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.~~

5. This Directive constitutes a specific Directive within the meaning of Article ~~2 (2) of Council Directive 89/336/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to electromagnetic compatibility.~~ 1(4) of Directive 2004/108/EC **~~of the European Parliament and of the Council (***).~~**

[5] See proposals MD 79 and MD 80

6. This Directive shall not apply to**:**

[6]**(a) 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;**

~~**(b) cosmetic products covered by Directive 76/768/EEC;**~~[7]

(~~c~~b) 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.~~**;**

(~~d~~c) 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 4a;

(~~e~~e) transplants or tissues or cells of animal origin, unless a device is manufactured utilizing animal tissue which is rendered non-viable or non-viable products derived from animal tissue.

Article 2

[8]Member States shall take all necessary steps to ensure that the devices ~~**referred to in Article 1 (2) (c) and (d)**~~ may be placed on the market and/**or** put into service only if they ~~**do not compromise the safety and health of patients, users and, where applicable, other persons when properly implanted**~~, **comply with the requirements laid down in this Directive when duly supplied and properly installed**, maintained and used in accordance with their intended purposes.

---

6 See Parliament amendment 27: 'medicinal products covered by Directive 2001/83/EC. In deciding whether a product falls under that Directive **by virtue of the application of the criteria laid down in Article 1(2)(b) of that Directive or under** the present Directive, particular account shall be taken of the principal mode of action of the product;' not accepted (Supported by Cion)

7 Implants can never be cosmetics.

8 See Parliament amendment 17

Article 3

The active implantable medical devices referred to in Article 1 (2) (c), (d) and (e) hereinafter referred to as 'devices', must satisfy the essential requirements set out in Annex 1, which shall apply to them account being taken of the intended purpose of the devices concerned. **Where the relevant hazard exists, devices which are also machinery within the meaning of Article 2(a) of Directive 2006/42/EC must also meet the essential health and safety requirements set out in Annex I of that Directive to the extent to which those essential health and safety requirements are more specific than the essential requirements set out in Annex I of this Directive.**[9]

Article 4

1. Member States shall not prevent the placing on the market or the putting into service within their territory of devices complying with the provisions of this Directive and bearing the CE marking provided for in Article 12 which indicate that they have been the subject of an ~~**evaluation**~~ **assessment** of their conformity in accordance with Article 9.

2. Member States shall not create any obstacles to:

- devices intended for clinical investigations being made available to ~~**specialist doctors**~~ **medical practitioners** ~~**or authorized persons**~~ for that purpose if they satisfy the conditions laid down in Article 10 and in Annex 6,[10]

- custom-made devices being placed on the market and put into service if they satisfy the conditions laid down in Annex 6 and are accompanied by the statement ~~**to be offered to the named, which shall be available to the particular identified patient**~~. referred to in that Annex.

These devices shall not bear the CE marking.

[9] The proposal by Cion

[10] In case of AIMD a medical practitioner should be responsible.

3. At trade fairs, exhibitions, demonstrations, etc., Member States shall not prevent the showing of devices which do not conform to this Directive, provided that a visible sign clearly indicates that such devices do not conform and cannot be put into service until they have been made to comply by the manufacturer or his authorized representative established within the Community.

4. When a device is put into service, Member States may require the information described in sections 13, 14 and 15 of Annex 1 to be in their national language(s).

5. (a) Where the devices are subject to other Directives concerning other aspects and which also provide for the affixing of the CE marking, the latter shall indicate that the devices are also presumed to conform to the provisions of the other Directives.

(b) However, where one or more of these Directives allow the manufacturer, during a transitional period, to choose which arrangements to apply, the CE marking shall indicate conformity to the provisions only of those Directives applied by the manufacturer. In this case, particulars of the Directives applied, as published in the *Official Journal of the European Communities*, must be given in the documents, notices or instructions required by the Directives and accompanying such devices; these documents, notices or instructions shall be accessible without it being necessary to destroy the packaging which keeps the device sterile.

Article 5

1. Member States shall presume compliance with the essential requirements referred to in Article 3 in respect of devices which are in conformity with the relevant national standards adopted pursuant to the harmonized standards the references of which have been published in the *Official Journal of the European Communities*; Member States shall publish the references of such national standards.
2. For the purposes of this Directive, reference to harmonised also includes the monographs of the European *Pharmacopoeia* notably on surgical sutures and on interaction between medical products and material used in devices containing such medicinal products, the references of which have been published in the *Official JOurnal of the European Communities*.[11]

[11] Text taken from Art. 5 (2) MDD, may be applicable to AIMDs as well. Proposal SE MD-82

Article 6 [12]

1. Where a Member State or the Commission considers that the harmonized standards referred to in Article 5 do not entirely meet the essential requirements referred to in Article 3, the Commission or the Member State concerned shall bring the matter before the Standing Committee set up under Directive 83/189/EEC, giving the reasons therefore. The Committee shall deliver an opinion without delay.

In the light of the opinion of the Committee, the Commission shall inform Member States of the measures to be taken with regard to the standards and the publication referred to in Article 5.

2. The Commission shall be assisted by a standing committee (hereinafter referred to as 'the Committee').

~~The Committee may be apprised, in accordance with the procedure referred to in this paragraph, of any matter to which the implementation and practical application of this Directive give rise.~~

[13] Where reference is made to this paragraph, Articles ~~3~~ 5 and 7 of Decision 1999/468/EC (1) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5 (6) of Decision 1999/468/EC shall be set at three months.

~~**3. The Committee shall adopt its rules of procedure.**~~

2a. Where reference is made to this paragraph, Article 5a (1) to (4), and Article 7 of Decision 1999/468/EC shall apply.

[12] Scrutiny reservation by all delegations.

[13] See Parliament amendment 58 (Supported by the CION).

2b. Where reference is made to this paragraph, Article 5a (1), (2) and (6), and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

~~**3. The Committee may examine any question connected with the implementation of this Directive.**~~

Article 7

1. Where a Member State finds that the devices referred to in Article 1 (2) (c) and (d) correctly put into service and used in accordance with their intended purpose, may compromise the health and/or safety of patients, users or, where applicable, other persons, it shall take all appropriate measures to withdraw such devices from the market or prohibit or restrict their being placed on the market or their being put into service.

The Member State shall immediately inform the Commission of any such measure, indicating the reasons for its decision and, in particular, whether non-compliance with this Directive is due to:

(a) failure to meet the essential requirements referred to in Article 3, where the device does not meet in full or in part the standards referred to in Article 5;
(b) incorrect application of those standards;
(c) shortcomings in the standards themselves.

2. The Commission shall enter into consultation with the parties concerned as soon as possible. Where, after such consultation, the Commission finds that:

- the measures are justified, it shall immediately so inform the Member State which took the initiative and the other Member States; where the decision referred to in paragraph 1 is attributed to shortcomings in the standards, the Commission shall, after consulting the parties concerned, bring

the matter before the Committee referred to in Article 6 (1) within two months if the Member State which has taken the decision intends to maintain it and shall initiate the procedures referred to in Article 6 (1),

- the measures are unjustified, it shall immediately so inform the Member State which took the initiative and the manufacturer or his authorized representative established within the Community.

3. Where a device which does not comply bears the CE marking, the competent Member State shall take appropriate action against whomsoever has affixed the mark and shall inform the Commission and the other Member States thereof.

4. The Commission shall ensure that the Member States are kept informed of the progress and outcome of this procedure.

Article 8

1. Member States shall take the necessary steps to ensure that information brought to their knowledge regarding the incidents mentioned below involving a device is recorded and evaluated in a centralized manner:

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

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

2.[14] **After carrying out an assessment, if possible together with the manufacturer,** Member States shall, without prejudice to Article 7, ~~forthwith~~ **immediately** inform the Commission and the other Member States **on measures that have been taken or are contemplated to minimize the re-occurence** of the incidents referred to in paragraph 1 ~~**and of the relevant measures taken or contemplated.**~~

[15]**The Commission, acting in accordance with the procedure referred to in Article 6 (2)**[16]**, shall take any appropriate measures to adopt procedures to implement this Article**

Article 9

1. In the case of devices other than those which are custom-made or intended for clinical investigations, the manufacturer must, in order to affix the CE marking, at his own choice:

(a) follow the procedure relating to the EC declaration of conformity set out in Annex 2; or
(b) follow the procedure relating to EC type-examination set out in Annex 3, coupled with:
(i) the procedure relating to EC verification set out in Annex 4, or
(ii) the procedure relating to the EC declaration of conformity to type set out in Annex 5.

2. In the case of custom-made devices, the manufacturer must draw up the declaration provided for in Annex 6 before placing each device on the market.

3. Where appropriate, the procedures provided for in Annexes 3, 4 and 6 may be discharged by the manufacturer's authorized representative established in the Community.

4. The records and correspondence relating to the procedures referred to in paragraphs 1, 2 and 3 shall be in an official language of the Member State in which the said procedures will be carried out and/or in a language acceptable to the notified body defined in Article 11.

---

14 See Parliament amendment 35 and MD-80 by SP
15 See Parliament amendment 36
16 regulatory comitology procedure as in art. 10.4 of MDD.

5. During the conformity assessment procedure for a device, the manufacturer and/or the notified body shall take account of the results of any assessment and verification operations which, where appropriate, have been carried out in accordance with this Directive at an intermediate stage of manufacture.

6. Where the conformity assessment procedure involves the intervention of a notified body, the manufacturer, or his authorized representative established in the Community, may apply to a body of his choice within the framework of the tasks for which the body has been notified.

7. The notified body may require, where duly justified, any information or data, which is necessary for establishing and maintaining the attestation of conformity in view of the chosen procedure.

8. Decisions taken by the notified bodies in accordance with Annexes **~~II~~2, 3** and **~~III~~5** shall be valid for a maximum of five years and may be extended on application, made at a time agreed in the contract signed by both parties, for further periods of **a maximum length of** five years.

9. By derogation from paragraphs 1 and 2 the competent authorities may authorize, on duly justified request, the placing on the market and putting into service, within the territory of the Member State concerned, of individual devices for which the procedures referred to in paragraphs 1 and 2 have not been carried out and the use of which is in the interest of protection of health.

[17]**In the light of technical progress and under consideration of intended users of devices concerned the Commission may, in accordance with the procedure referred to in Article 6 (~~3~~2a), adopt measures allowing the information laid down in Annex ~~I~~1 Section ~~13.1~~15 to be set out by other means.**

[17] See Parliament amendment 37, Still under concideration.

Article 9a

1. Where a Member State considers that

- the conformity of a device or family of devices should be established, by way of derogation from the provisions of Article 9, by applying solely one of the given procedures chosen from among those referred to in Article 9, it shall submit a duly substantiated request to the Commission and ask it to take the necessary measures~~.~~**;**

- **a decision is required as to whether a particular product falls within the definition of Article 1 (2) (a), (c), or (d).** [18]

~~These measures shall be adopted in accordance with the procedure referred to in Article 7 (2) of Directive 93/42/EEC~~. The Commission shall, as appropriate, adopt the measures in accordance with the procedure referred to in Article 6 (2)[19]**.**

2. The Commission shall inform the Member States of the measures taken **~~and, where appropriate, publish the relevant parts of these measures in the Official Journal of the European Communities~~**.

Article 10

1. In the case of devices intended for clinical investigations, the manufacturer or his authorized representative established in the Community shall, at least 60 days before the commencement of the investigations, submit the statement referred to in Annex 6 to the competent authorities of the Member State in which the investigations are to be conducted.

2. The manufacturer may commence the relevant clinical investigations 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 order.

Member States may however authorize manufacturers to start the clinical investigations in question before the expiry of the 60-day period, provided that the Ethical Committee concerned has **issued**

[18] SE MD-82

[19] the same comitology procedure foreseen as in article 13 MDD

~~**delivered**~~ a favourable opinion with respect to the investigation programme in question **including its review of the clinical investigation plan.**

2a. The authorization referred to in the second subparagraph of paragraph 2 may be subject to approval by the competent authority.

3. The Member States shall, if necessary, take the appropriate steps to ensure public health and ~~**order**~~ **public policy. Where a clinical investigation is refused or halted by a Member State, that Member State shall communicate its decision and the grounds for it to all Member States and the Commission. Where a Member State has called for a significant modification or temporary interruption of a clinical investigation, that Member State shall inform concerned Member States about its actions and the grounds for the actions taken.**

4. **The manufacturer or his authorized representative shall notify the competent authorities of the Member States concerned of the end of the clinical investigation, with a justification in case of early termination. In the case of early termination of the clinical investigation on safety reasons this notification has to be communicated to all Member States and the Commission. The manufacturer or his authorized representative shall keep the report referred to in point 2.3.7 of Annex 7 at the disposal of the competent authorities.**

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.

Member States may request to be informed of all data allowing for identification of devices together with the label and the instructions for use when such devices are put into service within their territory.

[20]2. Where a manufacturer who places ~~devices~~ **a device** 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 **in the European Union** ~~established in the Community~~.

For devices referred to in paragraph 1 the authorized representative shall inform the competent **authority** 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**~~ **all details as referred to in paragraph 1.**

3. The Member States shall on request inform the other Member States and the Commission of the **information referred to in paragraph 1 that was provided by the manufacturer or the authorised representative.** ~~**details referred to in**~~ **paragraphs 1 first sentence** ~~**and 2.**~~[21]

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 authorised representatives and devices in accordance with Article 10a;**~~[22]~~

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;

~~e) **the international generic medical devices code as referred to in Annex 1.**~~

[20] See Parliament amendment 19

[21] Information provided by authorised representatives has to be made available as well. MS should, however, not be obliged to forward the instructions for use of a specific device to other MS.

[22] Proposing to keep this paragraph as the information on the manufacturer or authorised representative is essential.

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 paragraphs 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**~~,~~ or subjected to particular requirements**, it may take any necessary and 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. **The Commission shall adopt its opinion, indicating whether the national measures are justified or not. The Commission shall inform all Member States and the consulted interested parties.**

[23] **~~Where the national measures are justified,~~ When appropriate**, the Commission shall adopt the necessary Community measures in accordance with the procedure referred to in Article 6 (**2a**)**. ~~If the national measures are unjustified, the Commission shall inform all Member States and the consulted interested parties.~~**

If, on imperative grounds of urgency, the timelimits for the procedure referred to in Article 6 (2a) cannot be complied with, the Commission shall adopt the necessary Community measures in accordance with the procedure referred to in Article 6 (2b).

[23] See Parliament amendment 20

Article 11

1. Member States shall notify the Commission and the other Member State of the bodies which they have appointed to carry out the procedures referred to in Article 9 together with the specific tasks which these bodies have been appointed to carry out and the identification numbers assigned to them beforehand by the Commission.

The Commission shall publish in the *Official Journal of the European Communities* a list of the notified bodies and their identification numbers and the tasks for which they have been notified. The Commission shall ensure that this list is kept up to date.

2. Member States shall apply the minimum criteria, set out in Annex 8, for the designation of bodies. Bodies that satisfy the criteria fixed by the relevant harmonized standards shall be presumed to satisfy the relevant minimum criteria.

When appropriate in the light of technical progress the Commission shall adopt the necessary measures to ensure a consistens application of the criteria set out in Annex 11 for the designation of bodies by the Member States in accordance with the procedure referred to in Article 6 (2). ~~**in the procedure referred to in Article 6(2) take the necessary measures to apply for the verification and monitoring of equivalence in the case of notification of bodies.**~~

3. A Member State that has notified a body shall withdraw that notification if it finds that the body no longer meets the criteria referred to in paragraph 2. It shall immediately inform the other Member States and the Commission thereof.

4. The notified body and the manufacturer or his ~~**agent**~~ **authorised representative** ~~**established in the Community**~~ shall fix, by common accord, the time limits for completion of the evaluation and verification operations referred to in Annexes 2 to 5.

5. The notified body shall inform ~~**the other notified bodies and**~~ its competent authority about all certificates **issued, modified, supplemented**, suspended , withdrawn or refused and **the other notified bodies within the scope of this directive, about certificates refused, suspended or withdrawn and**, on request, about certificates issued. ~~It~~ **The Notified Body** 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.

Article 12

1. Devices other than those which are custom made or intended for clinical investigations considered to meet the essential requirements referred to in Article 3 must bear the CE marking of conformity.

2. The CE marking of conformity, as shown in Annex 9, must appear in a visible, legible and indelible form on the sterile pack and, where appropriate, on the sales packaging, if any, and on the instruction leaflet.

It must be followed by the identification number of the notified body responsible for implementation of the procedures set out in Annexes 2, 4 and 5.

3. The affixing of markings on the devices which are likely to deceive third parties as to the meaning and form of the CE marking shall be prohibited. Any other marking may be affixed to the packaging or to the instruction leaflet accompanying the device provided that the visibility and legibility of the CE marking is not hereby reduced.

Article 13

Where prejudice to Article 7

(a) where a Member State establishes that the CE marking has been affixed unduly, the manufacturer or his authorized representative established within the Community shall be obliged to end the infringement under conditions imposed by the Member State;

(b) where non-compliance continues, the Member State must take all appropriate measures to restrict or prohibit the placing on the market of the device in question or to ensure that it is withdrawn from the market in accordance with the procedures laid down in Article 7.

Those provisions shall also apply where the CE marking has been affixed in accordance with the procedures in this Directive, but inappropriately, on products that are not covered by this Directive.

Article 14

Any decision taken pursuant to this Directive and resulting in the refusal of or restrictions on the placing on the market and/or putting into service of a device shall state the exact grounds on which it is based. Such a decision shall be notified without delay to the party concerned, who shall at the same time be informed of the remedies available to him under the laws in force in the Member State in question and of the time limits to which such remedies are subject.

In the event of a decision as referred to in the previous paragraph the manufacturer, or his authorized representative established in the Community, shall have an opportunity to put forward his viewpoint in advance, unless such consultation is not possible because of the urgency of the measures to be taken.

Article 15

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 obligations of Member States and notified bodies with regard to mutual information and the dissemination of warnings.

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 10a;

(b) information to users sent out by manufacturer, authorised representative or distributor in relation with a measure according to Article 8,

(c) information contained in certificates issued, modified, supplemented, suspended or withdrawn

(d) ~~a summary of the information and data related to active implantable medical devices.~~

The Commission may, in accordance with the procedure referred to in Article 6 (2a), determine the conditions under which other information may be made publicly available, and ~~for active implantable medical devices~~ an obligation for manufacturers to prepare and make available a summary of the information and data related to the device.

Article 16

Member States shall take appropriate measures to ensure that the competent authorities of the Member States cooperate with each other and with the Commission and transmit to each other the information necessary to enable this Directive to be applied uniformly.

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

~~24~~

~~24 See amendment 49; European reprocessing standard, still under consideration~~

ANNEX 1

ESSENTIAL REQUIREMENTS

I. GENERAL REQUIREMENTS

1. The devices must be designed and manufactured in such a way that, when implanted under the conditions and for the purposes laid down, their use does not compromise the clinical condition or the safety of patients. They must not present any risk to the persons implanting them or, where applicable, to other persons.

2. The devices must achieve the performances intended by the manufacturer, viz. be designed and manufactured in such a way that they are suitable for one or more of the functions referred to in Article 1 (2) (a) as specified by him.

3. The characteristics and performances referred to in sections 1 and 2 must not be adversely affected to such a degree that the clinical condition and safety of the patients or, as appropriate, of other persons are compromised during the lifetime of the device anticipated by the manufacturer, where the device is subjected to stresses which may occur during normal conditions of use.

4. The devices must be designed, manufactured and packed in such a way that their characteristics and performances are not adversely affected in the storage and transport conditions laid down by the manufacturer (temperature, humidity, etc.).

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

II. REQUIREMENTS REGARDING DESIGN AND CONSTRUCTION

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

7. Implantable devices must be designed, manufactured and packed in a non-reusable pack according to appropriate procedures to ensure they are sterile when placed on the market and, in the storage and transport conditions stipulated by the manufacturer, remain so until the packaging is removed and they are implanted.

8. Devices must be designed and manufactured in such a way as to remove or minimize as far as possible:
- the risk of physical injury in connection with their physical, including dimensional, features,
- risks connected with the use of energy sources with particular reference, where electricity is used, to insulation, leakage currents and overheating of the devices,
- risks connected with reasonably foreseeable environmental conditions such as magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure and acceleration,
- risks connected with medical treatment, in particular those resulting from the use of defibrillators or high-frequency surgical equipment,
- risks connected with ionizing radiation from radioactive substances included in the device, in compliance with the protection requirements laid down in Directive 80/836/Euratom, as amended by Directives 84/467/Euratom and 84/466/Euratom,
- risks which may arise where maintenance and calibration are impossible, including:
- excessive increase of leakage currents,
- ageing of the materials used,
- excess heat generated by the device,
- decreased accuracy of any measuring or control mechanism.

9. The devices must be designed and manufactured in such a way as to guarantee the characteristics and performances referred to in I. 'General requirements', with particular attention being paid to:
- the choice of materials used, particularly as regards toxicity aspects,
- mutual compatibility between the materials used and biological tissues, cells and body fluids, account being taken of the anticipated use of the device,
- compatibility of the devices with the substances they are intended to administer,
- the quality of the connections, particularly in respect of safety,
- the reliability of the source of energy,
- if appropriate, that they are leakproof,

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

10[25]. Where a device incorporates, as an integral part, a substance which, ~~when~~ if used separately, ~~is likely to~~ may be considered to be a medicinal product as defined in Article 1 of Directive ~~65/65/EEC~~ 2001/83/EC, and ~~whose action in combination with the device may result in its bioavailability~~ which is liable to act upon the body with action ancillary to that of the device, the ~~safety~~, quality, safety and usefulness of the substance~~,~~ **~~account being taken of the purpose of the device,~~** must be verified by analogy with the **~~appropriate~~** **~~relevant~~** methods specified in **Annex I of** Directive ~~75/318/EEC, as last amended by Directive 89/341/EEC~~ 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;~~

[25] See Parliament amendment 54

For the substances referred in the first paragraph, the notified body shall, having verified the usefulness of the substance as part of the medical device and taking account of the intended purpose of the device, seek a scientific opinion **from one of the competent authorities designated by the Member States or** the European Medicines Agency (EMEA**) acting particularly through its committee in accordance with Regulation (EC) No 726/2004** on the quality and safety of the substance **including the clinical benefit/risk profile of the incorporation of the substance into the device**. **The opinion shall be drawn up within 210 days after receipt of a valid documentation. ~~processing days~~**[26]**.** When issuing its opinion**, the competent authority** or the EMEA shall take into account the manufacturing process and the data related to the **usefulness of** incorporation of the substance into the device **as determined by the notified body**.

Where a device incorporated, as an integral part, a human blood derivative, the notified body shall, having verified the usefulness of the substance as part of the device and taking into account of the intended purpose of the device, seek a scientific opinion from the European Medicines Agency (EMEA) acting particularly throught its committee on the quality and safety of the substance, including the clinical benefit/risk profile of the incorporation of the human blood derivative into the device. **The opinion shall be drawn up within 210 days after receipt of a valid documentation ~~processing days~~**[27]**. When issuing its opinion, the EMEA shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the notified body.**

~~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.~~

[26] move of the sentence to annex 2 and annex 3 necessary ??
[27] move of the sentence to annex 2 and annex 3 necessary ??

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 (***). T**~~the notified body shall be informed of the changes and shall consult the relevant medicines competent authority (i.e. the one involved in the initial consultation), in order to confirm that the quality and safety of the ancillary substance are maintained. **The competent authority shall take into account the data related to the usefulness of the incorporation of the substance into the device as determined by the notified body, 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.

~~**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.**~~

When the relevant medicines competent authority (i.e. the one involved in to initial consultation) has obtained information on the ancillary substance, which could have an impact on the established benefit/risk profile of the addition of the substance to the device,

they shall provide the notified body with advice, whether this information has impact on the established benefit/risk profile of the addition of the substance to the device or not. The notified body shall take the updated scientific opinion into account in reconsidering its assessment of the conformity assessment procedure.

11. The devices and, if appropriate, their component parts must be identified to allow any necessary measure to be taken following the discovery of a potential risk in connection with the devices and their component parts.

12. Devices must bear a code by which they and their manufacturer can be unequivocably identified (particularly with regard to the type of device and year of manufacture); it must be possible to read this code, if necessary, without the need for a surgical operation.

13. When a device or its accessories bear instructions required for the operation of the device or indicate operating or adjustment parameters, by means of a visual system, such information must be understandable to the user and, as appropriate, the patient.

14. Every device must bear, legibly and indelibly, the following particulars, where appropriate in the form of generally recognized symbols:

14.1. On the sterile pack:
- the method of sterilization,
- an indication permitting this packaging to be recognized as such,
- the name and address of the manufacturer,
- a description of the device,
- if the device is intended for clinical investigations, the words: 'exclusively for clinical investigations',
- if the device is custom-made, the words 'custom-made device',
- a declaration that the implantable device is in a sterile condition,
- the month and year of manufacture,
- an indication of the time limit for implanting a device safely.

14.2. On the sales packaging:

- the name and address of the manufacturer **and the name and address of the authorized representative, where the manufacturer doesn't have a registered place of business in the Community**

- a description of the device,

- the purpose of the device,

- the relevant characteristics for its use,

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

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

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

- the month and year of manufacture,

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

- the conditions for transporting and storing the device.

– in the case of a device within the meaning of Article 1(4a), an indication that the device contains a ~~medicinal~~ substances ~~or~~ human blood derivative**s** **~~or a human tissue engineered product~~ ~~incorporated into the device as an integral part in accordance with Section 10.~~**

15.[28] When placed on the market, each device must be accompanied by instructions for use giving the following particulars:

- the year of authorization to affix the CE mark,

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

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

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

- information constituting the instructions for use allowing the physician and, where appropriate, the patient to use the device, its accessories and software correctly, as well as information on the nature, scope and times for operating controls and trials and, where appropriate, maintenance measures,

[28] See Parliament amendment 65, still under consideration

- information allowing, if appropriate, certain risks in connection with implantation of the device to be avoided,
- information regarding the risks of reciprocal interference (*) in connection with the presence of the device during specific investigations or treatment,
- the necessary instructions in the event of the sterile pack being damaged and, where appropriate, details of appropriate methods of resterilization,
- an indication, if appropriate, that a device can be reused only if it is reconditioned under the responsibility of the manufacturer to comply with the essential requirements.

The instruction leaflet must also include details allowing the physician to brief the patient on the contra-indications and the precautions to be taken. These details should cover in particular:
- information allowing the lifetime of the energy source to be established,
- precautions to be taken should changes occur in the device's performance,
- precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, etc.,
- adequate information regarding the medicinal products which the device in question is designed to administer.
- **date of issue or the latest revision of the instruction for use.**

~~15a. The manufacturer or his authorised representative shall make available to the authorities the international generic medical devices code.~~

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

EC DECLARATION OF CONFORMITY

(Complete quality assurance system)

1. The manufacturer shall apply the quality system approved for the design, manufacture and final inspection of the products concerned as specified in sections 3 and 4 and shall be subject to EC surveillance as specified in section 5.

2. The declaration of conformity is the procedure by means of which the manufacturer who satisfies the obligations of section 1 ensures and declares that the products concerned meet the provisions of this Directive which apply to them.

The manufacturer or his authorized representative established within the Community shall affix the CE marking in accordance with Article 12 and shall draw up a written declaration of conformity.

This declaration shall cover one or more **clearly** identified **devices by means of product name, product code or other unambiguous reference and must** ~~**examples of the product and shall**~~ be kept by the manufacturer. ~~**or his authorized representative established within the Community.**~~

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

3. Quality system

3.1. The manufacturer shall make an application for evaluation of his quality system to a notified body.
The application shall include:
- all the appropriate items of information for the category of products manufacture of which is envisaged,
- the quality-system documentation,
- an undertaking to fulfil the obligations arising from the quality system as approved,
- an undertaking to maintain the approved quality system in such a way that it remains adequate and efficacious,
- an undertaking by the manufacturer to institute and keep up-dated a post-marketing surveillance system **including the provisions referred to in Annex 7.** The undertaking shall include an obligation for the manufacturer to notify the competent authorities of the following incidents immediately on learning of them:
(i) any deterioration in the characteristics or performances, and any inaccuracies in the instruction leaflet for a device which might lead to or have led to the death of a patient or a deterioration in his state of health;
(ii) any technical or medical reason resulting in withdrawal of a device from the market by the manufacturer.

3.2. The application of the quality system must ensure that the products conform to the provisions of this Directive which apply to them at every stage, from design to final controls.

All the elements, requirements and provisions adopted by the manufacturer for his quality system shall be documented in a systematic and orderly manner in the form of written policies and procedures. This quality-system documentation must make possible a uniform interpretation of the quality policies and procedures such as quality programmes, quality plans, quality manuals and quality records. **It shall include in particular the corresponding documentation, data and records arising from the procedures referred to in Section 3.2c.**

It shall include in particular an adequate description of:

(a) the manufacturer's quality objectives;

(b) the organization of the business and in particular:

- the organizational structures, the responsibilities of the managerial staff and their organizational authority where quality of design and manufacture of the products is concerned,
- the methods of monitoring the efficient operation of the quality system and in particular its ability to achieve the desired quality of the design and of the products, including control of products which do not conform;

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

(c) the procedures for monitoring and verifying the design of the products and in particular:

- the design specifications, including the standards which will be applied and a description of the solutions adopted to fulfil the essential requirements which apply to the products when the standards referred to in Article 5 are not applied in full,
- the techniques of control and verification of the design, the processes and systematic actions which will be used when the products are being designed;
- a statement indicating whether or not the device incorporates, as an integral part, a substance~~,~~ **or** a human blood derivative ~~**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~~**, or**~~ human blood derivative ~~**or a human tissue engineered product,**~~ taking account of the intended purpose of the device,
- **the preclinical evaluation,**
- **the clinical evaluation referred to in Annex 7;**

(d) the techniques of control and of quality assurance at the manufacturing stage and in particular:

- - the processes and procedures which will be used, particularly as regards sterilization, purchasing and the relevant documents,
  - product-identification procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture;
  (e) the appropriate tests and trials which will be effected before, during and after production, the frequency with which they will take place, and the test equipment used.

3.3. Without prejudice to Article 13 of this Directive, the notified body shall effect an audit of the quality system to determine whether it meets the requirements referred to in 3.2. It shall presume conformity with these requirements for the quality systems which use the corresponding harmonized standards.

The team entrusted with the evaluation shall include at least one member who has already had experience of evaluations of the technology concerned. The evaluation procedure shall include **an assessment, on a representative basis, of the documentation of the design of the product(s) concerned**, an inspection on the manufacturer's premises **and in duly substantiated cases, on the premises of the manufacturer's suppliers and/or subcontractors to inspect the manufacturing processes.**

The decision shall be notified to the manufacturer after the final inspection. It shall contain the conclusions of the control and a reasoned evaluation.

3.4. The manufacturer shall inform the notified body which has approved the quality system of any plan to alter the quality system.

The notified body shall evaluate the proposed modifications and shall verify whether the quality system so modified would meet the requirements referred to in 3.2; it shall notify the manufacturer of its decision. This decision shall contain the conclusions of the control and a reasoned evaluation.

4. Examination of the design of the product

4.1. In addition to the obligations incumbent on him under section 3, the manufacturer shall make an application for examination of the design dossier relating to the product which he plans to manufacture and which falls into the category referred to in 3.1.

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

It shall include *inter alia*:
- the design specifications, including the standards which have been applied,
- the necessary proof of their appropriations, in particular where the standards referred to in Article 5 have not been applied in full. This proof must include the results of the appropriate tests carried out by the manufacturer or carried out under his responsibility,
- a statement as to whether or not the device incorporates, as an integral part, a substance as referred to in section 10 of Annex 1, whose action in combination with the device may result in its bioavailability, together with data on the relevant trials conducted,
- the clinical **~~data~~ evaluation** referred to in Annex 7,
- the draft instruction leaflet.

4.3. The notified body shall examine the application and, where the product complies with the relevant provisions of this Directive, shall issue the applicant with an EC design examination certificate. The notified body may require the application to be supplemented by further tests or proof so that compliance with the requirements of the Directive may be evaluated. The certificate shall contain the conclusions of the examination, the conditions of its validity, the data needed for identification of the approved design and, where appropriate, a description of the intended use of the product.

In the case of devices referred to in Annex 1, Section 10 ~~third~~ **second** paragraph, the notified body shall, as regards the aspects referred to in that section, consult one of the competent ~~**bodies**~~ **authorities** designated by the Member States in accordance with Directive 2001/83/EC or the EMEA before taking a decision. . **The opinion shall be drawn up within 210 days after receipt of a valid documentation. The scientific opinion of the competent body must be included in the documentation concerning the device.** The notified body will give due consideration to the views expressed in this consultation when making its decision. It will convey its final decision to the competent body concerned.

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

~~**In the case of devices 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].**~~

4.4. The applicant shall inform the notified body which issued the EC design examination certificate of any modification made to the approved design. Modifications made to the approved design must obtain supplementary approval from the notified body which issued the EC design examination certificate where such modifications may affect conformity with the essential requirements of this Directive or the conditions prescribed for the use of the product. This supplementary approval shall be given in the form of an addendum to the EC design examination certificate.

5. Surveillance

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

5.2. The manufacturer shall authorize the notified body to carry out all necessary inspections and shall supply it with all appropriate information, in particular:
- the quality-system documentation,
- the data stipulated in the part of the quality system relating to design, such as the results of analyses, calculations, tests, **preclinical and clinical evaluation, post-market clinical follow-up plan and the results of the post-market clinical follow up, if applicable** etc.,
- the data stipulated in the part of the quality system relating to manufacture, such as reports concerning inspections, tests, standardizations/calibrations and the qualifications of the staff concerned, etc.

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

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

6. Administrative provisions

6.1. For **~~a period~~** at least **~~equivalent to the intended lifetime of the product defined by the manufacturer~~** ~~but not less than five~~ fifteen years from the last date of manufacture of the product, the manufacturer **or his authorised representative** shall keep available for the national authorities:
— the declaration of conformity,
— the documentation referred to in the second indent of section 3.1, **and in particular the documentation, data and records referred to in the second paragraph of Section 3.2**
— the amendments referred to in section 3.4,
— the documentation referred to in section 4.2,
— the decisions and reports of the notified body referred to in sections 3.4, 4.3, 5.3 and 5.4.

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

~~**6.3. Where neither the manufacturer nor his authorized representative are established in the Community, the task of keeping available for the authorities the technical documentation referred to in Article 4 (2) shall fall to the person responsible for placing the appliance on the Community market.**~~

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.

1.1. EC TYPE-EXAMINATION

1. EC type-examination is the procedure whereby a notified body observes and certifies that a representative sample of the production envisaged satisfies the relevant provisions of this Directive.

2. The application for EC type-examination shall be made by the manufacturer, or by his authorized representative established in the Community, to a notified body.

The application shall include:
- the name and address of the manufacturer and the name and address of the authorized representative if the application is made by the latter,
- a written declaration specifying that an application has not been made to any other notified body,
- the documentation described in section 3 needed to allow an evaluation to be made of the conformity of a representative sample of the production in question, hereinafter referred to as 'type', with the requirements of this Directive.

The applicant shall make a 'type' available to the notified body. The notified body may request other samples as necessary.

3. The documentation must make it possible to understand the design, the manufacture and the performances of the product. The documentation shall contain the following items in particular:
- a general description of the type,
- design drawings, methods of manufacture envisaged, in particular as regards sterilization, and diagrams of parts, sub-assemblies, circuits, etc.,

- the descriptions and explanations necessary for the understanding of the abovementioned drawings and diagrams and of the operation of the product,
- a list of the standards referred to in Article 5, applied in full or in part, and a description of the solutions adopted to satisfy the essential requirements where the standards referred to in Article 5 have not been applied,
- the results of design calculations, investigations and technical tests carried out, etc.,
- ~~a statement as to whether or not the device incorporates, as an integral part, a substance as referred to in section 10 of Annex 1, whose action in combination with the device may result in its bioavailability, together with data on the relevant trials conducted~~ a declaration stating whether or not the device incorporates, as an integral part, a substance~~,~~ **or** a human blood derivative ~~**or a human tissue engineered product**~~ as referred to in Section~~**s**~~ 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~~**, or** human blood derivative **or human tissue engineered product,**~~ taking account of the intended purpose of the device,
- ~~**the clinical data referred to in Annex 7,**~~
- **the preclinical evaluation,**
- **the clinical evaluation referred to in Annex 7,**
- the draft instruction leaflet.

4.

The notified body shall:

4.1.

examine and evaluate the documentation, verify that the type has been manufactured in accordance with that documentation; it shall also record the items which have been designed in accordance with the applicable provisions of the standards referred to in Article 5, as well as the items for which the design is not based on the relevant provisions of the said standards;

4.2.

carry out or have carried out the appropriate inspections and the tests necessary to verify whether the solutions adopted by the manufacturer satisfy the essential requirements of this Directive where the standards referred to in Article 5 have not been applied;

4.3.

carry out or have carried out the appropriate inspections and the tests necessary to verify whether, where the manufacturer has chosen to apply the relevant standards, these have actually been applied;

4.4.

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

5.

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

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

In the case of devices referred to in Annex 1, Section 10 **~~third~~ second** paragraph, the notified body shall, as regards the aspects referred to in that section, consult one of the competent **~~bodies~~ authorities** designated by the Member States in accordance with Directive 2001/83/EC or the EMEA before taking a decision. . **The opinion shall be drawn up within 210 days after receipt of a valid documentation The scientific opinion of the competent body must be included in the documentation concerning the device.** The notified body will give due consideration to the views expressed in this consultation when making its decision. It will convey its final decision to the competent body concerned.

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

~~**In the case of devices 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].**~~

6.

The applicant shall inform the notified body which issued the EC type-examination certificate of any modification made to the approved product.

Modifications to the approved product must receive further approval from the notified body which issued the EC type-examination certificate where such modifications may affect conformity with the essential requirements or with the conditions of use specified for the product. This new approval shall be issued, where appropriate, in the form of a supplement to the initial EC type-examination certificate.

7. Administrative provisions

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

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

7.3. The manufacturer or his authorized representative shall keep at the disposal of the national authorities, the technical documentation, a copy of the EC type-examination certificates and the supplements to them for a period **of** at least ~~**equivalent to the intended lifetime of the product as defined by the manufacturer but not less than**~~ ~~five~~ fifteen years from the manufacture **of the last appliance**.

~~**7.4. Where neither the manufacturer nor his authorized representative are established in the Community, the task of keeping the technical documentation available for the authorities shall fall to the person responsible for placing the appliance concerned on the Community market.**~~

1.2. EC VERIFICATION

1.

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

2.

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

3.

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

4.

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

(i) any change in the characteristics or performances, and any inaccuracies in the instruction leaflet for a device which might lead to or have led to the death of a patient or deterioration in his state of health;
(ii) any technical or medical reason resulting in withdrawal of a device from the market by a manufacturer.

5.
The notified body shall carry out the appropriate examinations and test in order to check the conformity of the product to the requirements of this Directive by examination and testing of products on a statistical basis, as specified in section 6. The manufacturer must authorize the notified body to evaluate the efficiency of the measures taken pursuant to section 3, by audit where appropriate.

6.
Statistical verification

6.1.
The manufacturer shall present the products manufactured in the form of uniform batches and shall take all necessary measures in order that the manufacturing process ensures the uniformity of each batch produced.

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

6.3.

Statistical control of products will be based on attributes **and/or variables**, entailing ~~**a**~~ sampling ~~**system with the following characteristics:**~~

~~**- a level of quality corresponding to a probability of acceptance of 95 %, with a non-conformity percentage of between 0,29 and 1 %,**~~

~~**- a limit quality corresponding to a probability of acceptance of 5 %, with a non-conformity percentage of between 3 and 7 %.**~~

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 harmonized standards referred to in Article 5, taking account of the specific nature of the product categories in question.

6.4.

Where batches are accepted, the notified body shall affix, or cause to be affixed, its identification number to each product and draw up a written certificate of conformity relating to the tests carried out. All products in the batch may be placed on the market except for those products from the sample, which were found not to be in conformity.

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

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

6.5

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

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.

EC DECLARATION OF CONFORMITY TO TYPE
(Assurance of production quality)

1.

The manufacturer shall apply the quality system approved for the manufacture and shall conduct the final inspection of the products concerned as specified in 3; he shall be subject to the surveillance referred to in section 4.

2.

This declaration of conformity is the procedural element whereby the manufacturer who satisfies the obligations of section 1 guarantees and declares that the products concerned conform to the type described in the EC type-examination certificate and meet the provisions of the Directive which apply to them.

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

3.

Quality system

3.1.

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

- all appropriate information concerning the products which it is intended to manufacture,
- the quality-system documentation,
- an undertaking to fulfil the obligations arising from the quality system as approved,
- an undertaking to maintain the approved quality system in such a way that it remains adequate and efficacious,
- where appropriate, the technical documentation relating to the approved type and a copy of the EC type-examination certificate,
- an undertaking by the manufacturer to institute and keep up-dated a post-marketing surveillance system **including the provisions referred to in Annex 7.** The undertaking shall include an obligation for the manufacturer to notify the competent authorities of the following incidents immediately on learning of them:

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

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

3.2.

Application of the quality system must ensure that the products conform to the type described in the EC type-examination certificate.

All the elements, requirements and provisions adopted by the manufacturer for his quality system shall be documented in a systematic and orderly manner in the form of written policies and procedures. This quality-system documentation must make possible a uniform interpretation of the quality policies and procedures such as quality programmes, quality plans, quality manuals and quality records.

It shall include in particular an adequate description of:

(a) the manufacturer's quality objectives;

(b) the organization of the business and in particular:

- the organizational structures, the responsibilities of the managerial staff and their organizational authority where manufacture of the products is concerned,

- the methods of monitoring the efficient operation of the quality system and in particular its ability to achieve the desired quality of the products, including control of products which do not conform;

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

(c) the techniques of control and of quality assurance at the manufacturing stage and in particular:

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

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

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

3.3.

Without prejudice to Article 13, the notified body shall effect an audit of the quality system to determine whether it meets the requirements referred to in 3.2. It shall presume conformity with these requirements for the quality systems which use the corresponding harmonized standards.

The team entrusted with the evaluation shall include at least one member who has already had experience of evaluations of the technology concerned. The evaluation procedure shall include an inspection on the manufacturer's premises.

The decision shall be notified to the manufacturer after the final inspection. It shall contain the conclusions of the control and a reasoned evaluation.

3.4.

The manufacturer shall inform the notified body which has approved the quality system of any plan to alter that system.

The notified body shall evaluate the proposed modifications and shall verify whether the quality system so modified would meet the requirements referred to in 3.2; it shall notify the manufacturer of its decision. This decision shall contain the conclusions of the control and a reasoned evaluation.

4.

Surveillance

4.1.

The aim of surveillance is to ensure that the manufacturer duly fulfils the obligations which arise from the approved quality system.

4.2.

The manufacturer shall authorize the notified body to carry out all necessary inspections and shall supply it with all appropriate information, in particular:

- the quality-system documentation,
- **the technical documentation,**
- the data stipulated in the part of the quality system relating to manufacture, such as reports concerning inspections, tests, standardizations/calibrations and the qualifications of the staff concerned, etc.

4.3.

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

4.4.

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

5.

The notified body shall communicate to the other notified bodies all relevant information concerning approvals of quality systems issued, refused or withdrawn.

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

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 6

STATEMENT CONCERNING DEVICES INTENDED FOR SPECIAL PURPOSES

1.

The manufacturer or his authorized representative established within the Community shall draw up for custom-made devices or for devices intended for clinical investigations the statement comprising the elements stipulated in section 2.

2.

The statement shall comprise the following information:

[29]2.1.

For custom-made devices:

- the name and address of the manufacturer[30],

- ~~**data allowing the device in question to be identified,**~~ **the information necessary for the identification of the product in question,**

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

- the name of the ~~**doctor**~~ **medical practitioner** ~~**or other authorized person**~~ who drew up the prescription and, if applicable, the name of the clinic concerned,

- ~~**the particular features of the device as described by the medical prescription concerned,**~~ **the specific characteristics of the product revealed by the prescription**

- a statement affirming that the device complies with the essential requirements given in Annex 1 and, where applicable, indicating which essential requirements have not been wholly met, together with the grounds.

---

[29] See Parliament amendments 55 and 56

[30] and if applicable of his authorised representative

2.2.

For devices intended for clinical investigations covered in Annex 7:

- data allowing the devices in question to be identified,
- ~~an~~ **the clinical** investigation plan ~~**giving in particular the purpose, scope and number of the devices concerned,**~~
- **the investigator's brochure,**
- **the confirmation of insurance of subjects**,
- **the documents used to obtain informed consent,**
- **a declaration stating whether or not the device incorporates, as an integral part a substance or human blood derivative referred to in section 10 of Annex 1,**
- **the opinion of the ethics committee concerned and details of the aspects covered by its opinion**,
- the name of the ~~doctor~~ **medical practitioner or other authorized person** and of the institution responsible for the investigations,
- the place, date of commencement and duration scheduled for the investigations,
- a statement affirming that the device in question complies with the essential requirements apart from the aspects constituting the object of the investigations and that, with regard to these aspects, every precaution has been taken to protect the health and safety of the patient.

3.

The manufacturer shall undertake to keep available for the competent national authorities:

3.1.

For custom-made devices, documentation, **indicating manufacturing site(s) and** enabling the design, manufacture and performances of the product, including the expected performances to be understood, so as to allow conformity with the requirement of this Directive to be assessed.

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

3.2.

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

- a general description of the product **and its intended use**,
- design drawings, manufacturing methods, in particular as regards sterilization, and diagrams of parts, sub-assemblies, circuits, etc.,
- the descriptions and explanations necessary for the understanding of the said drawings and diagrams and of the operation of the product,
- **the results of the risk analysis and** a list of the standards laid down in Article 5, applied in full or in part, and a description of the solutions adopted to satisfy the essential requirements of the Directive where the standards in Article 5 have not been applied,
- **if the device incorporates, as an integral part, a substance or human blood derivative, referred to in sections 10 of Annex 1, the data on the tests conducted in this connection which are required to assess the safety, quality and usefulness of that substance, or-human blood derivative, taking account of the intended purpose of the device**,
- the results of the design calculations, checks and technical tests carried out, etc.

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

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

[31]**4. The information included in the declarations covered by this Annex shall be kept for a period at least fifteen years from the date of manufacture of the last product.**

[31] See Parliament amendment 57, still under examination

5.

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

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

CLINICAL EVALUATION

1. General provisions

1.1. **As a general rule, confirmation of conformity with the requirements concerning the characteristics and performances referred to in Sections 1 and 2 of Annex 1 under the normal conditions of use of the device and the evaluation of the side-effects and of the acceptability of the benefit/risk ratio referred to in Section 5 of Annex 1, 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 the clinical investigations made,

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

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

1.1.b 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.

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

1.1.d 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.

~~**1.1.**~~

~~**Adequacy of the clinical data presented, as referred to in section 4.2 of Annex 2, and in section 3 of Annex 3, shall be based, account being taken as appropriate of the relevant harmonized standards, on either:**~~

~~**1.1.1.**~~

~~**a collation of currently available relevant scientific literature covering the intended use of the device and the techniques therefore, as well as, if appropriate, a written report making a critical assessment of this collation; or**~~

~~**1.1.2.**~~

~~**the results of all clinical investigations made, including those carried out in accordance with section 2.**~~

1.2.

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

2.

Clinical investigation

2.1.

Purpose

The purpose of clinical investigation is to:

- verify that, under normal conditions of use, the performances of the device comply with those indicated in section 2 of Annex 1,
- determine any undesirable side effects, under normal conditions of use, and assess whether they are acceptable risks having regard to the intended performance of the device.

2.2.

Ethical consideration

Clinical investigations shall be made in accordance with the Declaration of Helsinki approved by the 18th World Medical Assembly in Helsinki, Finland, in 1964, and amended by the 29th World Medical Assembly in Tokyo, Japan, in 1975 and the 35th World Medical Assembly in Venice, Italy, in 1983. It is mandatory that all measures relating to the protection of human subjects are carried out in the spirit of the Declaration of Helsinki. This includes every step in the clinical investigation from first consideration of need and justification of the study to publication of results.

2.3.

Methods

2.3.1.

Clinical investigations shall be performed according to an appropriate state of the art plan of investigation defined in such a way as to confirm or refute the manufacturer's claims for the device; the investigations shall include an adequate number of observations to guarantee the scientific validity of the conclusions.

2.3.2.

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

2.3.3.

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

2.3.4.

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

2.3.5.

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

2.3.6.

The investigations shall be performed under the responsibility of an appropriately qualified medical specialist, in an appropriate environment.

The medical specialist shall have access to the technical data regarding the device.

2.3.7.

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

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

1. The body, its director and the staff responsible for carrying out the evaluation and verification operations shall not be the designer, manufacturer, supplier or installer of devices which they control, nor the authorized representative of any of those parties. They may not become directly involved in the design, construction, marketing or maintenance of the devices, nor represent the parties engaged in these activities. This does not preclude the possibility of exchanges of technical information between the manufacturer and the body.

2. The body and its staff must carry out the evaluation and verification operations with the highest degree of professional integrity and technical competence and must be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of the inspection, especially from persons or groups of persons with an interest in the results of verifications.

3. The body must be able to carry out all the tasks in one of Annexes 2 to 5 assigned to such a body and for which it has been notified, whether those tasks are carried out by the body itself or under its responsibility. In particular, it must have at its disposal the necessary staff and possess the necessary facilities to enable it to perform properly the technical and administrative tasks connected with evaluation and verification; it must also have access to the equipment necessary for the verifications required.

4. The staff responsible for control operations must have:
- sound vocational training covering all the evaluation and verification operations for which the body has been designated,
- satisfactory knowledge of the requirements of the controls they carry out and adequate experience of such operations,
- the ability required to draw up the certificates, records and reports to demonstrate that the controls have been carried out.

5. The impartiality of inspection staff must be guaranteed. Their remuneration must not depend on the number of controls carried out, nor on the results of such controls.

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

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

1.3. CE CONFORMITY MARKING

_____