EUROPEAN PARLIAMENT

2004 *2009*

Session document

FINAL
A6-0332/2006

10.10.2006

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REPORT

on the 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 of the Council as regards the review of the medical device directives
(COM(2005)0681 – C6-0006/2006 – 2005/0263(COD))

Committee on the Environment, Public Health and Food Safety

Rapporteur: Thomas Ulmer

Draftswoman (*):
Anneli Jäätteenmäki , Committee on the Internal Market and Consumer Protection

(*) Enhanced cooperation between committees - Rule 47 of the Rules of Procedure

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Symbols for procedures

*	Consultation procedure *majority of the votes cast*
**I	Cooperation procedure (first reading) *majority of the votes cast*
**II	Cooperation procedure (second reading) *majority of the votes cast, to approve the common position* *majority of Parliament's component Members, to reject or amend the common position*
***	Assent procedure *majority of Parliament's component Members except in cases covered by Articles 105, 107, 161 and 300 of the EC Treaty and Article 7 of the EU Treaty*
***I	Codecision procedure (first reading) *majority of the votes cast*
***II	Codecision procedure (second reading) *majority of the votes cast, to approve the common position* *majority of Parliament's component Members, to reject or amend the common position*
***III	Codecision procedure (third reading) *majority of the votes cast, to approve the joint text*

(The type of procedure depends on the legal basis proposed by the Commission.)

Amendments to a legislative text

In amendments by Parliament, amended text is highlighted in ***bold italics***. Highlighting in *normal italics* is an indication for the relevant departments showing parts of the legislative text for which a correction is proposed, to assist preparation of the final text (for instance, obvious errors or omissions in a given language version). These suggested corrections are subject to the agreement of the departments concerned.

CONTENTS

Page

DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

on the 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 of the Council as regards the review of the medical device directives (COM(2005)0681 – C6-0006/2006 – 2005/0263(COD))

(Codecision procedure: first reading)

The European Parliament,

– having regard to the Commission proposal to the European Parliament and the Council (COM(2005)0681)[1],

– having regard to Article 251(2) and Article 95 of the EC Treaty, pursuant to which the Commission submitted the proposal to Parliament (C6-0006/2006),

– having regard to Rule 51 of its Rules of Procedure,

– having regard to the report of the Committee on the Environment, Public Health and Food Safety and the opinions of the Committee on the Internal Market and Consumer Protection and the Committee on Industry, Research and Energy (A6-0332/2006),

1. Approves the Commission proposal as amended;

2. Calls on the Commission to refer the matter to Parliament again if it intends to amend the proposal substantially or replace it with another text;

3. Instructs its President to forward its position to the Council and Commission.

Text proposed by the Commission	Amendments by Parliament
	Amendment 1 RECITAL 2 A (new)
	(2a) As regards reprocessing, the Commission should engage in further reflection and wider consultation in order to explore the possible development of appropriate legislation ensuring a high level of patient safety.

[1] OJ C ..., 00.00.2006, p. ....

Justification

In recent years the reprocessing industry has developed validated and controlled procedures, which considerably reduce both costs in the health sector and the volume of hazardous hospital waste. However, the current lack of EU-wide regulation fails to mitigate the risks of the unregulated reprocessing of medical devices. It also prevents the establishment of level playing field for reprocessing services. The Commission should therefore produce a proposal, based on careful assessment of the current practices and their real costs as well as existing national regulations and market studies. This should ensure patient safety and provide homogeneous market standards in the healthcare sector.

Amendment 2
RECITAL 2 B (new)

(2b) Non-corrective contact lenses which are used to change the appearance of the eye are not regarded as medical devices for the purposes of this Directive. However, the non-prescribed sale and distribution of those lenses may in the absence of consultation or supervision from professional eye care practitioners lead to an increase in their incorrect use and therefore pose a potential health risk.

Amendment 3
RECITAL 2 C (new)

(2c) The Commission should investigate the current sale and distribution system of contact lenses in Member States, evaluate the potential risks to the health and safety of consumers and take the appropriate measures, legislative or non-legislative, in order to ensure a high level of health protection in the Community. A report on such findings and any eventual proceedings should be presented to the relevant committees of the European Parliament within six months of the adoption of this Directive.

Amendment 4
RECITAL 6

(6) It is necessary to clarify that ***consideration of a product having a medical purpose is intrinsic to the definition of a medical device and that***	(6) It is necessary to clarify that ***software in its own right, when specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the***

software in its own right can be defined as a medical device.	***definition of a medical device, is a medical device. Software for general purposes when used in a healthcare setting is not a medical device.***

Amendment 5
RECITAL 6 A (new)

	(6a) The current legal uncertainty makes it necessary to make clear the distinction between Directive 93/42/EEC and Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products[1]. In so doing, particular account should be taken of the basic intended purpose of the product.
	[1]OJ L 262, 27.9.1976, p. 169. Directive as last amended by Commission Directive 2006/78/EC (OJ L 271, 30.9.2006, p. 56.)

Justification

There are different interpretations of Article 1(5)(d) of Directive 93/42/EEC in the United Kingdom and Germany as regards the distinction between this Directive and Directive 76/768/EEC on cosmetic products. A clarification is needed to ensure the uniform application of European law. Particular account should be taken of the product's purpose as intended by the manufacturer, in line with the case law of the European Court of Justice on borderline products.

Amendment 6
RECITAL 6 B (new)

	(6b) The distinction between Directive 93/42/EEC and other directives, such as Directive 2001/83/EC, is not always clear. It would be useful, therefore, to publish a list with information that makes it easier for all parties to determine which directives apply to which products.

Justification

Several products fall into the grey area between Directive 93/42/EEC and other directives. To

make it easier for the authorities and manufacturers to decide whether or not a product is a medical device, the directive should contain examples, from which it should be clear whether or not a product is predestined to fall within the scope of Directive 93/42/EEC. These examples should not, however, take the place of decisions on individual cases.

Amendment 7
RECITAL 13

(13) For the appropriate and efficient functioning of Directive 93/42/EEC as regards regulatory advice on classification issues arising at national level, in particular on whether or not a product falls under the definition of a medical device, it is in the interest of national market surveillance and the health and safety of humans to establish a procedure for decisions on whether or not a *products* falls under the medical device definition.	(13) For the appropriate and efficient functioning of Directive 93/42/EEC as regards regulatory advice on classification issues arising at national level, in particular on whether or not a product falls under the definition of a medical device, it is in the interest of national market surveillance and the health and safety of humans to establish a procedure for decisions on whether or not a *product* falls under the medical device definition. ***To ensure greater legal certainty, such decisions should exclusively concern individual products, which may form part of a generic line of products, and should be geared towards the Member States and manufacturers. One of the key elements in defining a medical device is the manufacturer's intended purpose. The manufacturer should therefore be fully associated in the context of his right to be heard before any decision is taken on the product definition.***

Justification

Many product categories cover a wide range of products that do not always have the same characteristics and purpose. Decisions should therefore always be taken on the basis of individual products. Furthermore, the manufacturer's intended purpose is of integral importance in defining a medical device, which is why manufacturers should play an important role in the decision-making process.

Amendment 8
RECITAL 14

14) To ensure that, where a manufacturer does not have a registered place of business in the Community, authorities have a single individual person authorized by the	(14) To ensure that, where a manufacturer does not have a registered place of business in the Community, authorities have a single individual person authorized by the

manufacturer whom they can address in matters relating to the compliance of the devices with the Directives it is necessary to introduce an obligation for such manufacturers to designate an authorized representative for all classes of devices.	manufacturer whom they can address in matters relating to the compliance of the devices with the Directives it is necessary to introduce an obligation for such manufacturers to designate an authorized representative for all classes of devices. ***In this connection, it should be noted that any device imported into the European Union must comply with the rules laid down in this Directive.***

Justification

For safety reasons, any product imported into the Community should comply with the rules adopted within the European Union.

Amendment 9
RECITAL 15

(15) To further ensure public health and safety it is necessary to provide for a more consistent application of the provisions on health protection measures.	(15) To further ensure public health and safety it is necessary to provide for a more consistent application of the provisions on health protection measures. ***Particular care should be taken to ensure that, when in use, the products do not endanger patients' safety or health. As regards frequency of use, a uniform Europe-wide declaration of products should apply. Reprocessing measures should in principle continue to be governed by national legislation.***

Justification

It should be ensured that no medical device is simultaneously described as single-use in one Member State and multiple-use in another. Furthermore, in the event of reprocessing, there must be uniform hygiene standards.

Amendment 10
RECITAL 17

(17) To better coordinate the application and efficiency of national resources when applied to issues related to Directive 93/42/EEC the Member States should cooperate with each other and at	(17) To better coordinate the application and efficiency of national resources when applied to issues related to Directive 93/42/EEC the Member States should cooperate with each other and at

international level.	international level. ***In order to enable industry to compete globally on equal terms, there should be international standardisation and cooperation***.

Justification

The European medical devices industry sells its products world wide. European standards, based on an international standardisation process, are therefore preferable. More effort should be made to promote international cooperation, both in the form of bilateral agreements, as via more informal cooperation (e.g. the Global Harmonization Task Force).

Amendment 11
RECITAL 18

(18) As design for patient safety initiatives *play* an increasing role in public health policy it is necessary to *expressively* set out the need to consider ergonomic design in the essential requirements. In addition the level of training and knowledge of the user, such as in the case of a lay user, is further emphasised within the essential requirements.	(18) As design for patient safety initiatives *plays* an increasing role in public health policy it is necessary to *expressly* set out the need to consider ergonomic design in the essential requirements. In addition the level of training and knowledge of the user, such as in the case of a lay user, is further emphasised within the essential requirements. ***The product manufacturer should place particular emphasis on the consequences of misuse of the product and its adverse effects on the human body.***

Justification

The amendment places the emphasis on user health and safety.

Amendment 12
RECITAL 21

(21) In the light of the increased use of third parties to carry out the design and manufacture of devices on behalf of the manufacturer, it is important that the manufacturer demonstrates that he applies adequate controls to the third party to continue to ensure the efficient operating of the quality system.	(21) In the light of the increased use of third parties to carry out the design and manufacture of devices on behalf of the manufacturer, it is important that the manufacturer demonstrates that he applies adequate controls to the third party to continue to ensure the efficient operating of the quality system. ***The competent authorities may also decide to apply controls directly.***

Justification

In order to guarantee maximum safety, the authorities should be given the possibility of carrying out inspections.

Amendment 13
RECITAL 21 A (new)

(21a) The rules on the reprocessing of medical devices differ widely from one Member State to another. The Commission should study the impact which the different rules have on the protection of patients and cost-effectiveness.

Justification

A careful analysis should be made before any legislation on reprocessing is introduced.

Amendment 14
RECITAL 23 A (new)

(23a) In the light of the introduction, by Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission[1], of a regulatory procedure with scrutiny for measures of general scope designed to amend non-essential elements of a basic instrument adopted in co-decision, it is necessary to amend Directives 90/385/EEC and 93/43/EEC accordingly. Regulatory procedure with scrutiny should apply to the adoption of amendments to the Annexes to Directive 93/43/EEC, decisions with regard to classification of medical devices and decisions to withdraw from the market or prohibit or restrict the placing on the market of implantable medical devices.

[1] OJ L 184, 17.7.1999, p. 23. Decision as amended by Decision 2006/512/EC (OJ L 200, 22.7.2006, p. 11).

Justification

The amendment is needed to align the text to the provisions of the new commitology Decision, and in particular to replace the ordinary "regulatory committee" procedure with the "regulatory committee with scrutiny", since the measures concerned are measures of general scope designed to amend non-essential elements of the draft legislation. It lists the measures that should be covered by the new procedure.

Amendment 15
ARTICLE 1, POINT 1 (A) (I)
Article 1, paragraph 2, point (a), introductory part (Directive 90/385/EEC)

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

Justification

Only diagnostic and therapeutic software should be included in this Article and not all software as such. The addition of the sentence "for medical purpose" might allow certain products to be excluded from the Directive. This would create uncertainty among the users and has a potential for uncontrolled products to be used on patients.

Amendment 16
ARTICLE 1, POINT 1(D)
Article 1, paragraph 4b (Directive 90/385/EEC)

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***	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 Regulation (EC) No […] of the European Parliament and of the Council (**) [on advanced Therapies and amending Regulation (EC) No 726/2004]], that device must be assessed and authorized

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***.	in accordance with ***that Regulation***.

Justification

Products which are considered as Tissue Engineered Products contain parts of tissues or cell which shall replace, repair or regenerate human tissue. Thus, those products are very sensitive and interacting with living cells and should fall under the pharmaceutical legislation.

Amendment 17
ARTICLE 1, POINT 1 A (new)
Article 2 (Directive 90/385/EEC)

	(1a) Article 2 is replaced by the following:
	"Article 2
	1. Member States shall take all necessary steps to ensure that devices may be placed on the market and/or put into service only if they comply with the requirements laid down in this Directive when duly supplied and properly installed, maintained and used in accordance with their intended purpose.
	2. Member States shall also take all necessary steps to ensure that sales of medical devices via the Internet, by mail order and other alternative distribution channels do not put the health and safety of consumers at risk and that such sales comply with all the provisions of this Directive."

Justification

Sales of contact lenses over the internet, by mail order and other alternative distribution channels are becoming more and more common in many European countries and have potential health risks for European citizen since they are not subject to any consultation or counsel by eye care practitioners. In line with Treaty Article 152(1), it is important that a high level of human health protection shall be ensured in the definition and implementation of all Community policies and activities.

Amendment 18
ARTICLE 1, POINT 2 (A A) (new)
Article 6, paragraph 2 a (new) (Directive 90/385/EEC)

(aa) The following paragraph 2a is inserted:

"2a. Where reference is made to this paragraph, Articles 5a and 7 of Decision 1999/468/EC shall apply."

Justification

The amendment is needed to align the text to the provisions of the new "commitology" Decision, and in particular to include the "regulatory committee with scrutiny", since some the measures concerned are measures of general scope designed to amend non-essential elements of the draft legislation.

Amendment 19
ARTICLE 1, POINT 3
Article 10a, paragraph 2, subparagraph 2 (Directive 90/385/EEC)

For devices referred to in paragraph 1 the authorized representative shall inform the competent authorities of the Member State in which he has his registered place of business of the address of the registered place of business and the category of devices concerned.	For devices referred to in paragraph 1 the authorized representative shall inform the competent authorities of the Member State in which he has his registered place of business of the address of the registered place of business and the category of devices concerned. ***This may be done electronically. The authorized representative should also be available to answer any queries. Any medical device imported into the European Union shall comply with the rules laid down in this Directive.***

Justification

The role of the authorized representative should be defined as clearly as possible. For safety reasons, any product imported into the Community should comply with the rules adopted within the European Union.

Amendment 20
ARTICLE 1, POINT 3
Article 10c, paragraph 4 (Directive 90/385/EEC)

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

Justification

The amendment is needed to align the text to the provisions of the new commitology Decision, and in particular to include the "regulatory committee with scrutiny", since some the measures concerned are measures of general scope designed to amend non-essential elements of the draft legislation.

Amendment 21
ARTICLE 2, POINT -1 (new)
Recital 7 (Directive 93/42/EEC)

(-1) Recital 7 is replaced by the following:

"Whereas the essential requirements and other requirements set out in the Annexes to this Directive, including any reference to 'minimizing' or 'reducing' risk, must be interpreted and applied in such a way as to take account of best available products, technology and practice in design and of technical and economic considerations compatible with a high level of protection of health and safety."

Justification

The recital needs to be updated. Essential requirements must create an incentive to improve design and should therefore be based on best available design, rather than "grandfather in" old design.

Amendment 22
ARTICLE 2, POINT 1 (A) (I)
Article 1, paragraph 2, point (a), introductory phrase (Directive 93/42/EEC)

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

Justification

Only diagnostic and therapeutic software should be included in this article and not all software as such. The addition of the phrase 'for medical purposes' might allow certain products to be excluded from the Directive. This would create uncertainty among users and has a potential for uncontrolled products to be used on patients.

Amendment 23
ARTICLE 2, POINT 1 (A) (I A) (new)
Article 1, paragraph 2, point (a), subparagraph 2 (Directive 93/42/EEC)

	(ia) in point (a), the second subparagraph is replaced by the following:
	"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;
	- by its form or the manner in which the manufacturer presents it or places it on the market, encourage in persons generally the impression that the product has medicinal properties for the treatment or prevention of disease in humans;"

(First part of the text has been taken from the original Directive)

Justification

Patient safety has to be ensured. The distinction between medical device and medicinal products must be made clearer. The copy products must fall under the same category as the original one.

Amendment 24
ARTICLE 2, POINT 1 (A) (I A) (new)
Article 1, paragraph 2, point (h a) (new) (Directive 93/42/EEC)

(ia) the following point (ha) is inserted:

"(ha)'reprocessing' means the cleaning, disinfection and sterilization of a used single-use medical device, including the associated work as well as the testing and restoration of the functional and hygienic safety for a safe re-use. The legal or natural person and/or its authorised representative shall be deemed the manufacturer in accordance with this Article when reprocessing a medical device and placing it on the market."

Justification

See justification on amendment on article 21 (a) new. This amendment is also linked with the new recital 2a on reprocessing.

Amendment 25
ARTICLE 2, POINT 1 (A) (II A) (new)
Article 1, paragraph 2, point (l) (new) (Directive 93/42/EEC)

(ii a) The following point (l) is added:

"(l) 'biophysical and biomechanical data' means data deriving from biophysical, biomechanical, simulation or clinical test modelling studies or any scientific studies based on confirmed knowledge or technologies whose validity has been demonstrated. These data may be included,

	in particular to back up the clinical data mentioned in point (k)."

Justification

Establishing protocols and conducting clinical studies is difficult and sometimes impossible in the case of certain categories of medical device. Research now makes it possible to overcome these difficulties by establishing biophysical, simulation and modelling tools. This means that the preclinical stages can be made more reliable and clinical studies can be better targeted.

Amendment 26
ARTICLE 2, POINT 1 (E)
Article 1, paragraph 4b (Directive 93/42/EEC)

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

Justification

Products which are considered as Tissue Engineered Products contain parts of tissues or cell which shall replace, repair or regenerate human tissue. Thus, those products are very sensitive and interacting with living cells and should fall under the pharmaceutical legislation.

Amendment 27
ARTICLE 2, POINT 1 (F) (I)
Article 1, paragraph 5, point (c) (Directive 93/42/EEC)

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

Justification

Making the definition in the 'devices' directive stricter will ensure that medicinal products are not described and certified as medical devices, with the aim of evading the strict approval procedures and safety precautions relating to medicinal products. The medical devices directive does not apply if the product complies with the definition of 'medicinal product' in the medicinal products directive. For the purpose of determining whether a product is a medicinal product or a medical device, therefore, it is therefore important to consider, in accordance with Directive 2001/83, all the separate criteria stated for a medicinal product, as alternatives rather than cumulatively.

Amendment 28
ARTICLE 2, POINT 1 (F) (I A) (new)
Article 1, paragraph 5, point (d) (Directive 93/42/EEC)

	(ia) point (d) is replaced by the following:
	"(d) cosmetic products covered by Directive 76/768/EEC. In deciding whether a product falls under Directive 76/768/EEC or this Directive, particular account shall be taken of the principal intended purpose of the product and the relevant mechanism of action;"

Justification

In some cases cosmetic products have a medical intention (i.e. treatment of a disease) and should therefore be classified as medical devices. The decision which directive applies should thus be taken case by case on the basis of the intended purpose.

Amendment 29
ARTICLE 2, POINT 1 (G)
Article 1, paragraph 6 (Directive 93/42/EEC)

(g) Paragraph 6 is ***deleted.***	(g) Paragraph 6 is ***replaced by the following:***
	"6. Where a product is intended to be used in accordance with Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment[1] and this Directive, the relevant basic health and safety requirements of Directive 89/686/EEC

shall also be fulfilled.

[1] OJ L 399, 30.12.1989, p. 18. Directive as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1)."

Justification

There are some personal protection items which fall within the scope of Directive 93/42/EEC. This applies in particular to items which come into direct contact with internal parts of the body, such as gloves.

Amendment 30
ARTICLE 2, POINT 1 A (new)
Article 2, paragraph 1 a (new) (Directive 93/42/EEC)

(1a) In Article 2, the following paragraph is added:
"Member States shall also take all necessary steps to ensure that sales of medical devices via the Internet, by mail order and other alternative distribution channels do not put the health and safety of consumers at risk, and that such sales comply with all the provisions of this Directive."

Justification

The sale of medical devices on the internet in particular should be subject to monitoring. Care must be taken to ensure that this and other sales channels do not endanger consumers' health.

Amendment 31
ARTICLE 2, POINT 2
Article 4, paragraph 2, indent 2 (Directive 93/42/EEC)

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

shall be provided to the named patient.	***patient identified by an acronym or a numerical code***.

Justification

The term 'named patient' is already contained in the current Directive. It might also be possible, for the purposes of data protection and medical confidentiality, to provide for identification of the patient through an acronym or numerical code. With a view to the best possible provision of information to the patient, the original statement should continue to be kept in the patient's records held by the dentist and a copy supplied to the patient. Given that there is no obligation on the patient to keep the statement, this is a practical and appropriate arrangement which does not undermine the patient's rights.

Amendment 32
ARTICLE 2, POINT 2 A (new)
Article 7 (Directive 93/42/EEC)

(2a) Article 7 is amended as follows:
(a) The first subparagraph of paragraph 2 is replaced by the following:
"Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof."
(b) The following paragraph 2a is inserted:
"Where reference is made to this paragraph, Articles 5a and 7 of Decision 1999/468/EC shall apply."

Justification

The amendment is needed to align the text to the provisions of the new "commitology" Decision, and in particular to include the "regulatory committee with scrutiny", since some the measures concerned are measures of general scope designed to amend non-essential elements of the draft legislation.

Amendment 33
ARTICLE 2, POINT 2 B (new)
Article 8, paragraph 2, indent 2a (new) (Directive 93/42/EEC)

(2b) In Article 8(2), the following indent is added:

"- the measures are justified, it shall adopt, when necessary in the interests of public

	health, the appropriate Community measures in accordance with the procedure laid down in Article 7(2a)."

Justification

Invoking the safeguard clause should allow to have the justified national interim measures (taken in this context) mandatory applicable throughout the EU market. In addition it is useful to align the safeguard clause procedure in Article 8 MDD with the particular health monitoring measures procedure in Article 14b MDD.

Amendment 34
ARTICLE 2, POINT 3
Article 9, paragraph 3 (Directive 93/42/EEC)

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

Justification

The amendment is needed to align the text to the provisions of the new "commitology" Decision, and in particular to include the "regulatory committee with scrutiny", since some the measures concerned are measures of general scope designed to amend non-essential elements of the draft legislation.

Amendment 35
ARTICLE 2, POINT 3 A (new)
Article 10, paragraph 3 (Directive 93/42/EEC)

	(3a) In Article 10(3) is replaced by the following: ***"3. After carrying out an assessment, if possible together with the manufacturer, Member States shall, without prejudice to Article 8, immediately inform the***

Commission and the other Member States of the incidents referred to in paragraph 1 for which relevant measures are contemplated or have been taken. The Member States shall state the exact grounds underlying the measures that are contemplated or that have been taken. In particular, the Member States shall give the exact grounds, when appropriate, for deviating from the contemplated measure in the measure taken."

Justification

As the vigilance procedure relates to the notification of incidents it is of utmost importance that this is coordinated through the Commission and that the Commission and the Member States to have a complete overview of the EU market.

Amendment 36
ARTICLE 2, POINT 3 B (new)
Article 10, paragraph 4 (new) (Directive 93/42/EEC)

(3b) In Article 10, the following paragraph is added:

"4. The Commission, acting in accordance with the procedure referred to in Article 7(2), shall take any appropriate measures to adopt procedures to implement this Article."

Justification

Amendment ensuring that the vigilance system functions in more binding detail.

Amendment 37
ARTICLE 2, POINT 4 (B)
Article 11, paragraph 14 (Directive 93/42/EEC)

(b) The following paragraph is added:	***deleted***
"14. The Commission may, in accordance with the procedure referred to in Article 7 (2), adopt measures allowing instructions	

for use to be provided by other means."

Justification

This amendment was incorporated in the report without vote on the basis of Rule 47 of Rules of Procedure. There should be the possibility of providing information for the safe and correct use of medical devices by professionals through modern means of communication (e.g. e-labelling). New article 11 (14) should be deleted and section 13.1. of Annex I should therefore be amended.

Amendment 38
ARTICLE 2, POINT 5 (-A) (new)
Article 12, paragraph 2, subparagraph 2 a (new) (Directive 93/42/EEC)

	(-a) In paragraph 2, the following subparagraph is added:
	"In the case of networked medical information technology systems, this Article shall not apply for the overall network system. The conformity assessment must be performed separately for each medical device in the network, and not for the overall network system."

Justification

It must be possible to exchange individual parts of a large IT network, for example, without having to recertify the entire network. The individual components of such systems must therefore be certified separately.

Amendment 39
ARTICLE 2, POINT 5 (A)
Article 12, paragraph 3 (Directive 93/42/EEC)

(a) In paragraph 3, the words “Annex IV, V or VI” are replaced by “Annex II, IV, V or VI”.	(a) In paragraph 3, the words “Annex IV, V or VI” are replaced by “Annex II, IV, V or VI” ***and the words "the obtaining of sterility" are replaced by "the obtaining and maintaining of sterility for the shelf life of the device or until the sterile package is opened or damaged"***.

Amendment 40
ARTICLE 2, POINT 6
Article 13, paragraph 1 (Directive 93/42/EEC)

(6) ***In*** Article 13(1) ***the following point (d) is inserted:***	(6) Article 13(1) ***is replaced by the following:***
"or	***"1. Where a Member State considers that:***
(d) ***application of the classification rules set out in Annex IX requires a decision*** as to whether a product falls within one of the definitions in Article 1 paragraph 2, points (a) to (e)***";***	***(a) application of the classification rules set out in Annex IX requires a decision with regard to the classification of a given device or category of devices;***
	or
	(b) a given device or family of devices should be classified, by way of derogation from the provisions of Annex IX, in another class;
	or
	(c) the conformity of a device or family of devices should be established, by way of derogation from the provisions of Article 11, by applying solely one of the given procedures chosen from among those referred to in Article 11;
	or
	(d) ***a decision is required*** as to whether a particular product falls within one of the definitions in Article 1 paragraph 2, points (a) to (e)***,***
	it shall submit a duly substantiated request to the Commission and ask it to take the necessary measures. These measures shall be adopted in accordance with the procedure referred to in Article 7(2a)."

Justification

Decisions must be taken on the basis of specific individual products, as product categories are often wide-ranging and products within the same category do not always have the same characteristics or purpose. The amendment is needed to align the text to the provisions of the new "commitology" Decision, and in particular to include the "regulatory committee with scrutiny", since some the decisions with regard to classification are measures of general scope designed to amend non-essential elements of the draft legislation.

Amendment 41
ARTICLE 2, POINT 6 A (new)
Article 13, paragraph 1 a (new) (Directive 93/42/EEC)

	(6a) In Article 13, the following paragraph 1a is inserted:
	1a. Should the Commission receive a substantiated request from a Member State pursuant to paragraph 1(d) regarding a particular device or device category, it shall carry out a market survey to ascertain whether similar devices exist within the internal market. Decisions on the classification of these devices should be taken on this basis, in line with the procedure referred to in paragraph 1.

Justification

According to Article 1(2)(a) of Directive 93/42/EEC, the purpose intended by the manufacturer is an integral factor in the definition of a product as a medical device. It is important, therefore, for the manufacturer to be involved in all decisions in the run-up to the final decision. The European Court of Justice will ultimately decide whether or not a product falls within the scope of Directive 93/42/EEC. For this reason, manufacturers should have the opportunity to ensure that they are able to bring a case of this kind before the Court of Justice. Otherwise they would have to refer the matter to the Court in a procedure under Article 234 of the EU Treaty lasting many years.

Amendment 42
ARTICLE 2, POINT 7
Article 14, paragraph 2, subparagraph 1 (Directive 93/42/EEC)

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

Justification

It must be made clear that a manufacturer must designate a single authorized representative for a device but need not necessarily designate the same authorized representative for his entire range of devices.

Amendment 43
ARTICLE 2, POINT 8 (A A) (new)
Article 14a, paragraph 1a (new) (Directive 93/42/EEC)

(aa) The following paragraph 1a is inserted:
"***1a. For custom-made devices the databank shall contain only the data specified in paragraph 1(a).***"

Amendment 44
ARTICLE 2, POINT 8 (B A) (new)
Article 14a, paragraph 4 (new) (Directive 93/42/EEC)

(ba) The following paragraph is added:

"4. The provisions of this Article shall expire on ...*. No later than 12 months before the expiry of these provisions, the Commission shall evaluate their application and the added value provided by the databank. On the basis of this evaluation the Commission shall, if necessary, present a legislative proposal in accordance with Article 251 of the Treaty on the renewed establishment of the databank."

**** Five years after the entry into force of this Directive.***

Justification

Thirteen years after it was thought up, the database is not yet up and running. Consequently, several Member States have since set up their own database systems. The European vigilance system works outstandingly well.

Amendment 45
ARTICLE 2, POINT 9
Article 14b, paragraph 4 (Directive 93/42/EEC)

Where the national measures are justified, the Commission shall adopt the necessary	Where the national measures are justified, the Commission shall adopt the necessary

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

Justification

The amendment is needed to align the text to the provisions of the new "commitology" Decision, and in particular to include the "regulatory committee with scrutiny", since the measures concerned are measures of general scope designed to amend non-essential elements of the draft legislation.

Amendment 46
ARTICLE 2, POINT 10
Article 15, paragraph 2, subparagraph 1 (Directive 93/42/EEC)

2. In the case of devices falling within Class III and implantable and long-term invasive devices falling within Class IIa or IIb, the manufacturer may commence the relevant clinical investigation at the end of a period of 60 days after notification, unless the competent authorities have notified him within that period of a decision to the contrary based on considerations of public health or public policy. Such decisions shall be communicated by the competent authority to the other Member States.	2. In the case of devices falling within Class III and implantable and long-term invasive devices falling within Class IIa or IIb, the manufacturer may commence the relevant clinical investigation at the end of a period of 60 days after notification, unless the competent authorities have notified him within that period of a decision to the contrary based on considerations of public health or public policy. Such decisions***, and the justifications therefor,*** shall be communicated by the competent authority to the other Member States ***and to the interested parties***.

Amendment 47
ARTICLE 2, POINT 10 A (new)
Article 15, paragraph 5 (Directive 93/42/EEC)

	(10a) Article 15(5) is replaced by the following: ***"5. The clinical investigations must be conducted in accordance with the provisions of Annex X. The provisions of Annex X may be adjusted in accordance with the procedure referred to in Article***

7(2a)."

Justification

The amendment is needed to align the text to the provisions of the new "commitology" Decision, and in particular to include the "regulatory committee with scrutiny", since the measures concerned are measures of general scope designed to amend non-essential elements of the draft legislation.

Amendment 48
ARTICLE 2, POINT 13
Article 20, paragraph 1, subparagraph 2 (Directive 93/42/EEC)

This does not affect the obligation of Member States and notified bodies with regard to mutual information and the dissemination of warnings, nor the obligations of the persons concerned to provide information under criminal law.	This does not affect the obligation of Member States and notified bodies with regard to mutual information and the dissemination of warnings ***under the provisions of Article 10(1),*** nor the obligations of the persons concerned to provide information under criminal law.

Justification

IMCO amendment, which was incorporated in the report without vote on the basis of Rule 47. For the sake and clarity it is advisable to refer to Article 10, paragraph 1 which mentions the incidents occurring following placing of devices on the market.

Amendment 49
ARTICLE 2, POINT 14 A(new)
Article 21a (new) (Directive 93/42/EEC)

	(14a) The following Article 21a is inserted:
	"Article 21a
	European reprocessing standard
	Not later than ...*, the Commission shall, in accordance with the procedure laid down in Article 7 and after consulting the European Medicines Agency (EMEA), establish detailed rules for a European reprocessing standard.
	These rules shall provide scientifically based technical guidance for reprocessing of used (single or multiple use) medical devices and shall be updated regularly in

order to ensure a high degree of patient safety based on the precautionary principle.
For Member States whose national legislation does not authorise reprocessing or the use of re-processed medical devices, detailed rules for compulsory on-the-spot checks to be conducted by the competent national authorities shall be established. The national authorities shall monitor also the use of medical devices in those Member States, e.g. by analysing the ratio between treatments or surgeries performed and devices sold/recycled/disposed of in order to obtain reliable data on the amount of unauthorised reprocessing."
**** Two years after the entry into force of this Directive.***

Justification

Even when not legalised in a country, reprocessing of used medical devices for single or multiple-use is widespread practice in all EU-Member States. As unprofessional reprocessing can cause serious risks for patients' health (hospital infections etc.), the legislator is asked to provide guidance for the reprocessing of medical devices. The general question, whether to allow reprocessing or not may remain on national level. But the safety of the patients requires strict controls and surveillance if reprocessing is illegal in a Member State.

Amendment 50
ANNEX I, POINT 1 (-A) (new)
Annex I, section 1 (Directive 90/385/EEC)

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

"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 and the environment. They must not present any risk to the persons implanting them or, where applicable, to other persons."

Justification

In the light of the EU initiative around Better Regulation, the objective to integrate

environmental legislation in all community legislation, and in order to align these Directives with the EU Directive concerning medicines used in human beings to make more explicit the reference to the overall objectives being pursued by REACH already being integrated in these Directives. Unless the devices and REACH legislations are integrated, the health and safety as well as the environmental aspects can not be weighed jointly against the patient benefit, which would impact medical practice and access to healthcare in an irrational way.

Amendment 51
ANNEX I, POINT 1 (-A A) (new)
Annex I, section 3 (Directive 90/385/EEC)

(-aa) Section 3 is replaced by the following:

"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 or the environment 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."

Justification

In the light of the EU initiative around Better Regulation, the objective to integrate environmental legislation in all community legislation, and in order to align these Directives with the EU Directive concerning medicines used in human beings to make more explicit the reference to the overall objectives being pursued by REACH already being integrated in these Directives. Unless the devices and REACH legislations are integrated, the health and safety as well as the environmental aspects can not be weighed jointly against the patient benefit, which would impact medical practice and access to healthcare in an irrational way.

Amendment 52
ANNEX I, POINT 1 (A)
Annex I, section 9, indent 7 (Directive 90/385/EEC)

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.	For devices which incorporate software***, in terms of the software*** the principles of development lifecycle, risk management, validation and verification ***should be taken into account***. ***The concept of validation should always be based on the relevant risk classification of the medical device concerned.***

Justification

The term 'validation' should be replaced in order to prevent the collection of unnecessary data. With regard to the principles of validation the existing real risk should be taken into account. The demands made regarding software for a robotic device in neurosurgery would undoubtedly be rather different from those made of software for a UV lamp for hardening resin in dental fillings.

Amendment 53
ANNEX I, POINT 1 (A A) (new)
Annex I, section 9a (new) (Directive 90/385/EEC)

(aa) The following Section 9a is inserted:

"9a. Errors likely to be made when fitting or refitting certain parts which could be a source of risk must be made impossible by the design and construction of such parts. The same information must be given on moving parts and/or their housings where the direction of movement needs to be known in order to avoid a risk.

Where necessary, the instructions must give further information on these risks. Where a faulty connection can be the source of risk, incorrect connections must be made impossible by design or, failing this, by information given on the elements to be connected and, where appropriate, on the means of connection."

Justification

Life-preserving medical devices must also meet elementary construction principles as explicitly required in the Machinery Directive. Given the negative experiences on the ground, these principles should be included in the present directive.

Amendment 54
ANNEX I, POINT 1 (B)
Annex I, Section 10 (Directive 90/385/EEC)

10. Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a	10. Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a

medicinal product as defined in Article 1 of Directive 2001/83/EC and which is liable to act upon the body with action ancillary to that of the device, the quality, safety and usefulness of the substance must be verified by analogy with the methods specified in Directive 2001/83/EC.	medicinal product as defined in Article 1 of Directive 2001/83/EC and which is liable to act upon the body with action ancillary to that of the device, the quality, safety and usefulness of the substance must be verified by analogy with the ***relevant*** methods specified in ***Annex I to*** Directive 2001/83/EC.
For a substance which: ***— has already been granted, as a medicinal product, a Community marketing authorisation in accordance with Council Regulation (EEC) No 2309/93 (*) or Regulation (EC) No 726/2004; or*** ***— falls within the scope of the Annex to Regulation (EC) No 726/2004;*** ***or*** ***— is a human blood derivative;***	
the notified body shall, having verified the usefulness of the substance as part of the medical device and taking account of the intended purpose of the device, seek a scientific opinion from the European Medicines Agency (EMEA) on the quality and safety of the substance. When issuing its opinion, the EMEA shall take into account the manufacturing process and the data related to the incorporation of the substance into the device.	***The*** notified body shall, having verified the usefulness of the substance as part of the medical device and taking account of the ***safety, quality and*** 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 or from*** the European Medicines Agency (EMEA) on the quality and safety of the substance. 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***.
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***	For ***a substance which is a human blood derivative***, the notified body shall, having verified the usefulness of the substance as part of the medical device and taking account of the intended purpose of the device, seek a scientific opinion from ***the EMEA*** on the quality and safety of the substance. ***The opinion shall be drawn up within 210 processing days.*** When issuing its opinion, the ***EMEA*** shall take into

shall take into account the manufacturing process and the data related to the incorporation of the substance into the device.	account the manufacturing process and the data related to the ***usefulness of*** incorporation of the substance into the device ***as determined by the notified body***.
Where changes are made to an ancillary substance incorporated in a medical device, ***in particular related to its manufacturing process, they shall be assessed by analogy with the procedures for the evaluation of variations to medicinal products laid down in Commission Regulations (EC) No. 1084/2003 (**)and EC No. 1085/2003 (***).*** The notified body shall be informed of the changes and shall consult the relevant medicines competent authority (i.e. the one involved in the initial consultation), in order to confirm that the quality and safety of the ancillary substance are maintained, and to ensure that the changes have no negative impact on the established benefit/risk profile of the addition of the substance in the medical device.	Where changes are made to an ancillary substance incorporated in a medical device, the notified body shall be informed of the changes and shall consult the relevant medicines competent authority (i.e. the one involved in the initial consultation), in order to confirm that the quality and safety of the ancillary substance are maintained, and to ensure that the changes have no negative impact on the established benefit/risk profile of the addition of the substance in the medical device.

Justification

The current system, which allows notified bodies to consult any of the relevant national authorities, should be maintained in order to ensure timely and cost-effective consideration of the safety and quality of the substance in question. The usefulness of a substance cannot be evaluated without first taking into account the quality and safety of that substance. The notified body must take account of the authority's opinion when making its final assessment of the medical device.

Amendment 55
ANNEX I, POINT 5 A (new)
Annex 6, section 2.1, indent 1 (Directive 90/385/EEC)

(5a) In Annex 6 the first indent of section 2.1 is replaced by the following:

"– the information necessary for the identification of the product in question."

Amendment 56
ANNEX I, POINT 5 B (new)
Annex 6, section 2.1, indent 4 (Directive 90/385/EEC)

(5b) In Annex 6 the fourth indent of section 2.1 is replaced by the following:

"– the specific characteristics of the product as indicated by the written prescription concerned."

Justification

Article 1(d) states that the prescription mentioned above (for custom-made devices) may be issued by anyone with the requisite professional qualifications. However, the fourth indent of section 2.1 of Annex 6 refers only to a doctor's prescription. This contradiction should be removed.

Amendment 57
ANNEX I, POINT 5 C (new)
Annex 6, section 3a (new) (Directive 90/385/EEC)

(5c) In Annex 6, the following section is added:

"3a. The information included in the declarations covered by this Annex shall be kept for a minimum of five years from the date of manufacture."

Justification

There is no known case in which information has needed to be kept for longer than five years. The present wording seems to place an excessive burden on manufacturers of custom-made devices.

Amendment 58
ANNEX II, POINT 1 (A)
Annex I, Section 1 (Directive 93/42/EEC)

1. The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended ***and, where applicable, by virtue of***	1. The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, ***taking into consideration, in***

the technical knowledge, experience, education or training of intended users, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their intended use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health ***and*** safety. ***This shall include reducing, as far as possible,*** risks posed by user error ***due to the*** ergonomic features of the device and its intended user environment.	***particular, whether the device is intended for professional use or not,*** they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons ***or the environment***, provided that any risks which may be associated with their intended use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health***,*** safety ***and the environment***. ***The manufacturer shall evaluate and reduce potential*** risks posed by user error ***which may be associated with*** ergonomic features of the device and its intended user environment.

Justification

In order to align these Directives with the EU Directive concerning medicines used in human beings to making a more explicit reference to the overall objectives being pursued by REACH already being integrated in these Directives. Unless the devices and REACH legislations are integrated, the health and safety as well as the environmental aspects can not be weighed jointly against the patient benefit, which would impact medical practice and access to healthcare in an irrational way.

Reference to 'education and training' as well as' use errors' might trigger confusion and different interpretations. What is essential is to know whether it is intended for professional use or not and whether an internal risk analysis on the product design is conducted.

Amendment 59
ANNEX II, POINT 1 (A A) (new)
Annex I, Section 6 a (new) (Directive 93/42/EEC)

	(aa) The following Section 6a is inserted: ***"6a. As regards re-processing, manufacturers and/or authorized representatives must declare their products uniformly within the European Union. When declaring a product as a single-use device, the manufacturer and/or his representative shall be required to prove why the respective product can only be used once and he shall set out the characteristics and technical factors that***

would pose a risk were the product to be declared as a multiple-use device. The manufacturer and/or his representative shall also declare under which technical conditions the device could be designed and produced as a multiple-use product.

When declaring a product as a multiple-use device the manufacturer or his representative shall provide a detailed documentation on how the device can be safely reprocessed."

Justification

The classification of the usage of medical devices is at the moment under the responsibility of the manufacturers and not always comprehensible. Sometimes, products are designed and put on the market as single-use-products in order to enhance selling and boost profits whilst the construction as multiple-use device or the technical development in this direction would be easily possible. Economic pressure can force hospitals or physicians nevertheless to re-use single-use products without having the means and the knowledge to clean and treat them properly. This causes serious risks for patients through hospital infections etc. Therefore, it is proposed to require a justification from the manufacturer when declaring a product as single-use-device.

Amendment 60
ANNEX II, POINT 1 (B)
Annex I, Section 7.4 (Directive 93/42/EEC)

7.4. Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product as defined in Article 1 of Directive 2001/83/EC and which is liable to act upon the body with action ancillary to that of the device, the quality, safety and usefulness of the device, the quality, safety and usefulness of the substance must be verified by analogy with the methods specified in Directive 2001/83/EC.	***7.4.1*** Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product as defined in Article 1 of Directive 2001/83/EC and which is liable to act upon the body with action ancillary to that of the device, the quality, safety, and usefulness of the substance must be verified, ***taking account of the intended purpose of the device,*** by analogy with the appropriate methods specified in Directive 2001/83/EC. ***Authority to verify the usefulness of the substance remains with the notified body, whereas the role of the EMEA or the competent authorities designated by the Member States is to provide a scientific opinion on the quality and safety of the***

substance.

For a substance which:
- has already been granted, as a medicinal product, a Community marketing authorisation in accordance with Council Regulation (EEC) No 2309/93 (*) or Regulation(EC) No 726/2004;
or
- falls within the scope of the Annex to Regulation (EC) No 726/2004;
or
- is a human blood derivative;

the notified body shall, having verified the usefulness of the substance as part of the medical device and taking account of the intended purpose of the device, seek a scientific opinion ***from the European Medicines Agency (EMEA)*** on the quality and safety of the substance. ***When issuing its opinion, the EMEA shall take*** into account the manufacturing process and the data related to the incorporation of the substance into the device.

7.4.2 For the substances referred to in section 7.4.1, 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 on the quality and safety of the substance ***and on the clinical benefit/risk profile of the incorporation of the substance into the device. This scientific opinion shall be issued, taking*** into account the manufacturing process and the data related to the incorporation of the substance into the device.

For other substances, the notified body shall, ***having verified the usefulness of the substance as part of the medical device and taking account of the intended purpose of the device, seek a scientific opinion from*** one of the competent authorities designated by the Member States in accordance with Directive 2001/83/EC, ***on the quality and safety of the substance. When issuing its opinion, the concerned*** competent authority shall ***take into account the manufacturing process and the data related to the incorporation of the substance into the device.***

7.4.3 In order to obtain the scientific opinion referred to in section 7.4.2, the notified body shall ***turn to*** one of the competent authorities designated by the Member States in accordance with Directive 2001/83/EC.

This competent authority shall***, in accordance with the provisions of Regulation (EC) No 726/2004, either provide the scientific opinion to the notified body or refer the notified body to the European Medicines Agency (EMEA), through its committees, for the scientific opinion.***

7.4.4 Where a device incorporates, as an integral part, a human blood derivative, the notified body shall, having verified the usefulness of the substance as part of the

	medical device and taking account of the intended purpose of the device, seek a scientific opinion from the EMEA on the quality and safety of the substance and on the clinical benefit/risk profile of the incorporation of the substance into the device. When issuing its opinion, the EMEA shall take into account the manufacturing process and the data related to the incorporation of the substance into the device.
Where changes are made to an ancillary substance incorporated in a medical device, in particular related to its manufacturing process, ***they shall be assessed by analogy with the procedures for the evaluation of variations to medicinal products laid down in Commission Regulations (EC) No. 1084/2003 (**) and EC No.1085/2003 (***).*** The notified body shall be informed of the changes and shall consult the relevant medicines competent authority (i.e. the one involved in the initial consultation), in order to confirm that the quality and safety of the ancillary substance are maintained, and to ensure that the changes have no negative impact on the established benefit/risk profile of the addition of the substance in the medical device.	***7.4.5*** Where changes are made to an ancillary substance incorporated in a medical device, in particular related to its manufacturing process, the notified body shall be informed of the changes and shall consult the relevant medicines competent authority (i.e. the one involved in the initial consultation), in order to confirm that the quality and safety of the ancillary substance are maintained, 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.
	When the relevant medicines competent authority (i.e. the one involved in the initial consultation) has information on the ancillary substance which could have an impact on the established benefit/risk profile of the incorporation of the substance into the medical device, it shall provide the notified body with an updated scientific opinion. The notified body shall take the updated scientific opinion into account in reconsidering its assessment of the conformity assessment procedure.
(*) OJ L 214, 24.8.1993, p. 1. ***(**) OJ L 159, 27.6.2003, p. 1*** ***(***) OJ L 159, 27.6.2003, p. 24***	

Amendment 61
ANNEX II, POINT 1 (C)
Annex I, section 7.4a (Directive 93/42/EEC)

7.4a. Where a device incorporates, as an integral part, a product which, if used separately, may be considered to be a human tissue engineered product within the meaning of [Article 2 (2) of the Regulation on Advanced Therapies and amending Regulation (EC) No 726/2004] and which is liable to act upon the body with action that is ancillary to that of the device, the quality, safety and usefulness of the product must be verified by analogy with the methods specified in ***Regulation EC No. [...] [on Advanced Therapies and amending Regulation (EC) No 726/2004].***	7.4a. Where a device incorporates, as an integral part, a product which, if used separately, may be considered to be a human tissue engineered product within the meaning of [Article 2 (2) of the Regulation on Advanced Therapies and amending Regulation (EC) No 726/2004], ***and whose cellular or tissue part contains solely non-viable tissues or cells*** 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 ***Annex I, part IV, point 5 of Directive 2001/83/EC as last amended.***
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.***	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 ***EMEA*** on the quality and safety of the product.

Justification

The current system, which allows Notified Bodies to seek the opinion from any of the relevant national authorities, should be maintained in order to ensure timely and cost effective consideration of the safety and quality of the substance in question. The duty to evaluate the usefulness of including the medicinal substance in the medical device should remain in the hands of the evaluation body responsible for the overall assessment of the device.

Amendment 62
ANNEX II, POINT 1 (C A) (new)
Annex I, Section 7.5 (Directive 93/42/EEC)

(ca) Section 7.5 is replaced by the following:

"7.5. The devices must be designed and manufactured in such a way as to reduce to a minimum the risks posed by substances leaking from the device. Devices shall not contain substances classified as carcinogenic, mutagenic or toxic for reproduction, category 1 or 2, under Annex I to Directive 67/548/EEC, unless no alternative devices not containing such substances are available."

Justification

The use of CMR substances is already prohibited in EU law in substances and preparations for use of the general public and in cosmetics. Furthermore, certain phthalates that are toxic to reproduction have been banned from the use in all toys. However, the exposure to such phthalates from medical devices can be far higher. Patients are by definition vulnerable and should not be unnecessarily exposed to CMR substances. It needs to be clarified that medical devices containing CMR substances do not fulfil the essential requirements, when safer devices without CMR substances are available.

Amendment 63
ANNEX II, POINT 1 (D A) (new)
Annex I, Section 9.4. (new) (Directive 93/42/EEC)

(da) The following Section 9.4. is inserted:

"9.4. Errors likely to be made when fitting or refitting certain parts which could be a source of risk must be made impossible by the design and construction of such parts. The same information must be given on moving parts and/or their housings where the direction of movement needs to be known in order to avoid a risk.

Where necessary, the instructions must give further information on these risks. Where a faulty connection can be the source of risk,

	incorrect connections must be made impossible by design or, failing this, by information given on the elements to be connected and, where appropriate, on the means of connection."

Justification

Life-preserving medical devices must also meet elementary construction principles as explicitly required in the Machinery Directive. Given the negative experiences on the ground, these principles should be included in the present directive.

Amendment 64
ANNEX II, POINT 1 (E)
Annex I, section 12.1a (Directive 93/42/EEC)

12.1a For devices which incorporate software ***or which are medical software in themselves, the software must be validated according to the state of the art taking into account*** the principles of development lifecycle, risk management, validation and verification.	12.1a For devices which incorporate software, ***in terms of the software*** the principles of development lifecycle, risk management, validation and verification ***should be taken into account. The concept of validation should always be based on the relevant risk classification of the medical device concerned.***

Justification

The term 'validation' should be replaced in order to prevent the collection of unnecessary data. With regard to the principles of validation the existing real risk should be taken into account. The demands made regarding software for a robotic device in neurosurgery would undoubtedly be rather different from those made of software for a UV lamp for hardening resin in dental fillings.

Amendment 65
ANNEX II, POINT 1 (F)
Annex I, Section 13.1., paragraph 1 (Directive 93/42/EEC)

(f) ***In*** Section 13.1. ***the first paragraph*** is replaced by the following:	(f) Section 13.1. is replaced by the following:
"13.1. Each device must be ***accompanied by*** the information needed to use it safely and ***properly***, taking account of the training and knowledge of the potential users, and to identify the manufacturer."	"13.1. Each device must be ***provided with*** the information needed to use it safely and ***as intended***, taking account of the training and knowledge of the potential users, and to identify the manufacturer. ***This information comprises the details on***

	the label and the data in the instructions for use.
	As far as practicable and appropriate, the information needed to use the device safely must be set out on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging. If individual packaging of each unit is not practicable, the information must be supplied with one or more devices.
	By way of exception, no such instructions for use are needed for devices in Classes I or IIa if they can be used safely without any such instructions.
	Instructions for use must be provided for every device by a state of the art information delivery system. Providing instructions for use by means other than paper format may only be considered for medical devices intended for use by a healthcare professional in healthcare facilities. In such a case the manufacturer must afford healthcare facilities the opportunity to request the information in paper format in a timely manner."

Justification

There should be the possibility of providing information for the safe and correct use of medical devices by professionals through modern means of communication (e.g. e-labelling. New Article 11.14 should be deleted and section 13.1. of Annex I should therefore be amended.

Amendment 66
ANNEX II, POINT 1 (G) (II)
Annex I, Section 13.3., point (b) (Directive 93/42/EEC)

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

Justification

IMCO amendment which has been incorporated in the report without vote on the basis of Rule 47. The "internationally recognized nomenclature code" introduced by the draft proposal should be considered part of the information supplied by the manufacturer, but it shall not be required to appear on the label as suggested. The obligation of putting such a code, which is constantly updated, on the label of the product might lead to frequent changes on the labels, which represent a significant cost for industry and does not add to the safety of the product.
Adding more codes to products, packaging and instructions for use will only add administrative costs without offering any benefits to patients. GMDN codes are already being used for vigilance reporting, hence allowing authorities to assess potential risk issues.

Amendment 67
ANNEX II, POINT 1 (G) (II A) (new)
Annex I, Section 13.3., point (f) (Directive 93/42/EEC)

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

"(f) where appropriate, an indication that the liability of the manufacturer is limited to single use only. This indication does not exclude the reprocessing of the device according to a validated procedure."

Justification

There is currently lack of clarity over the exact significance of the term "single use of medical devices". Under the existing directive, the labels applied to medical devices set by manufacturers are required, if appropriate, to include an indication of whether the device is intended for single use only (Annex II, 13.3 (f)). Given the terminological confusion some Member States equate "single use" with "unprocessability". However, Member States where controlled reprocessing is permitted recognize that the question of reprocessability only depends on objective criteria making use of high quality and security standards. "Single use" label should be therefore interpreted as limiting the liability of the manufacturer to the device's first use, not as an indication of its suitability for reprocessing.

Amendment 68
ANNEX II, POINT 1 (H) (-I) (new)
Annex I, Section 13.6., point (i) (Directive 93/42/EEC)

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

"(i) date of latest revision of the instructions for use".

Justification

This provision appears in Directive 98/79/EEC on in vitro diagnostic medical devices and is highly relevant, given the frequency with which the instructions for use are modified, with new versions being introduced. This will enable users to establish whether or not they have the modified versions. It is all the more important if instructions may be supplied electronically. The modified versions often contain improvements based on the experience gained while using the device, with the aim of preventing adverse incidents or inappropriate use. This information is therefore relevant to the safety of the device.

Amendment 69
ANNEX II, POINT 1 (I A) (new)
Annex I, Section 15 (new) (Directive 93/42/EEC)

(ia) The following Section 15 is inserted:

"15. Where a combined product is being assessed, the opinion of the competent agency or national authority must be drawn up within 210 processing days."

Justification

A deadline should be set for drawing up opinions so that manufacturers know whether or not their devices are to be allowed onto the market within a reasonable period of time.

Amendment 70
ANNEX II, POINT 7 (A)
Annex VII, section 2 (Directive 93/42/EEC)

2. The manufacturer must prepare the technical documentation described in Section 3. The manufacturer or his authorized representative established in the Community must make this documentation, including the declaration of conformity, available to the national authorities for inspection purposes for a	2. The manufacturer must prepare the technical documentation described in Section 3. The manufacturer or his authorized representative established in the Community ***or the importer*** must make this documentation, including the declaration of conformity, available to the national authorities for inspection purposes

period ***at least equivalent to the intended lifetime of the product as defined by the manufacturer but not less than*** five years from the date of manufacture.	for a period ***of at least*** five years from the date of manufacture.

Justification

In order to cut down on bureaucracy, it should also be possible for the importer to keep the necessary documents.

Amendment 71
ANNEX II, POINT 7 (B) (III)
Annex VII, Section 3, indent 7 a (new) (Directive 93/42/EEC)

— the clinical evaluation in accordance with Annex X,	— ***where appropriate,*** the clinical evaluation in accordance with Annex X,

Justification

This annex is applicable to Class I products, such as tongue depressors, cotton gauzes, walking sticks and spectacles frames. It is not necessary to gather all the information for a clinical evaluation for this kind of products.

Amendment 72
ANNEX II, POINT 8 (A A) (new)
Annex VIII, section 2.1 (Directive 93/42/EEC)

	(aa) In section 2.1 the fourth indent is replaced by the following:
	"– the specific characteristics of the product as indicated by the prescription."

Justification

Article 1(d) states that the prescription mentioned above (for custom-made devices) may be issued by anyone with the requisite professional qualifications. However, the fourth indent of section 2.1 of Annex 6 refers only to a doctor's prescription. This contradiction should be removed.

Amendment 73
ANNEX II, POINT 8 (E)
Annex VIII, section 5, introductory paragraph (Directive 93/42/EEC)

5. For custom-made devices, the manufacturer must undertake ***to institute and keep up to date a systematic procedure*** to review experience gained ***from devices*** in the post-production phase***, including the provisions referred to in Annex X,*** and to implement appropriate means to apply any necessary corrective action. This undertaking must include an obligation for the manufacturer to notify the competent authorities of the following incidents immediately on learning of them:	5. For custom-made devices, the manufacturer must undertake to review experience gained in the post-production phase 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, ***near incidents and the relevant corrective action*** immediately on learning of them:

Justification

Manufacturers of custom-made devices are best able to trace their products, as the patients in question are known by name. The systematic procedure called for here (the introduction of ISO 13485) means additional annual costs for dental technicians, opticians, hearing aid and orthopaedic shoe technicians etc. of between EUR 2000 and 5000. This cannot be justified, as a general wording will also avert risks.

Amendment 74
ANNEX II, POINT 9 (B)
Annex IX, chapter II, section 2.6 (Directive 93/42/EEC)

2.6. In calculating the duration referred to in Section 1.1 of chapter I, continuous use means an uninterrupted actual use of the device for the intended purpose. However where usage of a device is discontinued in order for the device to be replaced immediately by the same or an identical device this shall be considered an extension of the continuous use of the device.	2.6. In calculating the duration referred to in Section 1.1 of chapter I, continuous use means an uninterrupted actual use of the device for the intended purpose. However where usage of a device is discontinued in order for the device to be replaced immediately by the same or an identical device this shall be considered an extension of the continuous use of the device ***unless it can be demonstrated that such replacement eliminates the risks arising from a continued use of the device.***

Justification

The current proposal may affect the classification of several products by putting these in a higher class, which is not justifiable as the duration of contact between a device and a patient is not the unique factor for determining the risk classification. The determination of the duration of the contact between the device and the patient should be linked to the analysis of the risks posed by such contact.

Amendment 75
ANNEX II, POINT 9 (C) (VII)
Annex IX, Chapter III, Section 4.4 (Directive 93/42/EEC)

(vii) ***in*** Section 4.4. ***the words 'Non active devices' are replaced by the word 'Devices'***	(vii) Section 4.4. ***is replaced by the following:***
	"4.4 Rule 16 ***Devices specifically intended for recording of X-Ray diagnostic images are in Class IIa.*** ***Note: this refers to primary recording media such as X-ray detectors and not to media used for subsequent reproduction or storage."***

Justification

This addition is intended to prevent the excessively wide application of restrictive requirements.

Amendment 76
ANNEX II, POINT 10
Annex X, Section 1.1., sub-sections 1.1.1., 1.1.2. and 1.1.3. (Directive 93/42/EEC)

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:	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,	— there is demonstration of equivalence of the ***functions, indications, benefit/risk ratio and therapeutic efficacy expected of the*** device to the device to which the data relates and,
— the data adequately demonstrate compliance with the relevant essential	— the data adequately demonstrate compliance with the relevant essential

requirements;	requirements;
1.1.2. or a critical evaluation of the results of all clinical investigations made;	1.1.2. or a critical evaluation of the results of all clinical investigations made;
1.1.3. or a critical evaluation of the combined clinical data provided in 1.1.1 and 1.1.2.	1.1.3. or a critical evaluation of the combined clinical data provided in 1.1.1 and 1.1.2 ***and the results of biophysical or modelling research whose validity has been demonstrated beforehand***.

Justification

1. Under sub-section 1.1.1: It needs to be specified which criteria of importance to the clinical evaluation are covered by the equivalence.
2. Under sub-section 1.1.3: This amendment enables Amendment 2 under Article 2 (above) to be applied. These new technologies, generally linked to virtual reality, may make a significant contribution. They have the advantage of being able to consider all possible scenarios and thus to predict what effects can be expected of a medical device.

EXPLANATORY STATEMENT

The proposal put forward by the Commission amending Directive 93/42/EEC concerning medical devices and Directive 90/385/EEC concerning active implantable medical devices and adapting Directive 98/79/EC is to be welcomed in principle.
However, closer inspection reveals various weaknesses, which are addressed below. In brief, the key points are as follows:

1. Differentiation from other directives

To ensure that the authorities can transpose the Directive smoothly and without bureaucracy, it is crucial to distinguish clearly between this and other laws and for there to be an unambiguous definition of medical devices. There should be as little overlapping with other directives and regulations as possible. In particular, it was important to the rapporteur to find a clear-cut solution in relation to the report on 'Advanced Therapies', which is likewise currently awaiting Parliament's consideration.

The issue of combined products, i.e. devices which contain both human or animal tissue and material components, needed to be dealt with. In agreement with the rapporteur on 'Advanced Therapies', only those products will be classified as medical devices which do not contain any viable tissue and cells and which are liable to act upon the body with action that is **ancillary** to that of the device: these will be assessed in accordance with the directive at issue.

2. Clear decision-making criteria for the classification of products

It must be possible for the authorities to match individual products to the directives governing them without difficulty. It is useful, therefore, for an additional annex to Directive 93/42/EEC to contain a list of information on individual products to aid the difficult task of classifying products in a clear and unbureaucratic way.

3. Software

One very vital issue was whether 'software in its own right' should be defined as a medical device or not. After much debate, it became clear that there was no fundamental difference of opinion between the Commission and Parliament on this subject. The debate did reveal numerous misunderstandings, but ultimately only boiled down to the question: 'How can the agreed position be formulated in such a way as to avoid leaving any scope for interpretation?'

In the end, the rapporteur decided to make the vital clarification in a recital:
'It is necessary to clarify that software in its own right, when specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of a medical device, is a medical device. Software for general purposes when used in a healthcare setting is not a medical device.'

Thus it also became clear in agreement with the Commission that the word 'software' needed to be deleted from the list in Article 1(2)(a) of Directive 93/42/EEC.

Otherwise, there would be a danger that for example electronic health cards might suddenly become medical devices on the grounds that they contain software. It would also become necessary in future to certify Excel or Word programmes at doctors' practices.

4. Reprocessing

The fundamental political issue in the debate concerning the Medical Device Directive was the reprocessing of medical devices. The directive currently in force does not contain any provisions on this subject. The matter has therefore been regulated, in accordance with subsidiarity, in the Member States. In Germany, reprocessing is possible. However, certain processes have to be adhered to for the purpose, which are summarised in guidelines issued by the Robert Koch Institute.

Reprocessing of single-use devices is not absolutely prohibited. However, if they are reprocessed, then – unlike in the case of multiple-use devices – responsibility for ensuring that they work properly is transferred to the reprocessor as if he had produced the device himself. The rapporteur would like to retain the subsidiarity-based provisions concerning reprocessing.

5. Contact lenses

In order to avoid creating a precedent, for example for piercings, the rapporteur decided that purely cosmetic contact lenses should not fall under the Medical Device Directive. Naturally, all medical contact lenses are medical devices, even if they are not explicitly mentioned in the Directive.

18.9.2006

OPINION OF THE COMMITTEE ON THE INTERNAL MARKET AND CONSUMER PROTECTION

for the Committee on the Environment, Public Health and Food Safety

on the 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 (COM(2005)0681 – C6-0006/2006 – 2005/0263(COD))

Draftswoman (*): Anneli Jäätteenmäki

(*) Enhanced cooperation between committees - Rule 47 of the Rules of Procedure

SHORT JUSTIFICATION

The purpose of this Proposal for a Directive amending three different Directives is very welcomed by the Draftsperson. Experiences of the last years since the adoption of the Directive 93/42/EEC on medical devices made this regulatory reform necessary. The need for an improved implementation of the existing rules justifies the proposal.

As far as the scope of the Directive is concerned, the Draftsperson supports the Commission's view not to include the reprocessing of medical devices in this regulatory reform. However, she calls on the Commission to consider future legislative work in this area, after a due reflection and consultation.

A problem with the definition of "medical device" may be that a particular product falls under the definition of this Directive and at the same time within the scope of other directives, e.g. medicinal products, cosmetics etc. In this case, the determination of the applicable Directive should be based on the evaluation of the principal intended purpose and the related relevant functioning and impact of the product.

The main goal of the amendments proposed is to strengthen the aspects of patient safety and public health as well as the safety and quality of substances. In order to meet these goals, the Draftsperson in some articles pleads for a clearer wording which should lead to a greater legal certainty for the involved stakeholders. In respect of patient safety, the Draftsperson aims to give emphasis to the demand that copy products should fall under the same category and

legislation as the original product.

AMENDMENTS

The Committee on the Internal Market and Consumer Protection calls on the Committee on the Environment, Public Health and Food Safety, as the committee responsible, to incorporate the following amendments in its report:

Text proposed by the Commission	Amendments by Parliament
Amendment 1 RECITAL 2 A (new)	
	(2a) As regards reprocessing, the Commission should engage in further reflection and wider consultation in order to explore the possible development of appropriate legislation ensuring a high level of patient safety.
Amendment 2 RECITAL 2 B (new)	
	(2b) The Commission should also appear before the relevant committees of the European Parliament within two months of the date of adoption of this Directive to report on progress made in this area.
Amendment 3 RECITAL 2 C (new)	
	(2c) Non-corrective contact lenses which are used to change the appearance of the eye are not regarded as medical devices for the purposes of this Directive. However, the non-prescribed sale and distribution of those lenses may in the absence of consultation or supervision from professional eye care practitioners lead to an increase in their incorrect use and therefore pose a potential health risk.

Amendment 4
RECITAL 2 D (new)

	(2d) The Commission should investigate the current sale and distribution system of contact lenses in Member States, evaluate the potential risks to the health and safety of consumers and take the appropriate measures, legislative or non-legislative, in order to ensure a high level of health protection in the Community. A report of such findings and any eventual proceedings should be presented to the relevant committees of the European Parliament within six months of the adoption of this Directive.

Amendment 5
RECITAL 6

(6) It is necessary to clarify that consideration of a product having a medical purpose is intrinsic to the definition of a medical device and that software in its own right can be defined as a medical device.	***deleted***

Justification

The program itself (as such) could not be a medical device

Amendment 6
RECITAL 15

(15) To further ensure public health and safety it is necessary to provide for a more consistent application of the provisions on health protection measures.	(15) To further ensure public health and safety it is necessary to provide for a more consistent application of the provisions on health protection measures***, and in particular make sure that the devices do not risk compromising the safety or health of patients at the time of use***.

Justification

For public health reasons, Member States have the responsibility to ensure proper use of the devices on their territory during the device life-time.

Amendment 7
RECITAL 20

(20) Taking account of the growing importance of software in the field of medical devices, be it as stand alone or as software incorporated in a device, validation of software in accordance with the state of the art should be an essential requirement.	***deleted***

Justification

The program itself (as such) could not be a medical device

Amendment 8
ARTICLE 1, POINT (1), POINT (A), POINT (I)
Article 1, paragraph 2, point (a), introductory part (Directive 90/385/EEC)

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

Justification

The program itself (as such) could not be a medical device

Amendment 9
ARTICLE 1, POINT (1 A) (new)
Article 2 (Directive 90/385/EEC)

	(1a) Article 2 is replaced by the following:
	"Article 2

	1. Member States shall take all necessary steps to ensure that devices may be placed on the market and/or put into service only if they comply with the requirements laid down in this Directive when duly supplied and properly installed, maintained and used in accordance with their intended purpose.
	2. Member States shall also take all necessary steps to ensure that sales of medical devices via the internet, by mail order and other alternative distribution channels do not put the health and safety of consumers at risk, and that such sales comply with all the provisions of this Directive."

Justification

Sales of contact lenses over the internet, by mail order and other alternative distribution channels are becoming more and more common in many European countries and have potential health risks for European citizen since they are not subject to any consultation or counsel by eye care practitioners. In line with Treaty article 152-1, it is important that a high level of human health protection shall be ensured in the definition and implementation of ***all*** *Community policies and activities.*

Amendment 10
ARTICLE 2, POINT (1), POINT (A), POINT (I)
Article 1, paragraph 2, point (a), introductory part (Directive 93/42/EEC)

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

Justification

The program itself (as such) could not be a medical device

Amendment 11
ARTICLE 2, POINT 1, POINT (A), POINT (I A) (new)
Article 1, paragraph 2, point (a), subparagraph 2 (Directive 93/42/EEC)

	(ia) in point (a), the second subparagraph is replaced by the following:
	"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;
	- by its form or the manner in which the manufacturer presents it or places it on the market, encourage in persons generally the impression that the product has medicinal properties for the treatment or prevention of disease in humans;"

(First part of the text has been taken from the original Directive)

Justification

The patient safety has to be ensured. The distinction between medical device and medicinal products must be made clearer. The copy products must fall under the same category as the original one.

Amendment 12
ARTICLE 2, POINT (1), POINT (F), POINT (I)
Article 1, paragraph 5, point (c) (Directive 93/42/EEC)

(c) medicinal products covered by Directive 2001/83/EC. In deciding whether a product falls under that Directive or the present Directive, particular account shall be taken of the principal mode of action of the product;	(c) 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 the second subparagraph of Article 1(2)*** or ***under*** the present Directive, particular account shall be taken of the principal mode of action of the product;

Justification

The analysis of the principal mode of action of the product should be made expressly relevant only to the second limb of the test of medicinal product. So the application of the second limb

of the test of medicinal product is not seen as taking precedence over the first limb of the definition.

Amendment 13
ARTICLE 2, POINT 1, POINT (F), POINT (I A) (new)
Article 1, paragraph 5, point (d) (Directive 93/42/EEC)

	(ia) point (d) is replaced by the following:
	"(d) cosmetic products covered by Directive 76/768/EEC. In deciding whether a product falls under that Directive or this Directive, particular account shall be taken of the principal intended purpose of the product and the relevant mode of action;"

(First sentence of the text has been taken from the original Directive)

Justification

When a product falls under the definition of a "medical device" and potentially within the scope of other directives (e.g. medicinal products, cosmetics, PPE, machinery), the determination of the directive which should apply shall be based on evaluation of the principal intended purpose and related relevant mechanism of action of the product, to provide legal certainty/clarity to the manufacturer and other interested persons.

Amendment 14
ARTICLE 2, POINT 1, POINT (G)
Article 1, paragraph 6 (Directive 93/42/EEC)

(g) Paragraph 6 is ***deleted.***	(g) Paragraph 6 is ***replaced by the following:***
	"6. This Directive does not apply to personal protective equipment covered by Directive 89/686/EEC. In deciding whether a product falls under that Directive, particular account shall be taken of the principal intended purpose of the product and the relevant mode of action."

(Part of this wording has been taken from the original Directive)

Justification

When a product falls under the definition of a "medical device" and potentially within the scope of other directives (e.g. medicinal products, cosmetics, PPE, machinery), the

determination of the directive which should apply shall be based on evaluation of the principal intended purpose and related relevant mechanism of action of the product, to provide legal certainty/clarity to the manufacturer and other interested persons.

Amendment 15
ARTICLE 2, POINT 2
Article 4, paragraph 2, indent 2 (Directive 93/42/EEC)

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

Justification

Self explanatory. Clear wording is needed in order to ensure high level of implementation and finally consumer protection.

Amendment 16
ARTICLE 2, POINT (4), POINT (B)
Article 11, paragraph 14 (Directive 93/42/EEC)

(b) The following paragraph is added:	***deleted***
"14. The Commission may, in accordance with the procedure referred to in Article 7 (2), adopt measures allowing instructions for use to be provided by other means."	

Justification

There should be the possibility of providing information for the safe and correct use of medical devices by professionals through modern means of communication (e.g. e-labelling). New article 11 (14) should be deleted and section 13.1. of Annex I should therefore be amended.

Amendment 17
ARTICLE 2, POINT (13)
Article 20, paragraph 1, subparagraph 2 (Directive 93/42/EEC)

This does not affect the obligation of Member States and notified bodies with	This does not affect the obligation of Member States and notified bodies with

regard to mutual information and the dissemination of warnings, nor the obligations of the persons concerned to provide information under criminal law.	regard to mutual information and the dissemination of warnings ***under the provisions of Article 10(1),*** nor the obligations of the persons concerned to provide information under criminal law.

Justification

For the sake and clarity it is advisable to refer to Article 10, paragraph 1 which mentions the incidents occurring following placing of devices on the market.

Amendment 18
ANNEX I, POINT (1), POINT (A)
Annex I, section 9, indent 7 (Directive 90/385/EEC)

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.	For devices which incorporate software, 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.

Justification

The program itself (as such) could not be a medical device

Amendment 19
ANNEX II, POINT (1), POINT (B)
Annex I, section 7.4, subparagraphs 1 to 4 (Directive 93/42/EEC)

7.4. Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product as defined in Article 1 of Directive 2001/83/EC and which is liable to act upon the body with action ancillary to that of the device, the quality, safety and usefulness of the substance must be verified by analogy with the methods specified in Directive 2001/83/EC.	7.4. Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product as defined in Article 1 of Directive 2001/83/EC and which is liable to act upon the body with action ancillary to that of the device, the quality, safety and usefulness of the substance must be verified by analogy with the ***relevant*** methods specified in ***Annex I of*** Directive 2001/83/EC.
For a substance which:	
- has already been granted, as a medicinal product, a Community marketing authorisation in accordance with Council Regulation (EEC) No 2309/93 (*) or	

Regulation (EC) No 726/2004;

or

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

or

- is a human blood derivative;

the notified body shall, having verified the usefulness of the substance as part of the medical device and taking account of the intended purpose of the device, seek a scientific opinion from the European Medicines Agency (EMEA) on the quality and safety of the substance. When issuing its opinion, the EMEA shall take into account the manufacturing process and the data related to the incorporation of the substance into the device.

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 or*** from the European Medicines Agency (EMEA) on the quality and safety of the substance. 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*** the 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***.***

For ***a substance which is a human blood derivative,*** the notified body shall, having verified the usefulness of the substance as part of the medical device and taking account of the intended purpose of the device, seek a scientific opinion from ***the EMEA*** on the quality and safety of the substance. When issuing its opinion, the ***EMEA*** shall take into account the manufacturing process and the data related to ***the usefulness of*** the incorporation of the substance into the device ***as determined by the notified body.***

(*) OJ L214, 24.8.1993, p. 1

Justification

The current system which allows Notified Bodies to seek the opinion from any of the relevant national authorities should be maintained in order to ensure timely and cost effective consideration of the safety and quality of the substance in question.

Amendment 20
ANNEX II, POINT 1, POINT (B)
Annex I, section 7.4., subparagraph 1 a (new) (Directive 93/42/EEC)

	Authority to verify the usefulness of the substance remains with the notified body, whereas the role of the EMEA or the competent authorities designated by the Member States is to provide a scientific opinion on the quality and safety of the substance.

Justification

Clarification on the role of notified bodies and EMEA/competent authorities will prevent that approval of medical devices with fully documented medicinal substances integrated in practice will be handled as a pharmaceutical, which would add disproportional costs and time without offering any benefits to patients.

Amendment 21
ANNEX II, POINT (1), POINT (B)
Annex I, section 7.4., subparagraph 5 (Directive 93/42/EEC)

Where changes are made to an ancillary substance incorporated in a medical device, in particular related to its manufacturing process, ***they shall be assessed by analogy with the procedures for the evaluation of variations to medicinal products laid down in Commission Regulations (EC) No. 1084/2003 (**) and EC No.1085/2003 (***). The*** notified body shall be informed of the changes and shall consult the relevant medicines competent authority (i.e. the one involved in the initial consultation), in order to confirm that the quality and safety of the ancillary substance are maintained, and to ensure that the changes have no negative impact on the established benefit/risk profile of the addition of the substance in the medical device. ***(**) OJ L 159, 27.6.2003, p. 1*** ***(***) OJ L 159, 27.6.2003, p. 24***	Where changes are made to an ancillary substance incorporated in a medical device, in particular related to its manufacturing process, ***the*** notified body shall be informed of the changes and shall consult the relevant medicines competent authority (i.e. the one involved in the initial consultation), in order to confirm that the quality and safety of the ancillary substance are maintained, 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.

Justification

The current system which allows Notified Bodies to seek the opinion from any of the relevant

national authorities should be maintained in order to ensure timely and cost effective consideration of the safety and quality of the substance in question.

Amendment 22
ANNEX II, POINT (1), POINT (E)
Annex I, section 12.1a. (Directive 93/42/EEC)

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

Justification

The program itself (as such) could not be a medical device

Amendment 23
ANNEX II, POINT (1), POINT (F)
Annex I, Section 13.1., paragraph 1 (Directive 93/42/EEC)

(f) ***In*** Section 13.1. ***the first paragraph*** is replaced by the following:	(f) Section 13.1. is replaced by the following:
"13.1. Each device must be ***accompanied by*** the information needed to use it safely and ***properly***, taking account of the training and knowledge of the potential users, and to identify the manufacturer."	"13.1. Each device must be ***provided with*** the information needed to use it safely and ***as intended***, taking account of the training and knowledge of the potential users, and to identify the manufacturer. ***This information comprises the details on the label and the data in the instructions for use.*** ***As far as practicable and appropriate, the information needed to use the device safely must be set out on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging. If individual packaging of each unit is not practicable, the information must be supplied with one or more devices.*** ***Instructions for use must be provided for every device by a state of the art information delivery system. Providing instructions for use by means other than***

	paper format may only be considered for medical devices intended for use by a healthcare professional in healthcare facilities. In such a case the manufacturer must afford healthcare facilities the opportunity to request the information in paper format in a timely manner. By way of exception, no such instructions for use are needed for devices in Classes I or IIa if they can be used safely without any such instructions."

(The text has been taken from the original Directive)

Justification

There should be the possibility of providing information for the safe and correct use of medical devices by professionals through modern means of communication (e.g. e-labelling. New Article 11.14 should be deleted and section 13.1. of Annex I should therefore be amended.

Amendment 24
ANNEX II, POINT (1), POINT (G), POINT (II)
Annex I, Section 13.3., point (b) (Directive 93/42/EEC)

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

(The text has been taken from the original Directive)

Justification

The "internationally recognized nomenclature code" introduced by the draft proposal should be considered part of the information supplied by the manufacturer, but it shall not be required to appear on the label as suggested. The obligation of putting such a code, which is constantly updated, on the label of the product might lead to frequent changes on the labels, which represent a significant cost for industry and does not add to the safety of the product.

Adding more codes to products, packaging and instructions for use will only add administrative costs without offering any benefits to patients. GMDN codes are already being used for vigilance reporting, hence allowing authorities to assess potential risk issues.

Amendment 25
ANNEX II, POINT (8), POINT (E)
Annex VIII, section 5, paragraph 1 (Directive 93/42/EEC)

5. For custom-made devices, the manufacturer must undertake ***to institute and keep up to date a systematic procedure*** to review experience gained ***from devices*** in the post-production phase***, including the provisions referred to in Annex X,*** and to implement appropriate means to apply any necessary corrective action. This undertaking must include an obligation for the manufacturer to notify the competent authorities of the following incidents immediately on learning of them:	5. For custom-made devices, the manufacturer must undertake to review experience gained in the post-production phase 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 ***and the relevant corrective action*** immediately on learning of them:

Amendment 26
ANNEX II, POINT (9), POINT (A), POINT (I)
Annex IX, chapter I, section 1.4 (Directive 93/42/EEC)

(i) in Section 1.4. the following sentence is added:	***deleted***
"Stand alone software is considered to be an active medical device."	

Justification

The program itself (as such) could not be a medical device

Amendment 27
ANNEX II, POINT (9), POINT (B)
Annex IX, chapter II, section 2.6. (Directive 93/42/EEC)

2.6 In calculating the duration referred to in Section 1.1 of chapter I, continuous use means an uninterrupted actual use of the device for the intended purpose. However where usage of a device is discontinued in order for the device to be replaced immediately by the same or an identical device this shall be considered an extension of the continuous use of the device.	2.6 In calculating the duration referred to in Section 1.1 of chapter I, continuous use means an uninterrupted actual use of the device for the intended purpose. However where usage of a device is discontinued in order for the device to be replaced immediately by the same or an identical device this shall be considered an extension of the continuous use of the device***, unless it can be demonstrated that such replacement***

eliminates any risk arising from a continued use of the device.

Justification

The current proposal may affect the classification of several products by putting these in a higher class, which is not justifiable as the duration of contact between a device and a patient is not the unique factor for determining the risk classification. The determination of the duration of the contact between the device and the patient should be linked to the analysis of the risks posed by such contact.

PROCEDURE

Title	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
References	COM(2005)0681 – C6-0006/2006 – 2005/0263(COD)
Committee responsible	ENVI
Opinion by Date announced in plenary	IMCO 1.2.2006
Enhanced cooperation – date announced in plenary	18.5.2006
Drafts(wo)man Date appointed	Anneli Jäätteenmäki 2.5.2006
Previous drafts(wo)man	
Discussed in committee	19.6.2006 20.6.2006 11/7/2006
Date adopted	14.9.2006
Result of final vote	+: 29 –: 0 0: 0
Members present for the final vote	Charlotte Cederschiöld, Janelly Fourtou, Evelyne Gebhardt, Małgorzata Handzlik, Anneli Jäätteenmäki, Pierre Jonckheer, Henrik Dam Kristensen, Alexander Lambsdorff, Kurt Lechner, Arlene McCarthy, Bill Newton Dunn, Zita Pleštinská, Guido Podestà, Giovanni Rivera, Zuzana Roithová, Luisa Fernanda Rudi Ubeda, Heide Rühle, Leopold Józef Rutowicz, Eva-Britt Svensson, Marianne Thyssen, Jacques Toubon, Bernadette Vergnaud, Barbara Weiler, Glenis Willmott
Substitute(s) present for the final vote	André Brie, Joel Hasse Ferreira, Syed Kamall, Othmar Karas, Joseph Muscat
Substitute(s) under Rule 178(2) present for the final vote	
Comments (available in one language only)	

13.7.2006

OPINION OF THE COMMITTEE ON INDUSTRY, RESEARCH AND ENERGY

for the Committee on the Environment, Public Health and Food Safety

on the 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 (COM(2005)0681 – C6-0006/2006 – 2005/0263(COD))

Draftsman: Šarūnas Birutis

SHORT JUSTIFICATION

This proposal aims at strengthening the competitiveness and safety of the medical devices sector. Medical devices form an increasingly important health-sector segment, with a major impact on both public health and healthcare expenditure. The term "medical device" covers a wide range of products. Approximately 400.000 different medical devices can be distinguished on the market, ranging from simple devices (such as syringes and glasses), through equipment to screen and diagnose disease and health conditions, to the most sophisticated and complex instruments (like life-saving implantable devices, diagnostic imaging and minimal invasive surgery equipment).

The general public rightly expects all those products to meet the highest safety standards. At the same time, the sector is of significant importance to European industry - consisting of 7.000 companies, employing more than 350.000 people and regularly recording one of the highest production growth rates - and requires a coherent and clear legislative framework that fosters competitiveness and innovation.

The current legislative framework, regulating such a diverse variety of products, consists of three Directives. Together, they define the essential requirements that medical devices have to meet when they are put on the market, depending on their classification (such as risk assessment, risk management and risk/benefit analysis). Furthermore, the Directives provide for a system of risk-based conformity assessment procedures, usually performed by independent bodies (the so-called "Notified bodies"). And finally, the Directives lay obligations on national authorities to ensure the proper functioning of the market, for example by instance by market surveillance, guidance, objections to standards or reclassification of devices.

In 2002, the Commission reviewed the functioning of the regulatory framework. The conclusion of the review was that on the whole the Directives provided an appropriate legal framework. However, regarding specific points, room for improvement was possible. The current proposed Directive intends to fill in this room for improvement. The most significant proposals concern clarifications in the following areas:

- Conformity assessment, including clear rules on design documentation and design review;
- Clinical evaluation requirements;
- Post market surveillance and compliance of custom-made device manufacturers;
- The working of and coordination between Notified bodies;
- Medical devices with an ancillary human tissue engineered product;
- Increased transparency to the general public.

Your draftsman welcomes the Commission's proposal, which has long been awaited by industry in the sector. The practical proposals in this Directive will improve harmonisation in this highly complex and diversified sector, by providing clearer and simpler rules. By increasing the legal clarity, transparency and certainty for all market players and by improving the overall regulatory framework, the proposal will support fast technical progress, while guaranteeing a high level of public health protection.

Your draftsman emphasises the fact that, even if the changes at first glance might seem small and technical, they can have a profound effect for the industry concerned. For example, reclassification of certain devices in a higher risk category could increase costs considerably. On the other hand, for devices operating on the borderline of different definitions or for combined devices, legal clarity and consistency can be very important, because it clarifies which directive and hence which procedure applies for them.

Your draftsman would like to draw attention to the fact that the scope of this revised directive should be exactly in line with the new proposed Regulation on Advanced Therapies Medicinal Products, in the sense that all products should be covered either by this directive or by the new regulation and that unnecessary overlap should be avoided. If necessary, the Commission should as soon as possible put forwards a proposal to clarify the scope of these legislative acts.

Finally, given the fact that industry in this sector operates on the global market, the process of international cooperation and harmonization of standards is a vital one. Your draftsman therefore believes that more effort should be made to promote international cooperation, both in the form of bilateral agreements (Mutual Recognition Agreements), as via more informal cooperation (e.g. the Global Harmonization Task Force).

AMENDMENTS

The Committee on Industry, Research and Energy calls on the Committee on the Environment, Public Health and Food Safety, as the committee responsible, to incorporate the following amendments in its report:

Text proposed by the Commission[1]	Amendments by Parliament

Amendment 1
RECITAL 17

(17) To better coordinate the application and efficiency of national resources when applied to issues related to Directive 93/42/EEC the Member States should cooperate with each other and at international level.	(17) To better coordinate the application and efficiency of national resources when applied to issues related to Directive 93/42/EEC the Member States should cooperate with each other and at international level. ***In order to enable industry to compete globally on equal terms, there should be international standardisation and cooperation***.

Justification

The European medical devices industry sells its products world wide. European standards, based on an international standardisation process, are therefore preferable. More effort should be made to promote international cooperation, both in the form of bilateral agreements, as via more informal cooperation (e.g. the Global Harmonization Task Force).

Amendment 2
RECITAL 21 A (new)

	(21a) Reprocessing medical devices is a sector that promises costs savings. Taking into account the current lack of a level playing field in the EU and the need to ensure patient safety, the Commission should come forward with a proposal on medical device reprocessing, based on an impact assessment and a study of the market.

Justification

Currently, the reprocessing of medical devices is not regulated on EU level. According to figures of EAMDR, cost savings of about 3 billion EUR a year could be achieved in the EU by making full use of the potential of medical device reprocessing. To ensure patient safety, the legislation should focus on the quality of reprocessing. Any proposal should be based on a proper impact assessment, focusing on existing regulation in Member States, and a study of the market.

[1] Not yet published in OJ.

Amendment 3

ARTICLE 2, POINT 1, POINT (A), POINT (I A) (new)
Article 1, paragraph 2, point (a) (Directive 93/42/EEC)

(ia) in point (a) the following closing phrase is added:

Under this Directive, all contact lenses should be deemed to be medical devices;

Justification

Cosmetic lenses are not currently regulated as medical devices in Europe, even though they have the same effects and potential health risks on the eye if improperly manufactured or used without the consultation and supervision of an eye care specialist.

Amendment 4
ARTICLE 2, POINT 1, POINT (F), POINT (I)
Article 1, paragraph 5, point (c) (Directive 93/42/EEC)

"(c) medicinal products covered by Directive 2001/83/EC. In deciding whether a product falls under that Directive or the present Directive, particular account shall be taken of the principal mode of action of the product;"	"(c) medicinal products covered by Directive 2001/83/EC. In deciding whether a product falls under that Directive ***by virtue of the application of the definition laid down in point (b) of Article 1(2) of Directive 2001/83/EC*** or ***under*** the present Directive, particular account shall be taken of the principal mode of action of the product;"

Justification

The proposed directive has to be altered in order to render more stringent the definition of medical devices. This would make it more difficult to have medication registered as medical devices. The draft Commission proposal for revision of the Directive includes amendments to the definitions section in Article 1. However, the definition of "medical device" at Article 1.2(a) is substantially the same as that set out in the existing Directive.

Amendment 5
ARTICLE 2, POINT 1, POINT (F), POINT (I A) (new)
Article 1, paragraph 5, point (d) (Directive 93/42/EEC)

(ia) point (d) is replaced by the following:

"(d) cosmetic products covered by Directive 76/768/EEC. In deciding whether a product

	falls under Directive 76/768/EC or this Directive, particular account shall be taken of the principal intended purpose of the product and the relevant mechanism of action;"

Justification

In some cases cosmetic products have a medical intention (i.e. treatment of a disease) and should therefore be classified as medical devices. The decision which directive applies should thus be taken case by case on the basis of the intended purpose.

Amendment 6
ARTICLE 2, POINT 1, POINT (G)
Article 1, paragraph 6 (Directive 93/42/EEC)

(g) Paragraph 6 is deleted.	***deleted***

Justification

This amendments seeks to reinstate the exemption of personal protective equipment from this Directive. These products are sufficiently covered by the Directive 89/686/EEC. Unnecessary application of two directives with different conformity assessment procedures should be avoided.

Amendment 7
ARTICLE 2, POINT 1 A (new)
Article 2, paragraph 1 a (new) (Directive 93/42/EEC)

	(1a) The following paragraph is added to Article 2:
	"Member States shall take all necessary steps to ensure that medical devices sold via the Internet, by mail order and other distribution channels do not put the health and safety of consumers at risk, and that they comply with all the provisions laid down in this Directive."

Justification

Sales of medical devices over the internet, by mail order and other alternative distribution channels are becoming more and more common in many European countries and have potential health risks for European citizen since they are not subject to any consultation or counsel by appropriate specialists.

Amendment 8
ARTICLE 2, POINT 3
Article 9, paragraph 3 (Directive 93/42/EEC)

3 Where a Member State considers that the classification rules set out in Annex IX require adaptation in the light of technical progress and any information which becomes available under the information system provided for in Article 10, it shall submit a duly substantiated request to the Commission and ask it to take the necessary measures. The Commission shall adopt these measures in accordance with the procedure referred to in Article 7 (2).	3 Where a Member State considers that the classification rules set out in Annex IX require adaptation in the light of technical progress and any information which becomes available under the information system provided for in Article 10, it shall submit a duly substantiated request to the Commission and ask it to take the necessary measures. The Commission shall adopt these measures in accordance with the procedure referred to in Article 7 (2). ***The Commission shall ensure that relevant information about envisaged measures is made available to interested parties without delay.***

Changes in the classification can be of great importance for industry because the different requirements in the different classes. In order for industry to be able to make well-planned and cost-effective investments in R&D and production, relevant information about envisaged changes to the classification should be made known as quickly as possible.

Amendment 9
ARTICLE 2, POINT 5, POINT (A)
Article 12, paragraph 3 (Directive 93/42/EEC)

(a) In paragraph 3, the words “Annex IV, V or VI” are replaced by “Annex II, IV, V or VI”.	(a) In paragraph 3, the words “Annex IV, V or VI” are replaced by “Annex II, IV, V or VI” ***and the words "the obtaining of sterility" are replaced by "the obtaining and maintaining of sterility for the shelf life of the device or until the sterile package is opened or damaged"***.

Amendment 10
ARTICLE 2, POINT 10
Article 15, paragraph 2, subparagraph 1 (Directive 93/42/EEC)

2. In the case of devices falling within Class III and implantable and long-term invasive devices falling within Class IIa or IIb, the manufacturer may commence the relevant clinical investigation at the end of a period	2. In the case of devices falling within Class III and implantable and long-term invasive devices falling within Class IIa or IIb, the manufacturer may commence the relevant clinical investigation at the end of a period

of 60 days after notification, unless the competent authorities have notified him within that period of a decision to the contrary based on considerations of public health or public policy. Such decisions shall be communicated by the competent authority to the other Member States.	of 60 days after notification, unless the competent authorities have notified him within that period of a decision to the contrary based on considerations of public health or public policy. Such decisions***, and the justifications for the decisions,*** shall be communicated by the competent authority to the other Member States ***and to the interested parties***.

Amendment 11
ARTICLE 4, PARAGRAPH 1, SUBPARAGRAPH 2

They shall apply those provisions from [***12 months*** from the transposition].	They shall apply those provisions from [***18 months*** from the transposition].

Justification

The transitional period should be sufficiently long to ensure that manufacturers will have enough time to perform the necessary tests and applications in order not to stop on-going production unnecessarily.

Amendment 12
ANNEX I, POINT 1, POINT (B)
Annex I, Section 10, paragraph 4 a (new) (Directive 90/385/EEC)

	The notified body shall verify the usefulness of the substance. The sole role of the EMEA and the competent authorities designated by the Member States is to provide a scientific opinion on the quality and safety of the substance.

Justification

Clarification of the role of notified bodies and EMEA/competent authorities will prevent that approval of medicinal devices with fully documented medicinal substances integrated in practice will be handled as a pharmaceutical, which would add disproportional costs and time without offering any benefits to patients.

Amendment 13
ANNEX II, POINT 1, POINT (B)
Annex I, Section 7.4, paragraph 2, final part (Directive 93/42/EEC)

the notified body shall, having verified the usefulness of the substance as part of the medical device and taking account of the intended purpose of the device, seek a scientific opinion from the ***European Medicines Agency (***EMEA***)*** on the quality and safety of the substance. When issuing its opinion, the EMEA shall take into account the manufacturing process and the ***data*** related ***to*** the incorporation of the substance into the device.	the notified body shall, having verified the usefulness of the substance as part of the medical device and taking account of the intended purpose of the device, seek a scientific opinion ***from the national competent authority, designated by a Member State in accordance with Directive 2001/83/EC or*** from the EMEA on the quality and safety of the substance. When issuing its opinion, ***the competent authority or*** the EMEA shall take into account the manufacturing process and the related ***data as well as*** the ***usefulness of*** incorporation of the substance into the device ***as determined by the notified body.***

Justification

The current system, which allows Notified Bodies to seek the opinion from any of the relevant national authorities, should be maintained in order to ensure timely and cost effective consideration of the safety and quality of the substance in question. The duty to evaluate the usefulness of including the medicinal substance in the medical device should remain in the hands of the evaluation body responsible for the overall assessment of the device.

Amendment 14
ANNEX II, POINT 1, POINT (F)
Annex I, Section 13.1, paragraph 1 (Directive 93/42/EEC)

13.1. ***Each*** device must be ***accompanied by*** the information needed to use it safely and ***properly***, taking account of the training and knowledge of the potential users, and to identify the manufacturer.	13.1. ***For each*** device***,*** the information needed to use it safely and ***as intended***, taking account of the training and knowledge of the potential users, and to identify the manufacturer***, must be provided***.

Justification

Creates legal clarity by introducing the generally accepted term of "Intended use".

Amendment 15
ANNEX II, POINT 1, POINT (G), POINT (II)
Annex I, Section 13.3, point (b) (Directive 93/42/EEC)

(ii) point (b) is replaced by the following:	***deleted***
"(b) the details strictly necessary for the user to identify the device and the contents of the packaging including the respective code of an internationally recognized generic medical device nomenclature;"	

Justification

Adding more codes to products, packaging and instructions for use will only add administrative costs without offering any benefits to patients. GMDN codes are already being used for vigilance reporting, hence allowing authorities to asses potential risk issues.

Amendment 16
ANNEX II, POINT 7, POINT (B), POINT (III)
Annex VII, Section 3, indent 7 a (new) (Directive 93/42/EEC)

- the clinical evaluation in accordance with Annex X,	- ***where appropriate,*** the clinical evaluation in accordance with Annex X,

Justification

This annex is applicable to Class I products, such as tongue depressors, cotton gauzes, walking sticks and spectacles frames. It is not necessary to gather all the information for a clinical evaluation for this kind of products.

Amendment 17
ANNEX II, POINT 9, POINT (C), POINT (VII)
Annex IX, Section 4.4 (Directive 93/42/EEC)

(vii) ***in*** Section 4.4. ***the words 'Non active devices' are*** replaced by the ***word 'Devices'***	(vii) Section 4.4. ***is*** replaced by the ***following: "Devices intended for recording X-rays to generate diagnostic images are in Class IIa."***

Justification

Clarification. The original text could unintentionally cover other devices (e.g. recording of diagnostic X-ray images on digital media) for which the classification into Class IIa seems to be disproportionate.

PROCEDURE

Title	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
References	COM(2005)0681 – C6-0006/2006 – 2005/0263(COD)
Committee responsible	ENVI
Opinion by Date announced in plenary	ITRE 16.3.2006
Enhanced cooperation – date announced in plenary	no
Drafts(wo)man Date appointed	Šarūnas Birutis 21.2.2006
Previous drafts(wo)man	
Discussed in committee	19.4.2006 29.5.2006 13.7.2006
Date adopted	13.7.2006
Result of final vote	+: 37 –: 0 0: 6
Members present for the final vote	Šarūnas Birutis, Jan Březina, Philippe Busquin, Jerzy Buzek, Joan Calabuig Rull, Pilar del Castillo Vera, Jorgo Chatzimarkakis, Giles Chichester, Den Dover, Lena Ek, Nicole Fontaine, Adam Gierek, Norbert Glante, Umberto Guidoni, Fiona Hall, David Hammerstein Mintz, Rebecca Harms, Erna Hennicot-Schoepges, Romana Jordan Cizelj, Werner Langen, Anne Laperrouze, Vincenzo Lavarra, Eugenijus Maldeikis, Eluned Morgan, Reino Paasilinna, Vladimír Remek, Herbert Reul, Teresa Riera Madurell, Paul Rübig, Andres Tarand, Britta Thomsen, Catherine Trautmann, Claude Turmes, Nikolaos Vakalis, Alejo Vidal-Quadras Roca
Substitute(s) present for the final vote	María del Pilar Ayuso González, Etelka Barsi-Pataky, Ivo Belet, Gunnar Hökmark, Peter Liese, Lambert van Nistelrooij, Vittorio Prodi, Esko Seppänen
Substitute(s) under Rule 178(2) present for the final vote	
Comments (available in one language only)	

PROCEDURE

Title	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 of the Council as regards the review of the medical device directives				
References	COM(2005)0681 – C6-0006/2006 – 2005/0263(COD)				
Date submitted to Parliament	22.12.2005				
Committee responsible Date announced in plenary	ENVI 1.2.2006				
Committees asked for opinions Date announced in plenary	IMCO 1.2.2006	ITRE 16.3.2006			
Not delivering opinion(s) Date of decision					
Enhanced cooperation Date announced in plenary	IMCO 18.5.2006				
Rapporteur(s) Date appointed	Thomas Ulmer 21.2.2006				
Discussed in committee	6.7.2006	4.10.2006			
Date adopted	4.10.2006				
Result of final vote	+ – 0	50 0 1			
Members present for the final vote	Adamos Adamou, Irena Belohorská, Johannes Blokland, John Bowis, Frieda Brepoels, Hiltrud Breyer, Dorette Corbey, Chris Davies, Avril Doyle, Mojca Drčar Murko, Edite Estrela, Jill Evans, Anne Ferreira, Karl-Heinz Florenz, Matthias Groote, Françoise Grossetête, Cristina Gutiérrez-Cortines, Satu Hassi, Gyula Hegyi, Caroline Jackson, Dan Jørgensen, Eija-Riitta Korhola, Holger Krahmer, Urszula Krupa, Aldis Kušķis, Peter Liese, Jules Maaten, Linda McAvan, Roberto Musacchio, Riitta Myller, Vittorio Prodi, Frédérique Ries, Dagmar Roth-Behrendt, Guido Sacconi, Karin Scheele, Carl Schlyter, Richard Seeber, Bogusław Sonik, María Sornosa Martínez, Antonios Trakatellis, Thomas Ulmer, Marcello Vernola, Anja Weisgerber, Åsa Westlund				
Substitute(s) present for the final vote	María del Pilar Ayuso González, Giovanni Berlinguer, Philip Bushill-Matthews, Milan Gaľa, Genowefa Grabowska, Erna Hennicot-Schoepges, Karsten Friedrich Hoppenstedt				
Substitute(s) under Rule 178(2) present for the final vote					
Date tabled	10.10.2006				
Comments **(available in one language only)**					