COMMISSION OF THE EUROPEAN COMMUNITIES

COM(92) 356 final - SYN 353

Brussels, 28 July 1992

Amended proposal for a

COUNCIL DIRECTIVE

relating to the medical devices

(presented by the Commission pursuant to Article 149(3)
of the EEC-Treaty)

EXPLANATORY MEMORANDUM

Following the opinion(1) from the European Parliament given at the first reading during the session held between 11 to 14 May 1992, the Commission has decided, in accordance with the terms of Article 149 paragraph 3 of the EEC Treaty , to amend the proposal for a Directive concerning medical devices COM (91) 287 final - SYN 353(2).

The Commission has accepted:

- a significant number of amendments improving the proposal for a Directive by the provision of more information, in particular in respect of the field of application, in the definitions and certain essential requirements,

- an addition in Article 15 on clinical investigations strengthening the importance of opinions expressed by the ethics committee concerned,

- a new article (17 (a)) providing for the adoption of a Community register on the implementation of the directive. This amendment aimed to improve transparency in the steps to be taken in the implementation of the directive,

- the extension of the transitional scheme for products in class I from one year to two years in order to allow the parties concerned to adapt more easily to the Community system.

The Commission did not wish to take:

- an amendment aiming to convert the regulatory Committee into a Consultative Committee. The tasks allocated to the regulatory Committee are in the field of public health protection being related to measures concerning certification and the control of clinical investigations on humans. Consequently, the regulatory Committee procedure was suitable,

- amendments proposing a formal consultation of manufacturers and of users in the context of the Committee. This consultation is not necessary and was not provided for in the decision 87/373/EEC on committee procedures. However, the Commission has always consulted the various parties concerned during preparatory work and had already established a practice of informal consultation in this sector,

- an amendment aiming to impose a system for all the Member States compelling the users to notify any incidents having taken place with devices. The Commission considered that by following the principles of subsidiarity, the decision to have such a system needs to be taken by each Member State individually,

(1) A3-0178 of 6.05.92
(2) OJ C237 OF 12.9.1991

- an amendment concerning the suppression of certification by product quality assurance for products of class IIa. The proposal ensures a high and suitable level of protection. The suppression of this certification option was not justified in particular in view of the difficulties which would result as a consequence for the medium-sized size undertaking which needs the flexibility of this alternative route,

- an amendment which aimed to suppress the obligation of the manufacturers to establish a post-marketing surveillance system. The incidents experienced in the past with certain implants (cardiac valves, breast implants) showed that the manufacturers of such sensitive products have to take post-marketing surveillance measures to be able to react quickly, when problems arise after marketing, and in order to limit the possibilities for repetition of similar problems,

- some amemdments covering changes of an editorial nature, dealing in particular with only one linguistic version and not providing any overall improvement.

In summary, the Commission accepted, entirely or partly, 36 of the 62 amendments approved by Parliament.

Amended proposal for a

COUNCIL DIRECTIVE

relating to the medical devices

On the left side you will find the initial text of the "Whereas", articles and annexes of the proposal for a Council Directive on medical devices COM(91) 287 final SYN 353.

On the right side you will find the modifications proposed by the Commission.

Initial text	Modified text
FOURTH RECITAL	**FOURTH RECITAL**
Whereas the harmonized provisions must be distinguish from the measures adopted by the Member States to manage the funding of public health and sickness insurance schemes relating directly or indirectly to such devices; whereas, therefore, these provisions do not affect the ability of the Member States to implement the abovementioned measures provided Community law is complied with;	Whereas the harmonized provisions must be distinguish from the measures adopted by the Member States to manage the funding of public health and sickness insurance schemes relating directly or indirectly to such devices; whereas, therefore, these provisions do not affect the ability of the Member States to implement the abovementioned measures provided Community law is complied with; whereas this means inter alia that Member States may determine which categories and types of device are eligible for reimbursement under such public health and sickness insurance schemes, but once those categories and types of device are determined, all devices within those categories or of those types which comply with the provisions of this present directive should in principle be reimbursable under such public health and insurance schemes;

Initial text	Modified text
SIXTH RECITAL	**SIXTH RECITAL**
Whereas certain medical devices are intended to administer medicinal products 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 89/381/EEC; whereas, in such cases, the placing of the medicinal product on the market is governed by Directive 65/65/EEC;	Whereas certain medical devices are intended to administer medicinal products 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 92/27/EEC (1); whereas, in such cases, the placing of the medicinal product on the market is governed by Directive 65/65/EEC and the placing of the device on the market by this present Directive;
whereas a distinction must be drawn between the above mentioned devices and medical devices incorporating, inter alia, substances which, if used separately, may be considered to be a medicinal substance within the meaning of Directive 65/65/EEC;	whereas a distinction must be drawn between the above mentioned devices and medical devices incorporating substances which, while not designed to be administered as a medicinal product, are bioavailable with the meaning of this Directive and if used separately, may be considered to be a medicinal substance within the meaning of Directive 65/65/EEC;
whereas, in such cases, if the substances are incorporated in the medical devices to help them operate, the placing of the devices on the market is governed by this Directive;	whereas, in such cases, if such substances are incorporated in a medical device to improve its safety, quality or performance, the placing of such devices on the market is governed by this present Directive;

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(1) OJ L 113 of 30 April 1992, page 8.

Initial text

6TH RECITAL (follow)

Whereas, in this context, in the event of the bioavailability of such substances, the safety, quality and usefulness of the substances must be verified by analogy with the appropriate methods specified in Council Directive 75/318/EEC of 20 May 1975 on the approximation of the laws of the Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of proprietary medicinal products, as last amended by Directive 89/341/EEC;

TWENTY-SECOND RECITAL

Whereas the application of some provisions of this Directive must be facilitated by means of guidelines published by the Commission;

Modified text

6TH RECITAL (follow)

Whereas, in this context, in the event of the bioavailability of such substances, the safety, quality and usefulness of the substances must be verified by means of control systems which may be analogous to the appropriate methods specified in Council Directive 75/318/EEC of 20 May 1975 on the approximation of the laws of the Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of proprietary medicinal products, as last amended by Directive 91/507/EEC;

RECITAL 7a (new)

Whereas the "essential requirements" and requirements set out in the Annexes to this Directive, including any reference to "minimising" or "reducing" risk must likewise be interpreted and applied in such a way as to take account of technology and practice existing at the time of design and of technical and economical considerations, bearing in mind the relationship between risk and cost and what may reasonably be expected in all circumstances by intended users of medical devices.

TWENTY-SECOND RECITAL

Whereas the application of some provisions of this Directive must be facilitated by means of guidelines published by the Commission; and by making available resources enabling the Commission successfully to carry out information programmes at national level;

Initial text	Modified text
ARTICLE 1	**ARTICLE 1**
1. This Directive shall apply to medical devices. It also covers the accessories to which the provisions for medical devices apply.	1. This Directive shall apply to medical devices. It also covers the accessories to which the provisions for medical devices apply, particularly the provisions governing the class to which these accessories belong.
2. For the purposes of this Directive, the following definitions shall apply :	2. unchanged
a) medical device (hereinafter referred to as "devices") means any instrument, apparatus, appliance, material or other article, including software, whether used alone or in combination, intended by the manufacturer to be used for human beings solely or principally for the purpose of :	a) unchanged
- diagnosis, prevention, monitoring, treatment or alleviation of disease, injury or handicap,	- diagnosis, prevention, monitoring, treatment or alleviation of disease, - diagnosis, monitoring, treatment or alleviation of injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,	- unchanged
- control of conception,	- unchanged
and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;	unchanged
b) "accessory" means an article which, while not a device, is required, according to the intended purpose attributed to it by the manufacturer, to enable the device to be used as specified;	b) "accessory" means an article which, while not being a device, is intended specifically by its manufacturer to be used together with a device to enable it to be used in accordance with the manufacturer's intentions;

Initial text

ARTICLE 1 (2)

(g) "manufacturer" means the natural or legal person with overall responsibility for the design, manufacturer, packaging and labelling of a device before it is placed on the market on his own behalf, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.

The natural or legal person who assembles, packages, processes and/or labels one or more ready-made products and/or assigns them to their intended purpose as a device with a view to their being placed on the market on his own behalf is also considered to be a manufacturer. This sub-paragraph does not apply to the person, who, while not a manufacturer within the meaning of the first sub-paragraph assembles or adapts devices already on the market to their intended purpose for an individual patient.

ARTICLE 1 (3)

3. Where a device is intended to administer a substance defined as a medicinal product within the meaning of Article 1 of Directive 65/65/EEC, that substance shall be subject to the marketing authorization system provided for in that Directive.

Modified text

ARTICLE 1 (2)

(g) "manufacturer" means the natural or legal person with responsibility for the design, manufacturer, packaging and labelling of a device before it is placed on the market on his own behalf, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.

The obligations imposed on manufacturers under the terms of this Directive shall also apply to the natural or legal person who assembles, packages, processes and/or labels one or more ready-made products and/or assigns them to their intended purpose as a device with a view to their being placed on the market on his own behalf. This sub-paragraph does not apply to the person, who, while not a manufacturer within the meaning of the first sub-paragraph assembles or adapts devices already on the market to their intended purpose for an individual patient.

ARTICLE 1 (3)

3. Where a device is intended to administer a substance defined as a medicinal product within the meaning of Article 1 of Directive 65/65/EEC, that substance shall be subject to the marketing authorization system provided for in that Directive.

If such a device is placed on the market or put into service by the manufacturer separately from the medicinal product, it shall be governed by this present Directive.

If, on the other hand, such a device is placed on the market by the manufacturer in such a way that the device and the medicinal product form a single unit, the combined product shall be governed by Directive 65/65/EEC and this present Directive respectively.

Initial text	Modified text
	ARTICLE 1
	5a (new)
	This Directive does not apply to personal protective equipment covered by Directive 89/686/EEC. The assessment of whether a product falls under the aforesaid Directive or under this Directive shall in particular take account of the principal intended purpose of the product and where and how it is to be used.
ARTICLE 10	**ARTICLE 10**
1. Member States shall take the necessary steps to ensure that any information brought to their knowledge, in accordance with the provisions of this Directive, regarding the incidents mentioned below involving a class IIa, IIb or III device is recorded and evaluated in a centralized manner :	1. unchanged
a) any deterioration in the characteristics and/or performance of a device, as well as any inaccuracies in the labelling or the instruction leaflet 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;	a) any malfunction of or deterioration in the characteristics and/or performance of a device as specified by the manufacturer, as well as any inaccuracies in the labelling or the instruction leaflet 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;
b) any technical or medical reason connected with the device leading to systematic recall of devices of the same type by the manufacturer.	b) any technical or medical reason to do with the characteristics or performance of a device leading, for the reasons referred to in subparagraph (a) above, to systematic recall of devices of the same type by the manufacturer.

Initial text

ARTICLE 11

9. Decisions taken by the notified bodies in accordance with Annexes II and III shall be valid for a maximum of five years and may be extended on application for further periods of five years.

ARTICLE 12

1. Any natural or legal person who assembles devices bearing the EC mark for their intended purpose and within the limits of use specified by the manufacturers with regard to their compatibility with other devices in order to put them on the market in the form of a system, kit or operation pack shall draw up a declaration in which he states that :

a) he has verified the mutual compatibility of the devices which make up the system, kit or operation pack in accordance with the manufacturers' instructions and that assembly has been carried out in accordance with these instructions;

b) the system, kit or operation pack has, where applicable, been packaged in accordance with the manufacturers' instructions or the limits applicable to the various devices;

Modified text

ARTICLE 11

9. Decisions taken by the notified bodies in accordance with Annexes II and III shall be valid for a maximum of five years and may be extended on application for further periods of five years. These decisions must be conveyed in good time.

ARTICLE 12

1. Any natural or legal person who assembles devices bearing the EC mark for their intended purpose and within the limits of use specified by the manufacturers with regard to their compatibility with other devices in order to put them on the market in the form of or as part of a system, kit or procedure pack with, when appropriate, any other compatible product shall inform the competent authority in accordance with the provisions of Article 14 that he is engaged in such an activity in general and shall draw up a declaration in which he states that :

a) he has verified the mutual compatibility of the devices and any other products which make up the system, kit or procedure pack in accordance with any instructions from the manufacturers and that assembly has been carried out in accordance with these instructions;

b) the system, kit or procedure pack has, where applicable, been packaged in accordance with any relevant instructions from the manufacturers or the limits applicable to the various devices or other products as the case may be;

Initial text	Modified text
ARTICLE 14	ARTICLE 14
1. Any manufacturer who, on his own behalf, places devices on the market in accordance with the procedures referred to in Article 11(4) and (5) shall inform the competent authorities of the Member State in which he has his registered place of business of the address of the registered place of business and the category of devices concerned.	1. Any manufacturer who, on his own behalf, places devices on the market in accordance with the procedures referred to in Article 11(4) and (5) 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 designation of the devices concerned.
ARTICLE 15	ARTICLE 15
1. In the case of devices falling within classes I, IIa and IIb which are intended for clinical investigations, the manufacturer, or his authorized representative established in the Community, shall follow the procedure referred to in Annex VIII and keep the statement concerned at the disposal of the competent authorities.	1. In the case of devices falling within classes I, IIa and IIb which are intended for clinical investigations duly justified in accordance with the provisions of Annex VIII, point 2.2, the manufacturer, or his authorized representative established in the Community, shall follow the procedure referred to in Annex VIII and keep the statement concerned at the disposal of the competent authorities.
2. In the case of devices falling within class III and implantable devices falling within class IIa or IIb intended for clinical investigations, the manufacturer, or his authorized representative established in the Community, shall follow the procedure referred to in Annex VIII and, at least 45 days before the commencement of the investigations, submit the statement referred to in the abovementioned Annex to the competent authorities of the Member State in which the investigations are to be conducted.	2. In the case of devices falling within class III and implantable devices falling within class IIa or IIb which are intended for clinical investigations duly justified in accordance with the provisions of Annex VIII, point 2.2, the manufacturer, or his authorized representative established in the Community, shall follow the procedure referred to in Annex VIII and, at least 45 days before the commencement of the investigations, submit the statement referred to in the abovementioned Annex to the competent authorities of the Member State in which the investigations are to be conducted.
The manufacturer may commence the relevant clinical investigations at the end of a period of 45 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.	unchanged

Initial text	Modified text
ARTICLE 15 (following)	**ARTICLE 15 (following)**
	Without prejudice to the power of the competent authorities to take the final decision, there is generally no reason for them to intervene on the basis of the previous subparagraph in sofar as the ethics committee concerned has issued a favourable opinion of the programme of investigations in question, referred to in Annex X.
ARTICLE 17	**ARTICLE 17**
2. The EC mark of conformity, as shown in Annex XII, must appear in a visible, legible and indelible form on the device, where practicable and appropriate, and/or on the sales packaging and the instruction leaflet.	2. unchanged
It shall be accompanied by the identification number of the notified body responsible for implementation of the procedures set out in Annexes II, IV, V and VI and the last two digits of the year in which the mark was affixed.	It shall be accompanied by the identification number of the notified body responsible for implementation of the procedures set out in Annexes II, IV, V and VI.
	ARTICLE 17a (new)
	The Commission shall take the necessary steps to create and ensure the operation of a Community register containing the necessary information for consistent implementation of this Directive.

Initial text	Modified text
ARTICLE 19	**ARTICLE 19**
2. In the event of a decision to withdraw devices from the market, 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 measure to be taken.	2. In the event of a decision referred to in paragraph 1, 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 measure to be taken.
ARTICLE 22	**ARTICLE 22**
3. The following paragraph 6 is added to Article 1 of Directive 90/385/EEC :	3. The definition in Article 1(2)(a) of Council Directive 90/385/EEC shall be replaced by the definition in Article 1(2)(a) of this present Directive; Following paragraph 6 is added to Article 1 of Directive 90/385/EEC :
"6. The following provisions of Council Directive .../.../EEC [on medical devices] also apply to active implantable medical devices : Article 1(2) g) and i); Article 11(6), (8) and (9); Article 13(1)(c) coupled with Article 7; Article 17(3); Article 19(2); Article 21 points (a) and (c) of the first paragraph".	"6. The following provisions of Council Directive .../.../EEC [on medical devices] also apply to active implantable medical devices : Article 1(2) b), g) and i); Article 11(6), (8) and (9); Article 13(1)(c) coupled with Article 7; Article 17(3); Article 19(2); Article 21 points (a) and (c) of the first paragraph"

Initial text

ARTICLE 23

4. In the case of devices which, for the purposes of this Directive, must be the subject of one of the procedures referred to in Annexes II to VI, Member States shall accept the placing on the market and putting into service of devices which conform to the rules in force in their territory on 30 June 1994 during the period up to 30 June 1997. In the case of other devices lawfully placed on the market before 30 June 1994, Member States shall accept their being put into service during the period up to 30 June 1995.

ANNEX I PARAGRAPH 1

1. The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of the patients, users and, where applicable, other persons. The risks associated with the devices must be reduced to an acceptable level compatible with a high level of protection of health and safety.

ANNEX I PARAGRAPH 1

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

Modified text

ARTICLE 23

4. In the case of devices which, for the purposes of this Directive, must be the subject of one of the procedures referred to in Annexes II to VI, Member States shall accept the placing on the market and putting into service of devices which conform to the rules in force in their territory on 30 June 1994 during the period up to 30 June 1997. In the case of other devices lawfully placed on the market before 30 June 1994, Member States shall accept their being put into service during the period up to 30 June 1996.

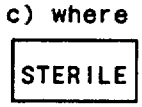
ANNEX I PARAGRAPH 1

1. The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of the patients, users and, where applicable, other persons, when used under the conditions and for the purposes intended provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.

ANNEX I PARAGRAPH 1

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

Initial text	Modified text
ANNEX I PARAGRAPH 11	**ANNEX I PARAGRAPH 11**
7.5 The devices must be designed and manufactured in such a way as to minimize the health risks posed by substances leaking from the device during use.	7.5 The devices must be designed and manufactured in such a way as to minimize risks posed by substances leaking from the device during use.
ANNEX I PARAGRAPH 11	**ANNEX I PARAGRAPH 11**
8.3 Sterile devices must be designed, manufactured and packed in a non-reusable pack and/or according to appropriate procedures to ensure that they are sterile when placed on the market and remain sterile, under the storage and transport conditions laid down, until the protective packaging is damaged or opened.	8.3 Sterile devices must be designed, manufactured and packed in a non-reusable pack and/or according to appropriate procedures to ensure that they are sterile when placed on the market and remain sterile, under normal storage and transport conditions as described in the instructions and information supplied by the manufactured, until the protective packaging is damaged or opened.
ANNEX I PARAGRAPH 11	**ANNEX I PARAGRAPH 11**
11.5 Instruments, apparatus or appliances emitting radiation must be fitted with visual displays and/or audible warnings of radiation emissions.	11.5 Devices intended to emit invisible, potentially hazardous radiation must be fitted with visual displays and/or audible warnings of radiation emissions.
ANNEX I PARAGRAPH 11	**ANNEX I PARAGRAPH 11**
12.1 Devices depending on software must be designed in such a way as to minimize the risks arising from errors in the programms.	12.1 Devices incorporating programmable electronic systems must be designed in such a way as to avoid so far as reasonably practicable risks arising from random and/or systematic failures.

Initial text	Modified text
ANNEX I PARAGRAPH II	**ANNEX I PARAGRAPH II**
12.7.5. Accessible parts of the devices and their surroundings must not attain potentially dangerous temperatures under normal use.	12.7.5. Accessible parts of the devices (excluding any parts or areas intended to supply heat or attain a high temperature) and their surroundings must not attain potentially dangerous temperatures under normal use.
ANNEX I PARAGRAPH II	**ANNEX I PARAGRAPH II**
12.8.2 Devices must be fitted with an interlock and/or alarm system to prevent and/or indicate any inadequacies in the flow rate which could pose a danger.	12.8.2 Devices must be fitted with means to prevent and/or indicate any inadequacies in the commanded output which could pose a danger.
ANNEX I PARAGRAPH II	**ANNEX I PARAGRAPH II**
12.9 The function of the controls and visual displays must be clearly specified on the devices.	12.9 The function of the controls and indicators must be clearly specified on the devices.
ANNEX I PARAGRAPH II	**ANNEX I PARAGRAPH II**
13.3 The label must bear the following particulars :	13.3 unchanged
a) the name or trade name and address of the manufacturer;	a) unchanged
b) the details strictly necessary for the user to identify the device and the contents of the packaging;	b) unchanged
c) where appropriate, the word "STERILE";	c) where appropriate, the symbol  ;
d) where appropriate, the batch code, preceded by the word "LOT", or the serial number;	d) where appropriate, the batch code, preceded by the symbol  , or the serial number;

Initial text	Modified text
ANNEX I PARAGRAPH 11	**ANNEX I PARAGRAPH 11**
	13.6a (new) The instructions for use shall contain an explicit request to the user or patient to inform his/her doctor or medical institution of any side-effect not referred to in the instructions for use.
ANNEX 11	**ANNEX 11**
2. The declaration of conformity is the procedure whereby the manufacturer who fulfils the obligations imposed by Section 1 ensures and declares that the products concerned meet the provisions of this Directive which apply to them.	2. unchanged
The manufacturer shall affix the EC mark in accordance with Article 17 and shall draw up a written declaration of conformity. This declaration of conformity shall cover a given number of identified specimens of the products manufactured and shall be kept by the manufacturer. The EC mark shall be accompanied by the identification number of the notified body which performs the tasks referred to in this Annex.	The manufacturer shall affix the EC mark in accordance with Article 17 and shall draw up a written declaration of conformity. This declaration of conformity shall cover a given number of products manufactured on the basis of the approval of the quality system and shall be kept by the manufacturer.
3. <u>Quality system</u>	3. <u>Quality system</u>
3.1 The manufacturer shall lodge an application for assessment of his quality system with a notify body.	3.1 unchanged
The application shall include :	
- the name and address of the manufacturer,	- unchanged
- all the relevant information on the product or product category covered by the procedure,	- unchanged
- a written declaration that no application has been lodged with any other notified body for the same products;	- a written declaration that no such application has been lodged with any other notified body for the same products;

Initial text	Modified text
ANNEX V	ANNEX V
2. The declaration of conformity is the part of the procedure whereby the manufacturer who fulfils the obligations imposed by Section 1 ensures and declares that the products concerned conform to the type described in the EC type-examination certificate and meet the provisions of this Directive which apply to them.	2. unchanged
The manufacturer shall affix the EC mark in accordance with Article 17 and shall draw up a written declaration of conformity. This declaration of conformity shall cover a given number of identified specimens of the products manufactured and shall be kept by the manufacturer. The EC mark shall be accompanied by the identification number of the notified body which performs the tasks referred to in this Annex.	The manufacturer shall affix the EC mark in accordance with Article 17 and shall draw up a written declaration of conformity. This declaration of conformity shall cover a given number of products manufactured on the basis of the approval of the quality system and shall be kept by the manufacturer.
3. Quality system	3. Quality system
3.1 The manufacturer shall lodge an application for assessment of his quality system with a notify body.	3.1 unchanged
The application shall include :	
- the name and address of the manufacturer,	- unchanged
- all the relevant information on the product or product category covered by the procedure,	- unchanged
- a written declaration that no application has been lodged with any other notified body for the same products;	- a written declaration that no such application has been lodged with any other notified body for the same products;

Initial text	Modified text
ANNEX VI	**ANNEX VI**
2. The declaration of conformity is the part of the procedure whereby the manufacturer who fulfils the obligations imposed by Section 1 ensures and declares that the products concerned conform to the type described in the EC type-examination certificate and meet the provisions of this Directive which apply to them.	2. unchanged
The manufacturer shall affix the EC mark in accordance with Article 17 and shall draw up a written declaration of conformity. This declaration of conformity shall cover a given number of identified specimens of the products manufactured and shall be kept by the manufacturer. The EC mark shall be accompanied by the identification number of the notified body which performs the tasks referred to in this Annex.	The manufacturer shall affix the EC mark in accordance with Article 17 and shall draw up a written declaration of conformity. This declaration of conformity shall cover a given number of products manufactured on the basis of the approval of the quality system and shall be kept by the manufacturer.
3. Quality system	3. Quality system
3.1 The manufacturer shall lodge an application for assessment of his quality system with a notify body.	3.1 unchanged
The application shall include :	
- the name and address of the manufacturer,	- unchanged
- all the relevant information on the product or product category covered by the procedure,	- unchanged
- a written declaration that no application has been lodged with any other notified body for the same products;	- a written declaration that no such application has been lodged with any other notified body for the same products;
ANNEX VIII	**ANNEX VIII**
2.2 For devices intended for the clinical investigations covered by Annex X :	2.2 unchanged

Initial text	Modified text
- data allowing identification of the device in question,	- unchanged
- an investigation plan stating in particular the purpose, scope and number of devices concerned,	- an investigation plan stating in particular the purpose, scientific, technical or medical justification, scope and number of devices concerned,
- the opinion of the ethics committee concerned and details of the aspects covered by its opinion,	- unchanged
- the name of the medical specialist or other authorized person and of the institution responsible for the investigations,	- unchanged
- the place, starting date and scheduled duration for the investigations,	- unchanged
- a statement that the device in question conforms to the essential requirements apart from the aspects covered by the investigations and that, with regard to those aspects, every precaution has been taken to protect the health and safety of the patient.	- unchanged
ANNEX IX PARAGRAPH 1	**ANNEX IX PARAGRAPH 1**
2.4 Rule 8	2.4 unchanged
All implantable device and long-term surgically invasive devices are in class IIb unless they are intended :	
- to be placed in the teeth, in which case they are in class IIa,	- to be placed in or on the teeth or dental protheses, in which case they are in class IIa;

Initial text	Modified text
ANNEX IX PARAGRAPH 1 (following)	ANNEX IX PARAGRAPH 1 (following)
- to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in class III,	- unchanged
- to undergo chemical change in the body, to be biologically active, to be wholly or mainly absorbed, to supply energy in the form of ionizing radiation or to administer medicines, in which case they are in class III, except if the devices are placed in the teeth.	- unchanged

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