EUROPEAN PARLIAMENT 2009 - 2014

Committee on the Internal Market and Consumer Protection

2012/0266(COD)

30.7.2013

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 regulation of the European Parliament and of the Council on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009
(COM(2012)0542 – C7-0318/2012 – 2012/0266(COD))

Rapporteur: Nora Berra

PA_Legam

SHORT JUSTIFICATION

Objectives of the proposal

A number of recent scandals have highlighted the shortcomings in current EU law on medical devices, in particular as regards the designation and functioning of notified bodies, clinical testing, market surveillance and the traceability of devices. Given that improvements were needed which covered all the phases in the life cycle of medical devices, from design to monitoring after they have been placed on the market, your rapporteur welcomes the Commission proposal and endorses the stated aim of introducing a regulation which is directly and immediately applicable and lays down harmonised provisions governing the entire life cycle of such devices. That approach is also consistent with the view expressed by the Committee on the Internal Market and Consumer Protection that wherever possible regulations rather than directives should be chosen as the preferred legal instrument for regulating the single market (see Parliament's resolution of 7 February 2013 with recommendations to the Commission on the governance of the Single Market).

The revision of the current directive is also designed to bring that legal instrument, for which our committee was responsible during the previous parliamentary term and whose purpose was to eliminate obstacles to the free movement of products, into line with the 'new approach'.

General comments

Your rapporteur takes the view that although the overriding objective must be the safety of patients and users, steps must also be taken to safeguard the free movement of products. For that reason, her amendments are principally designed to guarantee:

- that the scope of the future regulation covers all products on the market which meet the definition of medical device or have the chief characteristics of medical devices (equivalent aesthetic devices or 'borderline' products);
- that the reprocessing of medical devices already on the market does not call their safety and performance into question;
- a clearer definition of the responsibilities of economic operators, in an effort to ensure that monitoring is rigorous and effective;
- the rights of patients in the EU who suffer injury as a result of the use of faulty devices, by imposing more stringent requirements on manufacturers;
- that the same requirements as regards expertise, quality and probity apply to all Union certification bodies, given the vital role they play, and will continue to play, in the procedures governing the placing of medical devices on the market;
- a rapid and uniform response to problems on the part of the authorities and manufacturers, by strengthening the monitoring rules;
- all instances of fraud, default or deficiency can be ruled out by means of clearly defined surveillance rules.

An effective assessment mechanism tailored to high-risk devices

Your rapporteur agrees that a notified body should not have sole responsibility for authorising the placing on the market of innovative medical devices which present the highest levels of risk. If we are serious about strengthening the mechanisms governing the placing of medical devices on the market, it is essential that a given type of device should be required to undergo the same assessments, based on the same requirements, anywhere in the Union. This is difficult at present, however, given that there are few if any common assessment methods (guidelines) which manufacturers and notified bodies can employ. This difficulty is exacerbated by the fact that in many cases it is impossible to carry out exhaustive pre-marketing tests, so that post-marketing observational studies have to be relied upon to some extent instead.

Your rapporteur thus endorses the principle of clinical assessment at EU level for high-risk devices which are not covered by common guidelines.

With a view to establishing an effective system which will guarantee patient safety whilst cutting red tape and shortening lead-in times, your rapporteur is proposing:

- that the mechanism provided for in Article 44 should be applied systematically (in order to rule out discriminatory choices) in the case of class III devices which present the highest level of risk and which are not covered by common technical specifications or guidelines;
- that the opinion of the Medical Devices Coordination Group (MDCG) should be made binding: an opinion may be favourable, favourable but qualified (i.e. favourable for a certain period and subject to certain conditions) or negative, which would rule out final certification by the notified body and the placing of the device on the market;
- the gradual harmonisation of the requirements governing clinical assessments through the setting-up of groups of independent clinical and scientific experts under the authority of the MDCG (Article 81). These experts' main tasks would be to carry out the scrutiny referred to in Article 44, on the basis of which the MDCG would deliver its opinions, and to draw up guidelines and common technical specifications for manufacturers and notified bodies concerning clinical assessments and post-market follow-up;
- to make provision for the experts to dispense 'scientific advice' to manufacturers whose devices are covered by the assessment mechanism, in order to inform them of the latest recommendations concerning clinical assessments, so that they can draw up a suitable development plan.

This assessment mechanism would become increasingly effective, as more and more monitoring information is collated and more and more experience is gained with products placed on the market, clearing the way for the gradual approximation of requirements and practices. The scrutiny provided for in Article 44 would likewise become more and more effective and would increasingly focus on the most innovative devices, which, by their very nature, are not covered by clinical assessment guidelines. Given the wide array of products and the risks involved, we have a duty to establish a dynamic system which enhances patient safety whilst safeguarding the benefits of our internal market.

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:

Amendment 1

Proposal for a regulation
Recital 8

Text proposed by the Commission	*Amendment*
(8) It should be the responsibility of the Member States to decide on a case-by-case basis whether or not a product falls within the scope of this Regulation. If necessary, the Commission may decide, on a case-by-case basis, whether or not a product falls within the definition of a medical device or of an accessory to a medical device. Since in some cases it is difficult to distinguish between medical devices and cosmetic products, the possibility to take an EU-wide decision regarding the regulatory status of a product should also be introduced in Regulation No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products.	(8) It should be the responsibility of the Member States to decide on a case by case basis whether or not a product falls within the scope of this Regulation. If necessary, the Commission may decide, ***when necessary, as for example when for a same product the decisions taken at national level vary between Member States,*** on a case-by-case basis, whether or not a product falls within the definition of a medical device or of an accessory to a medical device. Since in some cases it is difficult to distinguish between medical devices and cosmetic products, the possibility to take an EU-wide decision regarding the regulatory status of a product should also be introduced in Regulation No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products.

Justification

It has to be consistent with the provisions of Article 3.1

Amendment 2

Proposal for a regulation
Recital 13

Text proposed by the Commission	*Amendment*
(13) There is scientific uncertainty about the risks and benefits of nanomaterials	(13) There is scientific uncertainty about the risks and benefits of nanomaterials

used for medical devices. In order to ensure a high level of health protection, free movement of goods and legal certainty for manufacturers, it is necessary to introduce a uniform definition for nanomaterials based on Commission Recommendation 2011/696/EU of 18 October 2011 on the definition of nanomaterial, with the necessary flexibility to adapt this definition to scientific and technical progress and subsequent regulatory development at Union and international level. In the design and manufacture of medical devices, the manufacturers should take special care when using nanoparticles ***that can be*** released ***to*** the human body and those devices should be subject to the most severe conformity assessment procedure.	used for medical devices. In order to ensure a high level of health protection, free movement of goods and legal certainty for manufacturers, it is necessary to introduce a uniform definition for nanomaterials based on Commission Recommendation 2011/696/EU of 18 October 2011 on the definition of nanomaterial, with the necessary flexibility to adapt this definition to scientific and technical progress and subsequent regulatory development at Union and international level. In the design and manufacture of medical devices, the manufacturers should take special care when using nanoparticles ***which are intended to be intentionally*** released ***in*** the human body and those devices should be subject to the most severe conformity assessment procedure.

Justification

The risk of the use of nanomaterials shall be taken into account in the risk assessment process. However, too many products with no serious concern for health may fall under this rule. Therefore, the up-classification in Class III shall be made only when the use of nanomaterials is intentional and part of the intended use of the product.

Amendment 3

Proposal for a regulation
Recital 19 a (new)

Text proposed by the Commission	*Amendment*
	(19a) With devices that consist of more than one implantable part, such as hip implants, compatibility of the parts of different manufacturers should be ensured in order to avoid the replacement of the functional part of the device and thus unnecessary risks and inconvenience for patients. The Commission should investigate the need for further measures to ensure the compatibility of the equivalent parts of hip implants from different manufacturers, bearing in mind

that the hip operations are most often made on older people for whom the health risks of operations are higher.

Amendment 4

Proposal for a regulation
Recital 20 a (new)

Text proposed by the Commission	*Amendment*
	(20a) The procedure for identification of common technical specification (CTS) provided for in this Regulation should not undermine the coherence of the European standardisation system as laid down in Regulation (EU) No 1025/2012 on European standardisation. Therefore, this Regulation should also provide for conditions under which it can be considered that a technical specification does not conflict with other European standards. In addition, before identifying CTS, the MDCG established by this Regulation should be used as a forum for consultation of European and national stakeholders, European standardisation organisations and Member States in order to ensure legitimacy of the process.

Justification

This is to ensure consistency with the recent Regulation on European standardisation and in particular to guarantee thebest use of the full range of relevant technical specifications.

Amendment 5

Proposal for a regulation
Recital 25 a (new)

Text proposed by the Commission	*Amendment*
	(25a) To ensure that the risk of damage as well as the risk of the manufacturer's insolvency are not shifted to patients

harmed by medical devices and that the payers are liable for the cost of treatment, manufacturers shall be obliged to take liability insurance with appropriate minimum coverage.

Justification

Pursuant to Directive 85/374/EEC on product liability, there is yet no obligation to take out insurance coverage for damage events. This unfairly shifts the risk of damage, as well as the risk of the manufacturer's insolvency, to the patients harmed by defective medical devices and the payers liable for the cost of treatment. In accordance with the rules already in force in the area of medicinal products, the manufacturers of medical devices should also be obliged to take out liability insurance with appropriate minimum sums for the coverage.

Amendment 6

Proposal for a regulation
Recital 31

Text proposed by the Commission	*Amendment*
(31) The findings of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), established by Commission Decision 2008/721/EC of 5 August 2008 setting up an advisory structure of Scientific Committees and experts in the field of consumer safety, public health and the environment and repealing Decision 2004/210/EC, in its scientific opinion of 15 April 2010 on the safety of reprocessed medical devices marketed for single-use, and of the Commission in its report of 27 August 2010 to the European Parliament and the Council on the issue of reprocessing of medical devices in the European Union, in accordance with Article 12a of Directive 93/42/EEC, call for regulation of the reprocessing of single-use devices in order to ensure a high level of protection of health and safety whilst allowing this practice to further develop under clear conditions. By reprocessing a single-use device its intended purpose is	(31)The findings of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), established by Commission Decision 2008/721/EC of 5 August 2008 setting up an advisory structure of Scientific Committees and experts in the field of consumer safety, public health and the environment and repealing Decision 2004/210/EC, in its scientific opinion of 15 April 2010 on the safety of reprocessed medical devices marketed for single-use, and of the Commission in its report of 27 August 2010 to the European Parliament and the Council on the issue of reprocessing of medical devices in the European Union, in accordance with Article 12a of Directive 93/42/EEC, call for regulation of the reprocessing of single-use devices in order to ensure a high level of protection of health and safety whilst allowing this practice to further develop under clear conditions. By reprocessing a single-use device its intended purpose is

modified and the reprocessor should therefore be considered the manufacturer of the reprocessed device.	modified and the reprocessor should therefore be considered the manufacturer of the reprocessed device. ***For more clarity, only 'intended single-use device' should be reprocessed and not 'single-use device'. Therefore, with regard to reprocessing, 'multiple-use device', 'intended single-use device' and 'single-use device' should be defined in this Regulation and those terms should be distinguished one from another***.

Justification

Manufacturers should not be able to name their products "single- use devices" without demonstrating objective grounds for the impossibility to reuse the medical device. Without such a demonstration, this device is an "intended single-use device" and can be reprocessed according to the porvisions of Article 15.

Amendment 7

Proposal for a regulation
Recital 32

Text proposed by the Commission	*Amendment*
(32) Patients who are implanted with a device should be given essential information related to the implanted device allowing it to be identified and containing any necessary warnings or precautions to be taken, for example indications as to whether or not it is compatible with certain diagnostic devices or with scanners used for security controls.	(32) Patients who are ***going to be*** implanted with a device should be given ***beforehand*** essential information related to the implanted device allowing it to be identified and containing ***information about the main characteristic of the device, the potential adverse effects, a warning of the potential health risks, post-operative follow-up care measures and*** any necessary warnings or precautions to be taken, for example indications as to whether or not it is compatible with certain diagnostic devices or with scanners used for security controls. ***Member States may introduce national provisions requiring that the implant card also includes information on post-operative follow-up care measures and that it is signed by both the patient and the surgeon responsible for the surgery.***

Justification

Information should be provided before the patients are implanted to help them make better informed and more conscious choices.

Amendment 8

Proposal for a regulation
Recital 34

Text proposed by the Commission	*Amendment*
(34) The traceability of medical devices by means of a Unique Device Identification (UDI) system based on international guidance should significantly enhance the effectiveness of the post-market safety of medical devices due to improved incident reporting, targeted field safety corrective actions and better monitoring by competent authorities. It should also help to reduce medical errors and to fight against counterfeit devices. Use of the UDI system should also improve purchase-policy and stock-management by hospitals.	(34) The traceability of medical devices by means of a Unique Device Identification (UDI) system based on international guidance should significantly enhance the effectiveness of the post-market safety of medical devices due to improved incident reporting, targeted field safety corrective actions and better monitoring by competent authorities. It should also help to reduce medical errors and to fight against counterfeit devices. Use of the UDI system should also improve purchase policy and stock management by hospitals***, and, where possible, the system should be compatible with the other authentication systems already in place in such environments***.

Amendment 9

Proposal for a regulation
Recital 39

Text proposed by the Commission	*Amendment*
(39) For high-risk medical devices, manufacturers should ***summarise the main*** safety and performance aspects of the device and the outcome of the clinical evaluation ***in a document that*** should be publicly available.	(39) For high-risk medical devices, manufacturers should ***draft a report of the*** safety and performance aspects of the device and the outcome of the clinical evaluation***. A summary of the safety and performance report*** should be publicly

available.

Amendment 10

Proposal for a regulation
Recital 42

Text proposed by the Commission	*Amendment*
(42) For high risk medical devices, authorities should be informed at an early stage about devices which are subject to conformity assessment and be given the right, ***on scientifically valid grounds***, to ***scrutinise the preliminary assessment conducted by notified bodies,*** in particular regarding novel devices, devices for which a novel technology is being used, devices belonging to a category of devices with increased serious incident rates, or devices for which significant discrepancies in the conformity assessments by different notified bodies have been identified in respect of substantially similar devices. The process foreseen in this Regulation does not prevent a manufacturer from informing voluntarily a competent authority of his intention to file an application for conformity assessment for a high risk medical device before submitting the application to the notified body.	(42) For ***innovative*** high risk medical devices, ***competent*** authorities should be informed at an early stage about devices which are subject to conformity assessment and be given the right, ***in absence of common technical specification or guideline for the conduct of clinical evaluation***, to ***assess clinical data and proceed with a scientific assessment*** in particular regarding novel devices, devices for which a novel technology is being used, devices belonging to a category of devices with increased serious incident rates, or devices for which significant discrepancies in the conformity assessments by different notified bodies have been identified in respect of substantially similar devices. The process foreseen in this Regulation does not prevent a manufacturer from informing voluntarily a competent authority of his intention to file an application for conformity assessment for a high risk medical device before submitting the application to the notified body.

Justification

A European assessement should be foreseen and made systematic for sensitive and innovating medical devices. The result of that assessment should be binding in order to guarantee that it does not constitute a simple consultation. Thus a negative assessment would prevent devices from being certified and introduced on the market.

Once gained experience, the Commission supported by expert panels should establish guidelines and common technical specifications addressed to manufacturers and notified bodies on clinical evaluation and post-market follow-up; this would progressively reduce this European assessment mechanism to first-in- class and innovative devices.

Amendment 11

Proposal for a regulation
Recital 42 a (new)

Text proposed by the Commission	*Amendment*
	(42a) High-risk devices manufacturer concerned by the scientific assessment should be provided with an advice for an appropriate assessment of the conformity of their devices, in particular with regard to the clinical data required for the clinical evaluation. This scientific advice could be provided by the Scientific Advisory Board or by an EU reference laboratory and published on a public database.

Justification

This advice should notably help manufacturers to conduct clinical evaluation in accordance with the state of the art and latest recommendations from the European experts group.

Amendment 12
Proposal for a regulation
Recital 54 a (new)

Text proposed by the Commission	*Amendment*
	(54a) Manufacturers should report periodically on medical devices classified as class III as regards the data relevant to the risk benefit ratio and the exposition of the population in order to evaluate whether any action concerning the medical device concerned is necessary.

Justification

It is important in the framework of the vigilance system to introduce an obligation for the manufacturers to report periodically for medical devices class III on safety data and volume of sales.

Amendment 13
Proposal for a regulation
Recital 56

Text proposed by the Commission	*Amendment*
(56) Rules on market surveillance should be included in this Regulation to reinforce the rights and obligations of the national competent authorities, to ensure effective coordination of their market surveillance activities and to clarify the applicable procedures.	(56) Rules on market surveillance should be included in this Regulation to reinforce the rights and obligations of the national competent authorities, to ensure effective coordination of their market surveillance activities and to clarify the applicable procedures. ***The Commission should clearly define the way these inspections should be conducted in order to ensure a full and harmonized implementation within the Union.***

Justification

Harmonisation of competent authority's control activities is essential to make the new overarching system efficient. The Regulation shall specify inspection modalities, extra EU inspections, cooperation mechanisms and inspector's appointment supported by Commission's guidelines.

Amendment 14
Proposal for a regulation
Recital 59

Text proposed by the Commission	*Amendment*
(59) An expert committee, the Medical Device Coordination Group (MDCG), composed of persons designated by the Member States based on their role and expertise in the field of medical devices and *in vitro* diagnostic medical devices should be established to fulfil the tasks conferred on it by this Regulation and by Regulation (EU) […/…] on *in vitro* diagnostic medical devices, to provide advice to the Commission and to assist the Commission and the Member States in ensuring a harmonised implementation of this Regulation.	(59) An expert committee, the Medical Device Coordination Group (MDCG), composed of persons designated by the Member States based on their role and expertise in the field of medical devices and *in vitro* diagnostic medical devices should be established to fulfil the tasks conferred on it by this Regulation and by Regulation (EU) […/…] on *in vitro* diagnostic medical devices, to provide advice to the Commission and to assist the Commission and the Member States in ensuring a harmonised implementation of this Regulation. ***That experts committee should be supported by a Scientific Advisory Board composed of expert***

panels for specific medical disciplines in order to proceed with the assessment of high risk device and provide guidelines and common technical specifications for clinical evaluation.

Justification

The MDCG scientific assessment on clinical evaluation foreseen in Article 44 should rely on a board of experts. These experts will contribute to the establishment of guidelines and common technical specifications addressed to manufacturers and accredited bodies for clinical evaluation and post-market follow-up in order to harmonize practices.

Amendment 15

Proposal for a regulation
Recital 64

Text proposed by the Commission	*Amendment*
(64) In order to maintain a high level of health and safety, the power to adopt acts in accordance with Article 290 ***TFEU*** should be delegated to the Commission in respect of the ***products subject to this Regulation that are similar to medical devices but do not necessarily have a medical purpose; adaptation*** of the ***definition of nanomaterial to technical progress and to developments at*** Union ***and international level; adaptation to technical progress of the general safety and performance requirements, of the elements to be addressed in the technical documentation,*** of the ***minimum content of the EU declaration of conformity and of the certificates issued by notified bodies,*** of the ***minimum*** requirements to be met by notified bodies, of the classification rules***, of the conformity assessment procedures,*** and of the documentation to be submitted for the approval of clinical ***investigations***; the establishment of the UDI system; the information to be submitted for the registration of medical devices and certain economic operators;	(64) In order to maintain a high level of health and safety, the power to adopt acts in accordance with Article 290 of the ***Treaty on the Functioning*** of the ***European*** Union should be delegated to the Commission in respect of the requirements to be met by notified bodies, of the classification rules and of the documentation to be submitted for the approval of clinical ***performance studies***; the establishment of the UDI system; the information to be submitted for the registration of medical devices and certain economic operators; the level and structure of fees for the designation and monitoring of notified bodies; the publicly available information in respect of clinical ***performance studies***; the adoption of preventive health protection measures at EU level; and the tasks of and criteria for European Union reference laboratories and the level and structure of fees for scientific opinions delivered by them***. However, substantial elements of this Regulation such as general safety and performance requirements, elements to be addressed in***

the level and structure of fees for the designation and monitoring of notified bodies; the publicly available information in respect of clinical ***investigations***; the adoption of preventive health protection measures at EU level; and the tasks of and criteria for European Union reference laboratories and the level and structure of fees for scientific opinions delivered by them. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.	***technical documentation, the minimum content of the EU declaration of conformity, amending or supplementing the conformity assessment procedures, should only be amended through the ordinary legislative procedure***. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.

Justification

The mentioned parts are an essential element of the legislation and therefore according to article 290 of the treaty cannot be modified through a delegated act.

Amendment 16
Proposal for a regulation
Article 1 – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
This Regulation establishes rules to be complied with by medical devices ***and*** accessories to medical devices that are placed on the market or put into service in the Union for human use.	This Regulation establishes rules to be complied with by medical devices, accessories to medical devices ***and aesthetic assimilated devices*** that are placed on the market or put into service in the Union for human use.

Justification

Aesthetic assimilated device should be clearly covered by the scope of this Regulation.

Amendment 17

Proposal for a regulation

Article 2 – paragraph 1 – subparagraph 1 – point 1 – indent 5 – paragraph 2

Text proposed by the Commission	*Amendment*
The implantable or other invasive products, intended to be used for human beings, which are listed in Annex XV shall be considered medical devices, regardless of whether or not they are intended by the manufacturer to be used for a medical purpose.	The implantable or other invasive products, ***as well as products using external physical agents,*** intended to be used for human beings, which are listed ***on a non-exhaustive basis*** in Annex XV*,* shall be considered medical devices ***for the purposes of this Regulation***, regardless of whether or not they are intended by the manufacturer to be used for a medical purpose.

Amendment 18
Proposal for a regulation
Article 2 – paragraph 1 – point 4

Text proposed by the Commission	*Amendment*
(4) 'active device' means any device, the operation of which depends on a source of electrical energy or any source of power other than that directly generated by gravity and which acts by changing the density of or converting this energy.	(4) 'active device' means any device, the operation of which depends on a source of electrical energy or any source of power other than that directly generated ***by the human body or*** by gravity and which acts by changing the density of or converting this energy.
Devices intended to transmit energy, substances or other elements between an active device and the patient, without any significant change, shall not be considered to be active devices.	Devices intended to transmit energy, substances or other elements between an active device and the patient, without any significant change, shall not be considered to be active devices.
Stand alone software shall be considered an active device;	Stand alone software shall be considered an active device;

Justification

The energy generated by the human body can hardly be considered at the same level than electricity. This provision would lead to the up-classification as active devices of syringes, lancets or scalpels.

Amendment 19

Proposal for a regulation

Article 2 – paragraph 1 – subparagraph 1 – point 4 – paragraph 1

Text proposed by the Commission	*Amendment*
Stand alone software shall be considered an active device;	***deleted***

Justification

Due to systematic reasons: Move the sentence "Stand alone software shall be considered an active device" from article 2.1 (4) to Annex VII, Rule 9.

Amendment 20
Proposal for a regulation
Article 2 – paragraph 1 – point 8

Text proposed by the Commission	*Amendment*
(8) 'single-use device' means a device that is intended to be used on an individual patient during a single procedure.	(8) 'single-use device' means a device that is to be used on an individual patient during a single procedure ***and which has been tested and demonstrated to be impossible to reuse.***
The single procedure may involve several uses or prolonged use on the same patient;	The single procedure may involve several uses or prolonged use on the same patient;

Justification

Manufacturers have to provide detailed information justifying why a medical device cannot be reused or why its reuse would endanger the safety of patients/users. If on objective grounds the impossibility of reuse has been demonstrated, the medical device shall not be reprocessed. This specific provision should avoid medical devices being excessively labelled as "single-use" and allow a better supervision of reprocessing.

Amendment 21
Proposal for a regulation
Article 2 – paragraph 1 – point 8 a (new)

Text proposed by the Commission	*Amendment*
	(8a) "intended for single-use device" means a device that is to be used on an individual patient during a single procedure for which impossibility of reuse has not been demonstrated;

Justification

By extension of the definition of 'single-use device', if impossibility of reusing the single-use device has not been demonstrated, the possibility of reprocessing shall be left open to the reprocessor if such a reprocessing is proven to be safe and in accordance with the provisions of Art 15. Information on the label and information in the instructions for use (as laid down in section 19.2 and 19.3 of Annex I) should be modified accordingly to reflect the distinction introduced between a "single-use" device and an "intended single-use" device.

Amendment 22
Proposal for a regulation
Article 2 – paragraph 1 – point 8 b (new)

Text proposed by the Commission	*Amendment*
	(8b) 'multiple-use device' means a device which is reusable and must be provided with information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of sterilization of the device to be re-sterilized, and any restriction on the number of reuses;

Justification

For more clarity and contrary to devices "intended for single-use", devices which have been demonstrated as reusable should be defined as "multiple-use" devices.

Amendment 23

Proposal for a regulation
Article 2 – paragraph 1 – subparagraph 1 – point 32

Text proposed by the Commission	*Amendment*
(32) 'clinical evaluation' means the assessment and analysis of clinical data pertaining to a device in order to verify the safety ***and performance*** of the device when used as intended by the manufacturer;	(32) 'clinical evaluation' means the assessment and analysis of clinical data pertaining to a device in order to verify the safety***, performance and clinical benefits*** of the device when used as intended by the manufacturer;

Amendment 24

Proposal for a regulation
Article 2 – paragraph 1 – subparagraph 1 – point 36 a (new)

Text proposed by the Commission	*Amendment*
	(36a) 'performance' means the ability of a device to produce the effect intended by the manufacturer relative to the medical condition, including attainment of technical capabilities and clinical claims;

Amendment 25

Proposal for a regulation
Article 2 – paragraph 1 – subparagraph 1 – point 37

Text proposed by the Commission	*Amendment*
(37) 'sponsor' means an individual, company, institution or organisation which takes responsibility for the initiation ***and management*** of a clinical investigation;	(37) 'sponsor' means an individual, company, institution or organisation which takes responsibility for the initiation***, management or funding*** of a clinical investigation;

Amendment 26

Proposal for a regulation
Article 2 – paragraph 1 – subparagraph 1 – point 40 – introductory part

Text proposed by the Commission	*Amendment*
(40) 'device deficiency' means any inadequacy in the identity, quality, durability, reliability, safety or performance of an investigational device, including malfunction, ***use errors*** or inadequacy in the information supplied by the manufacturer;	(40) 'device deficiency' means any inadequacy in the identity, quality, durability, reliability, safety or performance of an investigational device, including malfunction, or inadequacy in the information supplied by the manufacturer;

Amendment 27
Proposal for a regulation
Article 3 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The Commission ***may at the request of a Member State or on its own initiative*** by means of implementing acts, determine whether or not a specific product, or category or group of products, falls within the definitions of 'medical device' or 'accessory to a medical device. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).	1. The Commission ***may on its own initiative or shall at the request*** of a Member State by means of implementing acts, determine whether or not a specific product, or category or group of products, falls within the definitions of 'medical device' or 'accessory to a medical device. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).

Amendment 28

Proposal for a regulation
Article 3 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Commission shall ***ensure the sharing of expertise between Member States*** in the fields of medical devices, in vitro diagnostic medical devices, medicinal products, human tissues and cells, cosmetics, biocides***, food and, if necessary, other products in order to determine the appropriate regulatory status of a product, or category or group of products***.	2. The Commission shall***, by means of implementing act determine the regulatory status of border line products on the basis of the opinion of the EU multidisciplinary experts group composed of experts*** in the fields of medical devices, in vitro diagnostic medical devices, medicinal products, human tissues and cells, cosmetics, biocides ***and food. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3)***.

Amendment 29

Proposal for a regulation
Article 3 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2 a. For products or groups of products composed of substances or combination of substances that are intended to penetrate inside the body, either through a body orifice or through the surface of the body, which have been considered as medical devices by the multidisciplinary expert group, the Commission shall, by means of implementing acts, determine the risk classification on the basis of the actual risks and on the ground of valid scientific evidence. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).

Amendment 30

Proposal for a regulation
Article 4 – paragraph 5

Text proposed by the Commission	*Amendment*
5. The Commission shall be empowered to adopt delegated acts in accordance with Article 89 amending or supplementing, in the light of technical progress and considering the intended users or patients, the general safety and performance requirements set out in Annex I, including the information supplied by the manufacturer.	***deleted***

Justification

The general safety and performance requirement constitute an essential element of the legislation and therefore according to article 290 of the treaty cannot be modified through a delegated act.

Amendment 31
Proposal for a regulation
Article 7 – paragraph 1

Text proposed by the Commission	*Amendment*
1. ***Where no harmonised standards exist or where relevant harmonised standards are not sufficient,*** the Commission shall be empowered to adopt common technical specifications (CTS) in respect of the general safety and performance requirements set out in Annex I, the technical documentation set out in Annex II or the clinical evaluation and post-market clinical follow-up set out in Annex XIII. The CTS shall be adopted by means of implementing acts in accordance with the examination procedure referred to in Article 88(3).	1. The Commission shall be empowered to adopt common technical specifications (CTS) in respect of the general safety and performance requirements set out in Annex I, the technical documentation set out in Annex II or the clinical evaluation and post-market clinical follow-up set out in Annex XIII. The CTS shall be adopted by means of implementing acts in accordance with the examination procedure referred to in Article 88(3).

Justification

This is in order to ensure consistency with the recent Regulation on European standardisation and in particular to guarantee the best use of the full range of relevant technical specifications. See also amendment introducing in that regard a new subparagraph 1 a (new).

Amendment 32
Proposal for a regulation
Article 7 – paragraph 1 – subparagraph 1 a (new)

Text proposed by the Commission	*Amendment*
	When adopting CTS referred to in paragraph 1, the Commission shall not undermine the coherence of the European standardisation system. CTS are coherent if they do not conflict with European standards, that is to say they cover areas where no harmonised standards exist, the adoption of new European standards is not foreseen within a reasonable period, where existing standards have not gained market uptake or where those standards have become obsolete or have been demonstrated as clearly insufficient according to vigilance or surveillance data, and where the transposition of the technical specifications into European standardisation deliverables is not

foreseen within a reasonable period.

Justification

This is to ensure consistency with the recent Regulation on European standardisation and in particular to guarantee the best use of the full range of relevant technical specifications.

Amendment 33
Proposal for a regulation
Article 7 – paragraph 1 – subparagraph 1 b (new)

Text proposed by the Commission	*Amendment*
	Commission shall adopt CTS referred to in paragraph 1 after consulting the MDCG, which shall also include a representative of the European standardisation organisations.

Amendment 34

Proposal for a regulation
Article 8 – paragraph 2 – subparagraph 2

Text proposed by the Commission	*Amendment*
The Commission shall be empowered to adopt delegated acts in accordance with Article 89 amending or supplementing, in the light of technical progress, the elements in the technical documentation set out in Annex II.	***deleted***

Justification

The general safety and performance requirement constitute an essential element of the legislation and therefore according to article 290 of the treaty cannot be modified through a delegated act.

Amendment 35

Proposal for a regulation
Article 8 – paragraph 6 – subparagraph 1

Text proposed by the Commission	*Amendment*
Proportionate to the risk class and the type of device, manufacturers of devices, other than custom-made devices, shall institute and keep up to date a systematic procedure to collect and review experience gained from their devices placed on the market or put into service and to apply any necessary corrective action, hereinafter referred to as **'**post-market surveillance plan**'**. The post-market surveillance plan shall set out the process for collecting, recording and investigating complaints and reports from healthcare professionals, patients or users on suspected incidents related to a device, keeping a register of non-conforming products and product recalls or withdrawals, and if deemed appropriate due to the nature of the device, sample testing of marketed devices. Part of the post-market surveillance plan shall be a plan for post-market clinical follow-up in accordance with Part B of Annex XIII. Where post-market clinical follow-up is not deemed necessary, this shall be duly justified and documented in the post-market surveillance plan.	Proportionate to the risk class and the type of device, manufacturers of devices, other than custom-made devices, shall institute and keep up to date a systematic procedure to collect and review experience gained from their devices placed on the market or put into service and to apply any necessary corrective action, hereinafter referred to as post-market surveillance plan**'**. The post-market surveillance plan shall set out the process for collecting, recording***, communicating to the electronic system on vigilance referred to in Article 62*** and investigating complaints and reports from healthcare professionals, patients or users on suspected incidents related to a device, keeping a register of non-conforming products and product recalls or withdrawals, and if deemed appropriate due to the nature of the device, sample testing of marketed devices. Part of the post-market surveillance plan shall be a plan for post-market clinical follow-up in accordance with Part B of Annex XIII. Where post-market clinical follow-up is not deemed necessary, this shall be duly justified and documented in the post-market surveillance plan ***and subject to approval by the competent authority***. ***However, this derogation shall not apply to class III medical devices***.

Justification

All manufacturers of marketed class III devices should communicate incidents to electronic system to improve the surveillance of medical devices. For devices that support or sustain life, this is essential for early detection of adverse events and device defects before large patient populations have been exposed. The centralized reporting is also important to enhance automated surveillance systems of clinical experience, to accumulate the data needed to guide patient care as well as for comparison of new devices with established products.

Amendment 36
Proposal for a regulation
Article 8 – paragraph 7

Text proposed by the Commission	*Amendment*
Manufacturers shall ensure that the device is accompanied by the information to be supplied in accordance with Section 19 of Annex I in ***an official Union*** language which can be easily understood by the intended user or patient. ***The language(s) of the information to be supplied by the manufacturer may be determined by the law of the Member State where the device is made available to the user or patient.***	Manufacturers shall ensure that the device is accompanied by ***the instructions and safety*** information to be supplied in accordance with Section 19 of Annex I in ***a*** language which can be easily understood by the intended user or patient***, as determined by the Member-State concerned***.

Justification

Patients and users have to be provided with information in their own language.

Amendment 37
Proposal for a regulation
Article 8 – paragraph 9

Text proposed by the Commission	*Amendment*
9. Manufacturers shall, in response to a reasoned request from a competent authority, provide it with all the information and documentation necessary to demonstrate the conformity of the device, in an official Union language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any corrective action taken to eliminate the risks posed by devices which they have placed on the market or put into service.	9. Manufacturers shall, in response to a reasoned request from a competent authority, provide it with all the information and documentation necessary to demonstrate the conformity of the device, in an official Union language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any corrective action taken to eliminate the risks posed by devices which they have placed on the market or put into service. ***If a competent authority considers or has reason to believe that a device has caused damages, it shall ensure that the potentially harmed user, the user's successor in title, the user's health insurance company or other third parties affected by the damage caused to the user may request the information referred to in***

the first subparagraph from the manufacturer, while ensuring due respect to the intellectual property rights.

Justification

A reinforced right to information eliminates the risk of lack of relevant information in case of damage.

Amendment 38
Proposal for a regulation
Article 8 – paragraph 10 – subparagraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. Manufacturers shall have an appropriate liability insurance covering any damages that may be caused by their medical devices to patients or users in the event of the death of or injury to patient or user or in the event of the death of or injury to multiple patients or users due to the use of the same medical device.

Justification

Pursuant to Directive 85/374/EEC on product liability, there is yet no obligation to take insurance coverage for damage events. This unfairly shifts the risk of damage, as well as the risk of the manufacturer's insolvency, to the patients harmed by defective medical devices and the payers liable for the cost of treatment. In accordance with the rules already in force in the area of medicinal products, the manufacturers of medical devices should also be obliged to take out liability insurance with appropriate minimum sums for the coverage.

Amendment 39
Proposal for a regulation
Article 11 – paragraph 2 – point b

Text proposed by the Commission	*Amendment*
(b) that an authorised representative in accordance with Article 9 has been designated by the manufacturer;	(b) that ***the manufacturer is identified and that*** an authorised representative in accordance with Article 9 has been designated by the manufacturer

Justification

It is important to ensure that the importer has identified the manufacturer.

Amendment 40
Proposal for a regulation
Article 11 – paragraph 2 – point f a (new)

Text proposed by the Commission	*Amendment*
	(fa) that the manufacturer has taken out appropriate liability insurance coverage pursuant to Article 8(10) unless the importer himself can ensure sufficient coverage corresponding to the same requirements.

Justification

Importers should make sure that manufacturers fulfil their obligations regarding insurance.

Amendment 41
Proposal for a regulation
Article 11 – paragraph 7

Text proposed by the Commission	*Amendment*
7. Importers who consider or have reason to believe that a device which they have placed on the market is not in conformity with this Regulation shall immediately inform the manufacturer and his authorised representative and, if appropriate, ***take*** the necessary corrective action to bring that device into conformity, withdraw or recall it. Where the device presents a risk, they shall also immediately inform the competent authorities of the Member States in which they made the device available and, if applicable, the notified body that issued a certificate in accordance with Article 45 for the device in question, giving details, in particular, of the non-compliance and of any corrective action ***taken***.	7. Importers who consider or have reason to believe that a device which they have placed on the market is not in conformity with this Regulation shall immediately inform the manufacturer, and ***where applicable*** his authorised representative and, if appropriate, ***ensure that*** the necessary corrective action to bring that device in conformity, withdraw or recall it***, is taken and, implement that action***. Where the device presents a risk, they shall also immediately inform the competent authorities of the Member States in which they made the device available and, if applicable, the notified body that issued a certificate in accordance with Article 45 for the device in question, giving details, in particular, of the non-compliance and of any corrective action ***they have***

implemented.

Justification

To avoid any dilution of information and responsibility, the manufacturer or where appropriate its authorised representative shall be the only one responsible for taking corrective actions on the product. Importers should not take any corrective actions by themselves but only implement those actions in accordance with manufacturers' decisions.

Amendment 42
Proposal for a regulation
Article 15 – title

Text proposed by the Commission	*Amendment*
Single-use devices and their reprocessing	***Intended*** single-use devices and their reprocessing

Justification

Only devices for which the impossibility of reprocessing has not been demonstrated should be reprocessed in accordance with the provisions laid down in this article.

Amendment 43
Proposal for a regulation
Article 15 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Any natural or legal person who reprocesses a single-use device to make it suitable for further use within the Union shall be considered to be the manufacturer of the reprocessed device and shall assume the obligations incumbent on manufacturers laid down in this Regulation.	1. Any natural or legal person who reprocesses an ***intended*** single-use device to make it suitable for further use within the Union shall be considered to be the manufacturer of the reprocessed device and shall assume the obligations incumbent on manufacturers laid down in this Regulation.

Amendment 44
Proposal for a regulation
Article 15 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Only single-use devices that have been	2. Only ***intended*** single-use devices that

placed on the Union market in accordance with this Regulation, or prior to [date of application of this Regulation] in accordance with Directive 90/385/EEC or Directive 93/42/EEC may be reprocessed.	have been placed on the Union market in accordance with this Regulation, or prior to [date of application of this Regulation] in accordance with Directive 90/385/EEC or Directive 93/42/EEC may be reprocessed.

Amendment 45
Proposal for a regulation
Article 15 – paragraph 3

Text proposed by the Commission	*Amendment*
3. In the case of reprocessing of single-use devices for critical use, only reprocessing that is considered safe according to the latest scientific evidence may be carried out.	3. In the case of reprocessing of ***intended*** single-use devices for critical use, only reprocessing that is considered safe according to the latest scientific evidence may be carried out.

Amendment 46
Proposal for a regulation
Article 15 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The Commission, by means of ***implementing acts***, shall establish and regularly update a list of categories or groups of ***single-use devices*** for critical use which may be reprocessed in accordance with paragraph 3. Those ***implementing acts*** shall be adopted in accordance ***with the examination procedure referred to in Article 88(3)***.	4. The Commission, by means of ***delegated acts,*** shall establish and regularly update a list of categories or groups of ***intended single-use devices*** for critical use which may be reprocessed in accordance with paragraph 3. Those ***delegated acts shall be adopted in accordance Article 89***.

Amendment 47

Proposal for a regulation
Article 15 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. The Commission shall, by means of implementing acts, establish practical guidelines and EU standards to ensure the safe reprocessing of intended for

	single use medical devices that guarantee at least the same level of safety and performance as compared to the original device. In doing so, the Commission shall ensure that such standards are consistent with the latest scientific evidence, the relevant ISO standards or other international technical standards adopted by recognized international standard-setting organizations, provided that they guarantee at least the same level of safety and performance as ISO standards.
	Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).

Amendment 48
Proposal for a regulation
Article 15 – paragraph 5 – subparagraph 2

Text proposed by the Commission	*Amendment*
The name and address of the manufacturer of the original single-use device shall no longer appear on the label, but shall be mentioned in the instructions for use of the reprocessed device.	The name and address of the manufacturer of the original ***intended*** single-use device shall no longer appear on the label, but shall be mentioned in the instructions for use of the reprocessed device.

Amendment 49
Proposal for a regulation
Article 15 – paragraph 6 – point a

Text proposed by the Commission	*Amendment*
(a) the reprocessing of single-use devices and the transfer of single-use devices to another Member State or to a third country with a view to their reprocessing;	(a) the reprocessing of ***intended*** single-use devices and the transfer of ***intended*** single-use devices to another Member State or to a third country with a view to their reprocessing;

Amendment 50
Proposal for a regulation
Article 15 – paragraph 6 – point b

Text proposed by the Commission	*Amendment*
(b) the making available of reprocessed single-use devices.	(b) the making available of reprocessed ***intended*** single-use devices.

Amendment 51

Proposal for a regulation
Article 16 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The manufacturer of an implantable device shall ***provide together*** with the device an implant card ***which shall be made available to the particular patient who has been implanted with the device***.	1. The manufacturer of an implantable***,*** ***sterile-packaged*** device shall ***make available in advance to the healthcare professional or where relevant, to the particular patient who is going to be implanted*** with the device***, the information to be included in an implant passport or in*** an implant card***.***

Amendment 52

Proposal for a regulation
Article 16 – paragraph 1 – subparagraph 1 a (new)

Text proposed by the Commission	*Amendment*
	The following implants are excluded from this obligation: sutures, staples, dental implants, screws and plates.

Amendment 53

Proposal for a regulation
Article 16 – paragraph 1 – subparagraph 1 b (new)

Text proposed by the Commission	*Amendment*
	The Commission shall, by means of implementing acts, regularly update the

	list of implantable devices which do not have to fulfil this obligation. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).

Amendment 54

Proposal for a regulation
Article 16 – paragraph 2 – subparagraph 1 – point c a (new)

Text proposed by the Commission	*Amendment*
	(ca) a short description of the characteristics of the devices, including the materials used;

Amendment 55

Proposal for a regulation
Article 16 – paragraph 2 – subparagraph 1 – point c b (new)

Text proposed by the Commission	*Amendment*
	(cb) the potential adverse events that might occur on the basis of the data from the clinical evaluation and investigation.

Amendment 56

Proposal for a regulation
Article 17 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The Commission shall be empowered to adopt delegated acts in accordance with Article 89 amending or supplementing the minimum content of the EU declaration of conformity set out in Annex III in the light of technical progress.	***deleted***

Justification

As the main means of showing compliance to the legislation, the declaration of conformity is an essential element of the legislation and therefore according to article 290 of the treaty cannot be modified through a delegated act.

Amendment 57
Proposal for a regulation
Article 21 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Any natural or legal person who makes available on the market an article intended specifically to replace an identical or similar integral part or component of a device that is defective or worn in order to maintain or re-establish the function of the device without ***significantly*** changing its performance or safety characteristics, shall ensure that the article does not adversely affect the safety and performance of the device. Substantiating evidence shall be kept available to the competent authorities of the Member States.	1. Any natural or legal person who makes available on the market an article intended specifically to replace an identical or similar integral part or component of a device that is defective or worn in order to maintain or re-establish the function of the device without changing its performance or safety characteristics, shall ensure that the article does not adversely affect the safety and performance of the device. Substantiating evidence shall be kept available to the competent authorities of the Member States.

Justification

The term 'significant'can lead to differing interpretations of the facts and, because of its indeterminacy, to incoherent implementation of the requirements. Changes to or in the performance and security features should under all circumstances lead to a classification of the article as a new medical device.

Amendment 58

Proposal for a regulation
Article 21 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Any natural or legal person who makes available on the market an article intended specifically to replace an identical or similar integral part or component of a device that is defective or worn in order to maintain or re-establish the function of the	1. Any natural or legal person who makes available on the market an article intended specifically to replace an identical or similar integral part or component of a device that is defective or worn in order to maintain or re-establish the function of the

device without significantly changing its performance or safety characteristics, shall ensure that the article does not adversely affect the safety and performance of the device. Substantiating evidence shall be kept available to the competent authorities of the Member States.	device without significantly changing its performance or safety characteristics, shall ensure that the article does not adversely affect the safety and performance of the device. ***When the article is a part of an implantable device, the natural or legal person who makes it available on the market shall cooperate with the manufacturer of the device to ensure its compatibility with the functioning part of the device in order to avoid the replacement of the whole device and its consequences for patient safety.*** Substantiating evidence shall be kept available to the competent authorities of the Member States.

Amendment 59
Proposal for a regulation
Article 21 – paragraph 2

Text proposed by the Commission	*Amendment*
2. An article that is intended specifically to replace a part or component of a device and that ***significantly*** changes the performance or safety characteristics of the device shall be considered a device.	2. An article that is intended specifically to replace a part or component of a device and that changes the performance or safety characteristics of the device shall be considered ***as a*** device ***and shall meet the requirements laid down in this Regulation.***

Justification

The term 'significant' can lead to differing interpretations of the facts and, because of its indeterminacy, to incoherent implementation of the requirements. Changes to or in the performance and security features should under all circumstances lead to a classification of the article as a new medical device.

Amendment 60

Proposal for a regulation
Article 21 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. Any natural or legal person who

refurbishes a device according to the provisions formally laid down by the manufacturer of the device shall ensure that the refurbishment does not adversely affect the safety and performance.

Amendment 61

Proposal for a regulation
Article 21 – paragraph 2 b (new)

Text proposed by the Commission	*Amendment*
	2b. Any natural or legal person who refurbishes a device either in the absence of provisions formally laid down by the manufacturer of the device or disregarding or violating such provisions to make it suitable for further use within the Union shall be considered to be the manufacturer of the refurbished device and shall assume the obligations incumbent on manufacturers as laid down in this Regulation.

Amendment 62

Proposal for a regulation
Article 24 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. It shall be updated with the results of the post-market clinical follow-up evaluation report referred to in Section 3 of Part B of Annex XIII.

Amendment 63

Proposal for a regulation
Article 24 – paragraph 8 – point b

Text proposed by the Commission	*Amendment*
(b) the legitimate interest in protecting commercially sensitive information;	(b) the legitimate interest in protecting commercially sensitive information***, providing that it does not conflict with public health protection***;

Amendment 64

Proposal for a regulation
Article 24 – paragraph 8 – point e a (new)

Text proposed by the Commission	*Amendment*
	(ea) compatibility with the other traceability systems used by medical device stakeholders.

Amendment 65

Proposal for a regulation
Article 25 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Before a device, other than a custom-made or investigational device, is placed on the market the manufacturer or his authorised representative shall submit to the electronic system the information referred to in paragraph 1.	2. Before a device, other than a custom-made or investigational device, is placed on the market the manufacturer or his authorised representative shall submit to the electronic system the information referred to in paragraph 1. ***It shall be ensured that besides the European registration no national registrations in individual Member States can additionally be required.***

Justification

It needs to be made sure that, beside the European registration, no national registrations in individual EU-countries can be required.

Amendment 66
Proposal for a regulation
Article 26 – paragraph 1

Text proposed by the Commission	*Amendment*
1. In the case of devices classified as class III and implantable devices, other than custom-made or investigational devices, the manufacturer shall draw up a summary of safety and clinical performance. It shall be written in a way that is clear to the intended user. The draft of this summary shall be part of the documentation to be submitted to the notified body involved in the conformity assessment in accordance with Article 42 and shall be validated by that body.	1. In the case of devices classified as class III and implantable devices, other than custom-made or investigational devices, the manufacturer shall draw up a summary of safety and clinical performance ***and shall update it with the conclusions of the post market clinical follow-up evaluation report referred to in point 3 of Part B of Annex XIII.*** It shall be written in a way that is clear to the intended use ***and in the language of the country where the medical device is made available on the market***. The draft of this summary shall be part of the documentation to be submitted to the notified body involved in the conformity assessment in accordance with Article 42 and shall be validated by that body.

Justification

Manufacturer's post market clinical follow-up should be transparent for health professionals and patients in order to be able to scrutinise. Results from this follow-up could be fed into the public summaries of safety and performance information.

This document should be publicly available and written in a language easily understandable by user/patients and healthcare professionals.

Amendment 67

Proposal for a regulation
Article 28 – paragraph 7

Text proposed by the Commission	*Amendment*
7. Member States shall provide the Commission and the other Member States with information on their procedures for the assessment, designation and notification of conformity assessment	7. Member States shall provide the Commission and the other Member States with information on their procedures for the assessment, designation and notification of conformity assessment

bodies and for the monitoring of notified bodies, and of any changes thereto.	bodies and for the monitoring of notified bodies, and of any changes thereto. ***Based on this exchange of information and on best practices established across Member States, the Commission shall define, within two years after the entry into force of this Regulation, guidelines for the procedures for the assessment, designation and notification of conformity assessment bodies and for the monitoring of notified bodies to be carried out by national authorities concerned.***

Amendment 68
Proposal for a regulation
Article 29 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Notified bodies shall satisfy the organisational and general requirements and the quality management, resource and process requirements that are necessary to fulfil their tasks for which they are designated in accordance with this Regulation. ***Minimum*** requirements to be met by notified bodies are set out in Annex VI.	1. Notified bodies shall satisfy the organisational and general requirements and the quality management, resource and process requirements that are necessary to fulfil their tasks for which they are designated in accordance with this Regulation. Requirements to be met by notified bodies are set out in Annex VI.

Justification

In order to establish equal requirements for notified bodies in all European Member States and to ensure fair and uniform conditions, the term 'minimum' should be deleted.

Amendment 69

Proposal for a regulation
Article 29 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Commission shall be empowered to adopt delegated acts in accordance with Article 89 amending or supplementing the minimum requirements in Annex VI, in the light of technical progress and	***deleted***

considering the minimum requirements needed for the assessment of specific devices, or categories or groups of devices.

Amendment 70

Proposal for a regulation
Article 30 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1 a. Subcontracting shall be limited to only specific tasks connected with the conformity assessment and the need to subcontract such tasks shall be duly justified to the national authority.

Amendment 71

Proposal for a regulation
Article 31 – paragraph 1 b (new)

Text proposed by the Commission	*Amendment*
	1b. Any subsidiaries of the applicant conformity assessment body which are involved in the conformity assessment process, in particular those located in third countries, shall be subject to the application for notification mechanism and its assessment as described in Article 32.

Amendment 72

Proposal for a regulation
Article 33 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Member States may notify only conformity assessment bodies which satisfy the requirements set out in Annex VI.	2. Member States may notify only conformity assessment bodies which satisfy the requirements set out in Annex VI ***and which have successfully passed an initial assessment performed by the joint assessment team according to Article 32(3)***.

Amendment 73
Proposal for a regulation
Article 33 – paragraph 4 – subparagraph 1

Text proposed by the Commission	*Amendment*
The notification shall clearly specify the scope of the designation indicating the conformity assessment activities, the conformity assessment procedures and the type of devices which the notified body is authorised to assess.	The notification shall clearly specify the scope of the designation indicating the conformity assessment activities, the conformity assessment procedures, ***the risk-class*** and the type of devices which the notified body is authorised to assess.

Justification

Notification should, if necessary specify which class of medical devices the notified bodies is allowed to assess. Some high risk medical devices should only be assessed by notified bodies fulfilling specific requirements laid down by EC through implementing act.

Amendment 74
Proposal for a regulation
Article 33 – paragraph 4 – subparagraph 2

Text proposed by the Commission	*Amendment*
The Commission may, by means of implementing acts, set up a list of codes and the corresponding types of devices to define the scope of the designation of notified bodies which the Member States shall indicate in their notification. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 88(2).	The Commission may, by means of implementing acts, set up a list of codes and the corresponding ***risk-classes*** and types of devices to define the scope of the designation of notified bodies which the Member States shall indicate in their notification. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 88(2).

Amendment 75

Proposal for a regulation
Article 35 – paragraph 4

Text proposed by the Commission	*Amendment*
4. ***Three*** years after notification of a notified body, and again every ***third*** year thereafter, the assessment to determine whether the notified body still satisfies the requirements set out in Annex VI shall be conducted by the national authority responsible for notified bodies of the Member State in which the body is established and a joint assessment team designated in accordance with the procedure described in Article 32(3) and (4). At the request of the Commission or of a Member State, the MDCG may initiate the assessment process described in this paragraph at any time when there is reasonable concern about the ongoing compliance of a notified body with the requirements set out in Annex VI.	4. ***Two*** years after notification of a notified body, and again every ***second*** year thereafter, the assessment to determine whether the notified body still satisfies the requirements set out in Annex VI shall be conducted by the national authority responsible for notified bodies of the Member State in which the body is established and a joint assessment team designated in accordance with the procedure described in Article 32(3) and (4). At the request of the Commission or of a Member State, the MDCG may initiate the assessment process described in this paragraph at any time when there is reasonable concern about the ongoing compliance of a notified body with the requirements set out in Annex VI.

Amendment 76

Proposal for a regulation
Article 37 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The Commission shall investigate all cases where concerns have been brought to its attention regarding the continued fulfilment by a notified body of the requirements set out in Annex VI or the obligations to which it is subject. It may also commence such investigations on its own initiative.	1. The Commission shall investigate all cases where concerns have been brought to its attention regarding the continued fulfilment by a notified body of the requirements set out in Annex VI or the obligations to which it is subject. It may also commence such investigations on its own initiative***, including the unannounced inspection of the notified body by a joint assessment team whose composition meets the conditions set out in Article 32(3)***.

Amendment 77

Proposal for a regulation
Article 41 – paragraph 2 – subparagraph 2

Text proposed by the Commission	*Amendment*
At least 14 days prior to any decision, the competent authority shall notify the MDCG and the Commission of its envisaged decision.	At least 14 days prior to any decision, the competent authority shall notify the MDCG and the Commission of its envisaged decision. ***The final decision shall be made publically available in the Eudamed.***

Amendment 78
Proposal for a regulation
Article 41 – paragraph 3 – subparagraph 1

Text proposed by the Commission	*Amendment*
The Commission may, at the request of a Member State, on its own initiative, by means of implementing acts, decide on the application of the classification criteria set out in Annex VII to a given device, or category or group of devices, with a view to determining their classification.	The Commission may, at the request of a Member State ***or*** on its own initiative, by means of implementing acts, decide on the application of the classification criteria set out in Annex VII to a given device, or category or group of devices, with a view to determining their classification. ***Such decision should in particular be taken in order to resolve diverging decisions between Member States.***

Justification

The current version of Article 41 does not contain a clear procedure for cases of a different assessment of medical devices by different competent authorities. In such cases the commission shall finally decide on the application of a specific rule related to a given device in order to ensure a uniform European wide implementation.

Amendment 79
Proposal for a regulation
Article 42 – paragraph 2 – subparagraph 1

Text proposed by the Commission	*Amendment*
Manufacturers of devices classified as class III, other than custom-made or investigational devices, shall be subject to a conformity assessment based ***on full quality assurance and design dossier examination as specified in Annex VIII. Alternatively, the manufacturer may choose to apply a conformity assessment based*** on type examination as specified in Annex IX coupled with a conformity assessment based on product conformity verification as specified in Annex X.	Manufacturers of devices classified as class III, other than custom-made or investigational devices, shall be subject to a conformity assessment based on type examination as specified in Annex IX coupled with a conformity assessment based on product conformity verification as specified in Annex X.

Justification

For class III devices, conformity assessment based on full quality assurance and design examination may not be enough. Through the introduction of EU type-examination as an obligatory procedure the approach of product-related testing of medical devices ('hands-on-product') is strengthened.

Amendment 80

Proposal for a regulation
Article 42 – paragraph 10 – subparagraph 1 – introductory part

Text proposed by the Commission	*Amendment*
The Commission ***may***, by means of implementing acts, specify the modalities and the procedural aspects with a view to ensuring harmonised application of the conformity assessment procedures by the notified bodies for any of the following aspects:	The Commission ***shall***, by means of implementing acts, specify the modalities and the procedural aspects with a view to ensuring harmonised application of the conformity assessment procedures by the notified bodies for any of the following aspects:

Amendment 81
Proposal for a regulation
Article 42 – paragraph 10 – indent 2

Text proposed by the Commission	*Amendment*
- the minimum frequency of	***deleted***

unannounced factory inspections and sample checks to be conducted by notified bodies in accordance with Section 4.4 of Annex VIII, taking into account the risk-class and the type of device;

Justification

The number of unannounced inspections in section 4.4 of Annex VIII has to be clearly defined in order to strengthen the necessary controls and to guarantee unannounced inspections at the same level and frequency in all Member States. Therefore unannounced inspections should be performed at least once in a certification cycle and for each manufacturer and generic device group. Because of the vital importance of this instrument, the scope and procedures of the unannounced inspections should be stated in the Regulation itself instead of in down streamed rules such as an implementing act.

Amendment 82

Proposal for a regulation
Article 42 – paragraph 10 a (new)

Text proposed by the Commission	*Amendment*
	10a. Unannounced inspections, in terms of their nature and extent, may be counted as regular inspections, with offsetting of economic operators' costs resulting from unannounced inspections, provided that no significant non-conformities are recorded during unannounced inspections. Account must be taken at all times, when ordering unannounced inspections and carrying them out, of the proportionality principle, with due regard, in particular, for the risk potential of each individual product.

Amendment 83

Proposal for a regulation
Article 42 – paragraph 11

Text proposed by the Commission	*Amendment*
11. In the light of technical progress and any information which becomes available in the course of the designation or monitoring of notified bodies set out in Articles 28 to 40, or of the vigilance and market surveillance activities described in Articles 61 to 75, the Commission shall be empowered to adopt delegated acts in accordance with Article 89 amending or supplementing the conformity assessment procedures set out in Annexes VIII to XI.	***deleted***

Justification

The description of the conformity assessment procedures constitutes an essential element of the legislation and therefore according to article 290 of the treaty cannot be modified through a delegated act.

Amendment 84
Proposal for a regulation
Article 43 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Where the conformity assessment procedure requires the involvement of a notified body, the manufacturer may apply to a notified body of his choice, provided that the body is notified for the conformity assessment activities, the conformity assessment procedures and the devices concerned. An application ***may*** not be lodged in parallel with more than one notified body for the same conformity assessment activity	1. Where the conformity assessment procedure requires the involvement of a notified body, the manufacturer may apply to a notified body of his choice, provided that the body is notified for the conformity assessment activities, the conformity assessment procedures and the devices concerned. An application ***shall*** not be lodged in parallel with more than one notified body for the same conformity assessment activity

Justification

To avoid any divergent interpretation, this provision should be made clear.

Amendment 85
Proposal for a regulation
Article 44 – title

Text proposed by the Commission	*Amendment*
Mechanism for scrutiny of certain conformity assessments	***Scientific assessment provided by MDCG***

Justification

A European assessment should be foreseen and made systematic for sensitive and innovating medical devices. The result of that assessment should be binding in order to guarantee that it does not constitute a simple consultation. Thus a negative assessment would prevent devices from being certified and introduced on the market.

Once gained experience, the Commission supported by expert panels should establish guidelines and common technical specifications addressed to manufacturers and notified bodies on clinical evaluation and post-market follow-up; this would progressively reduce this European assessment mechanism to first class and innovative devices.

Amendment 86
Proposal for a regulation
Article 44 – paragraph 1

Text proposed by the Commission	*Amendment*
1. ***Notified bodies shall notify the Commission of applications for conformity assessments for devices classified as class III, with the exception of applications to supplement or renew existing certificates. The notification shall be accompanied by the draft instructions for use referred to in Section 19.3 of Annex I and the draft summary of safety and clinical performance referred to in Article 26. In its notification the notified body shall indicate the estimated date by which the conformity assessment is to be completed. The Commission shall immediately transmit the notification and the accompanying documents to the MDCG.***	1. ***For implantable devices, classified as class III, the notified body, before delivering the certificate of conformity, shall request a scientific assessment provided by MDCG on the clinical evaluation and the post-market clinical follow-up.***
	Notwithstanding first subparagraph of Article 44(1), this requirement shall not apply to devices for which specifications

	referred to in Articles 6 and 7 have been published for the clinical evaluation and the post-market clinical follow-up and devices for which the application for certification only aims at supplementing or renewing existing certificates.

Amendment 87
Proposal for a regulation
Article 44 – paragraph 2 – subparagraph 1

Text proposed by the Commission	*Amendment*
Within 28 days of receipt of the information referred to in paragraph 1, the MDCG may request the notified body to submit a summary of the preliminary conformity assessment prior to issuing a certificate. Upon suggestion by any of its members or by the Commission, the MDCG shall decide on making such request in accordance with the procedure set out in Article 78(4). In its request the MDCG shall indicate the scientifically valid health reason for having selected the specific file for submission of a summary of the preliminary conformity assessment. When selecting a specific file for submission, the principle of equal treatment shall be duly taken into account.	***The MDCG shall communicate the result of its scientific assessment at the latest 45 days after submission of the clinical evaluation report as referred to in Part A of Annex XIII, including the results of clinical investigations as referred to in Annex XIV; the post-market clinical follow-up referred to in Part B of Annex XIII; the draft instructions for use referred to in Section 19.3 of Annex I and the draft summary of safety and clinical performance referred to in Article 26 and the technical documentation related to annex XIII. Within that time period and at the latest 45 days after submission of those documents, the MDCG may request the submission of additional information necessary for the scientific assessment. Until the submission of additional information, that time period of 45 days shall be suspended. Subsequent requests of MDGC for additional information shall not suspend the period for MDCG scientific assessment.***

Amendment 88
Proposal for a regulation
Article 44 – paragraph 2 – subparagraph 2

Text proposed by the Commission	*Amendment*
Within 5 days after receipt of the request by the MDCG, the notified body shall	***deleted***

inform the manufacturer thereof.

Amendment 89
Proposal for a regulation
Article 44 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The MDCG ***may submit comments on the summary of the preliminary conformity assessment at the latest 60 days after submission of this summary. Within that period and at the latest 30 days after submission, the MDCG may request the submission of additional information that for scientifically valid grounds are necessary for the analysis of the notified body's preliminary conformity assessment. This may include a request for samples or an on-site visit to the manufacturer's premises. Until submission of the additional information requested, the period for comments referred to in the first sentence of this subparagraph shall be suspended. Subsequent requests for additional information from the MDCG shall not suspend the period for the submission of comments.***	3. The MDCG ***scientific assessment is based on an assessment of the dossier by the Scientific Advisory Board referred to in Article 80a. If for a device concerned, the manufacturer requested a scientific advice following the procedure referred to in Article 82a, the outcome of that procedure shall be submitted together with the notification or as soon as that procedure is completed. The scientific advice shall be duly taken into account by the MDCG and the Commission in the course of the implementation of this Article.***

Amendment 90
Proposal for a regulation
Article 44 – paragraph 4

Text proposed by the Commission	*Amendment*
4. ***The notified body shall give due consideration to any comments received in accordance with paragraph 3. It shall convey to the Commission an explanation of how they have been taken into consideration, including any due justification for not following the comments received, and its final decision regarding the conformity assessment in question. The Commission shall***	4. ***In case of a favourable scientific assessment, the notified body may proceed with the certification. However, if the favourable scientific assessment is dependant on the application of specific measures (e.g. adaptation of the post-market clinical follow-up plan, certification with a time limit), the notified body shall issue the certificate of conformity only on the condition that***

immediately transmit this information to the MDCG.	***those measures are implemented.***
	In case of unfavourable scientific assessment, the notified body shall not deliver the certificate of conformity. Nevertheless, the notified body may submit new information in response to the explanation included in the MDCG scientific assessment.
	At the request of the manufacturer, the Commission shall organise a hearing allowing discussion on the scientific grounds for the unfavourable scientific assessment and any action that the manufacturer may take or data that may be submitted to address the MDCG concerns

Amendment 91
Proposal for a regulation
Article 44 – paragraph 5 – subparagraph 1

Text proposed by the Commission	*Amendment*
Where deemed necessary for the protection of patient safety and public health, the Commission, may determine, by means of implementing acts, specific categories or groups of devices, other than devices ***of class III,*** to which paragraphs 1 to 4 shall apply during a predefined period of time. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).	Where deemed necessary for the protection of patient safety and public health, the Commission, may determine, by means of implementing acts, specific ***devices***, categories or groups of devices, ***other than devices referred to in paragraph 1*** to which paragraphs 1 to 4 shall apply during a predefined period of time. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).

Amendment 92
Proposal for a regulation
Article 44 – paragraph 5 – subparagraph 2 – point a

Text proposed by the Commission	*Amendment*
a) ***the novelty of the device or of the technology on which it is based and the*** significant clinical or public health impact	a) ***technological novelty or new therapeutic use***, ***which can have***

thereof;	significant clinical or public health impact;

Amendment 93
Proposal for a regulation
Article 44 a (new)

Text proposed by the Commission	*Amendment*
	Article 44a
	Notification before placing on the market
	1. Notified bodies shall notify the Commission of applications for conformity assessments for devices classified as class III, except applications to supplement or renew existing certificates. Those notifications shall be accompanied by the draft instructions for use referred to in Section 19.3 of Annex I and the draft summary of safety and clinical performance referred to in Article 26. In its notifications the notified body shall indicate the estimated date by which the conformity assessment is to be completed. The Commission shall immediately transmit the notification and the accompanying documents to the MDCG.
	2. The Commission shall be empowered to adopt delegated acts in accordance with Article 89 to extend the scope of devices which must be notified before placing on the market as referred to in paragraph 1.

Justification

The pre-market notification as foreseen in Artcile 44 paragraph 1 and 5 first sub-paragraph of the proposal of the Commission should be maintained in a new Article in order to allow the Commission to have market knowledge and surveillance.

Amendment 94

Proposal for a regulation

Article 49 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Where demonstration of conformity with general safety and performance requirements based on clinical data is not deemed appropriate, adequate justification for any such exception shall be given based on the results of the manufacturer's risk management and on consideration of the specifics of the interaction between the device and the human body, the clinical performances intended and the claims of the manufacturer. The adequacy of demonstration of conformity with the general safety and performance requirements based on the results of non-clinical testing methods alone, including performance evaluation, bench testing and pre-clinical evaluation, has to be duly substantiated in the technical documentation referred to in Annex II.	3. ***Except for class III devices,*** where demonstration of conformity with general safety and performance requirements based on clinical data is not deemed appropriate, adequate justification for any such exception shall be given based on the results of the manufacturer's risk management and on consideration of the specifics of the interaction between the device and the human body, the clinical performances intended and the claims of the manufacturer. The adequacy of demonstration of conformity with the general safety and performance requirements based on the results of non-clinical testing methods alone, including performance evaluation, bench testing and pre-clinical evaluation, has to be duly substantiated in the technical documentation referred to in Annex II. ***Exemption from demonstration of conformity with general safety and performance requirements based on clinical data under the first subparagraph shall be subject to prior approval by the competent authority.***

Justification

To avoid a loop hole risking an easy opt-out from clinical evaluations, namely in what concerns high-risk devices.

Amendment 95

Proposal for a regulation
Article 49 – paragraph 5 – subparagraph 1 a (new)

Text proposed by the Commission	*Amendment*
	For devices classified as class III and implantable devices, the summary of safety and clinical performance referred

to in Article 26(1) shall be updated at least annually with clinical evaluation reports.

Amendment 96

Proposal for a regulation
Article 50 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. Clinical investigations shall be subject to Articles 50-60 and Annex XIV if they are conducted for one or more of the following purposes:	1. Clinical investigations ***whether they are carried out with the purpose of placing on the market of a medical device or its post-marketing study*** shall be subject to Articles 50-60 and Annex XIV if they are conducted for one or more of the following purposes:

Justification

The same level of quality standards and ethical principles need to be ensured.

Amendment 97

Proposal for a regulation
Article 51 – paragraph 6 – subparagraph 1

Text proposed by the Commission	*Amendment*
Member States shall ensure that the persons assessing the application do not have conflicts of interest and that they are independent of the sponsor, the institution of the investigation site(s) and the investigators involved, as well as free of any other undue influence.	Member States shall ensure that the persons assessing the application do not have conflicts of interest and that they are independent of the sponsor, the institution of the investigation site(s) and the investigators involved, as well as free of any other undue influence. ***Member States shall ensure that the assessment is done jointly by a reasonable number of persons who collectively have the necessary qualifications and experience. In the assessment, the view of at least one person whose primary area of interest is non-scientific shall be taken into account. The view of at least one patient shall be taken***

	into account. Realization of the clinical investigation shall be subject to an examination by the concerned Ethics Committee.

Amendment 98

Proposal for a regulation
Article 52 – paragraph 3 – point b

Text proposed by the Commission	*Amendment*
(b) protection of commercially sensitive information;	(b) protection of commercially sensitive information; ***data on adverse events and safety data shall not be considered commercially sensitive information;***

Amendment 99

Proposal for a regulation
Article 53 – paragraph 1 – point da (new)

Text proposed by the Commission	*Amendment*
	(da) the clinical investigation report referred to in Annex XIV.

Amendment 100

Proposal for a regulation
Article 53 – paragraph 2

Text proposed by the Commission	*Amendment*
2. When setting up the electronic system referred in paragraph 1, the Commission shall ensure that it is interoperable with the EU database for clinical trials on medicinal products for human use set up in accordance with Article […] of Regulation (EU) No […/…]. With the exception of the information referred to in Article 52, the information collated and processed in the	2. When setting up the electronic system referred in paragraph 1, the Commission shall ensure that it is interoperable with the EU database for clinical trials on medicinal products for human use set up in accordance with Article [...] of Regulation (EU) No [.../...]. With the exception of the information referred to in Article 52, ***and point (d) of Article 53(1) which shall be***

electronic system shall be accessible only to the Member States and to the Commission.	***publicly accessible,*** the information collated and processed in the electronic system shall be accessible only to the Member States and to the Commission. ***The clinical data collected during the investigation referred to in Annex XIV point (2.7) shall be made accessible, upon request and within 20 days, to healthcare professionals and to independent medical societies. A non-disclosure agreement covering the clinical data may be requested.***

Justification

For transparency and public health reasons. There is no reason to prevent access by the public and independent academics to data on clinical adverse events.

Amendment 101

Proposal for a regulation
Article 53 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Commission shall be empowered to adopt delegated acts in accordance with Article 89 ***determining which other information regarding clinical investigations collated and processed in the electronic system shall be publicly accessible*** to allow interoperability with the EU database for clinical trials on medicinal products for human use set up by Regulation (EU) No [**…/…**]. ***Article 52(3) and (4) shall apply.***	3. The Commission shall be empowered to adopt delegated acts in accordance with Article 89 ***for determining the technical requirements and parameters*** to allow interoperability with the EU database for clinical trials on medicinal products for human use set up by Regulation (EU) No [**.../...**].

Amendment 102

Proposal for a regulation
Article 55 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The sponsor may implement the modifications referred to in paragraph 1 at the earliest 30 days after notification, unless the Member State concerned has notified the sponsor of its refusal ***based on considerations of public health, patient safety or public policy***.	2. The sponsor may implement the modifications referred to in paragraph 1 at the earliest 30 days after notification, unless the Member State concerned has notified the sponsor of its ***duly justified*** refusal.

Justification

Restricting the grounds for refusal as proposed in the original text would wrongly exclude aspects such as insufficiently relevant or robust data and other ethical considerations. Modifications to clinical investigations proposed by sponsors should not allow any reduction in scientific or ethical standards motivated by commercial interests.

Amendment 103

Proposal for a regulation
Article 55 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. Assessment by the Member State of the request by the sponsor for a substantial modification to a clinical investigation shall be in accordance with Article 51(6).

Amendment 104

Proposal for a regulation
Article 56 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Where a Member State has refused, suspended or terminated a clinical investigation, or has called for a substantial modification or temporary halt of a clinical investigation, or has been notified by the sponsor of the early termination of a	1. Where a Member State has refused, suspended or terminated a clinical investigation, or has called for a substantial modification or temporary halt of a clinical investigation, or has been notified by the sponsor of the early termination of a

clinical investigation on safety grounds, that Member State shall communicate its decision and the grounds therefor to all Member States and the Commission by means of the electronic system referred to in Article 53.

clinical investigation on safety grounds, that Member State shall communicate ***such facts and*** its decision and the grounds therefor to all Member States and the Commission by means of the electronic system referred to in Article 53.

Amendment 105

Proposal for a regulation
Article 57 – paragraph 2 – subparagraph 2

Text proposed by the Commission	*Amendment*
If the investigation is conducted in more than one Member State the sponsor shall notify all Member States concerned of the overall end of the clinical investigation. That notification shall be made within 15 days from the ***overall*** end of the clinical investigation.	If the investigation is conducted in more than one Member State the sponsor shall notify all Member States concerned of the ***early termination in one Member State and of the*** overall end of the clinical investigation. That notification shall be made within 15 days from the end of the clinical investigation ***in one or more Member States***.

Amendment 106

Proposal for a regulation
Article 57 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Within one year from the end of the clinical investigation, the sponsor shall submit to the Member States concerned a summary of the results of the clinical investigation in form of a clinical investigation report referred to in Section 2.7 of Chapter I of Annex XIV. Where, for scientific reasons, it is not possible to submit the clinical investigation report within one year, it shall be submitted as soon as it is available. In this case, the clinical investigation plan referred to in Section 3 of Chapter II of Annex XIV shall	3. Within one year from the end of the clinical investigation, the sponsor shall submit to the Member States concerned a summary of the results of the clinical investigation in form of a clinical investigation report referred to in Section 2.7 of Chapter I of Annex XIV***, together with all the data collected during the clinical investigation, including negative findings***. Where, for scientific reasons, it is not possible to submit the clinical investigation report within one year, it shall be submitted as soon as it is available. In

specify when the results of the clinical investigation are going to be submitted, together with an explanation.	this case, the clinical investigation plan referred to in Section 3 of Chapter II of Annex XIV shall specify when the results of the clinical investigation are going to be submitted, together with an explanation.

Justification

Such data is already available to the sponsor and shall be communicated to the Member State for adequate statistical scrutiny.

Amendment 107

Proposal for a regulation
Article 58 – paragraph 2

Text proposed by the Commission	*Amendment*
2. ***In the single application, the sponsor shall propose one of the Member States*** concerned ***as coordinating*** Member ***State. If that Member State does not wish to be the coordinating Member State, it*** shall agree, within six days of submission of the single application, ***with another*** Member State ***concerned that the latter*** shall be the coordinating Member State. ***If no other*** Member ***State accepts to be the coordinating Member State, the Member State proposed by the sponsor shall be the coordinating Member State. If another Member State than the one proposed by the sponsor becomes*** coordinating Member State***, the deadline referred to in Article 51(2) shall start on the day following the acceptance***.	2. Concerned Member ***States*** shall agree, within six days of submission of the single application, ***which*** Member State shall be the coordinating Member State. Member ***States and the Commission shall agree, in the framework of the attributions of the MDCG, on clear rules for designating the*** coordinating Member State.

Justification

The solution proposed by the Commission text allows sponsors to cherry pick the competent authorities applying less stringent standards, those less resourced or overburdened with high number of requests which aggravates the proposed tacit approval of clinical investigations. A framework for deciding on the coordinating Member State can be set up by the already proposed MDCG, in line with its tasks described in Article 80.

Amendment 108

Proposal for a regulation
Article 59 – paragraph 4 – subparagraph 1

Text proposed by the Commission	*Amendment*
In the case of a clinical investigation for which the sponsor has used the single application referred to in Article 58, the sponsor shall report any event as referred to in ***paragraph*** 2 by means of the electronic system referred to in Article 53. Upon receipt, this report shall be transmitted electronically to all Member States concerned.	In the case of a clinical investigation for which the sponsor has used the single application referred to in Article 58, the sponsor shall report any event as referred to in ***paragraphs 1 and*** 2 by means of the electronic system referred to in Article 53. Upon receipt, this report shall be transmitted electronically to all Member States concerned.

Amendment 109
Proposal for a regulation
Article 61 – paragraph 1 – subparagraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) any ***serious*** incident in respect of devices made available on the Union market;	(a) any incident in respect of devices made available on the Union market;

Justification

Reporting of incidents and field safety corrective actions should not only mention serious incidents but all incidents and, by extension regarding definition of incident Art 2 (43), include undesirable side-effects.

Amendment 110

Proposal for a regulation
Article 61 – paragraph 3 – subparagraph 1

Text proposed by the Commission	*Amendment*
The Member States shall take all appropriate measures to encourage healthcare professionals, users and patients to report to their competent authorities suspected serious incidents referred to in	The Member States shall take all appropriate measures to encourage healthcare professionals, ***including pharmacists,*** users and patients to report to their competent authorities suspected

point (a) of paragraph 1. They shall record such reports centrally at national level. Where a competent authority of a Member State obtains such reports, it shall take the necessary steps to ensure that the manufacturer of the device concerned is informed of the incident. The manufacturer shall ensure the appropriate follow-up	serious incidents referred to in point (a) of paragraph 1. They shall record such reports centrally at national level. Where a competent authority of a Member State obtains such reports, it shall take the necessary steps to ensure that the manufacturer of the device concerned is informed of the incident. The manufacturer shall ensure the appropriate follow-up.

Amendment 111
Proposal for a regulation
Article 61 – paragraph 3 – subparagraph 2

Text proposed by the Commission	*Amendment*
The Member States shall coordinate between them the development of standard web-based structured forms for reporting of serious incidents by healthcare professionals, users and patients.	The Member States shall coordinate between them the development of standard web-based structured forms for reporting of serious incidents by healthcare professionals, users and patients. ***The Member States shall also provide healthcare professionals, users and patients with another forms for reporting of suspected incidents to national competent authorities.***

Justification

This could represent a limit for some patients and users that may not have access to the web or necessary experience in using such tools. Hence, another format for reporting should be foreseen by the national authorities.

Amendment 112

Proposal for a regulation
Article 61 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. Member States and the Commission shall develop and guarantee the interoperability between national records and the electronic system on vigilance

	referred to in Article 62, to ensure the automated export of data to this system, while avoiding duplication of registries.

Justification

High quality registries for broad populations will avoid fragmentation of registries and will enable a more adequate picture of safety and efficacy of medical devices.

Amendment 113
Proposal for a regulation
Article 62 – paragraph 1 – point d a (new)

Text proposed by the Commission	*Amendment*
	(da) the periodic safety update reports drawn by manufacturers, as referred to in Article 63a;

Amendment 114

Proposal for a regulation
Article 62 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The information collated and processed by the electronic system shall be accessible to the competent authorities of the Member States, to the Commission ***and*** to the notified bodies.	2. The information collated and processed by the electronic system shall be accessible to the competent authorities of the Member States, to the Commission***, and without prejudice to the preservation of intellectual property and commercially sensitive information*** to the notified bodies ***healthcare professionals and independent medical societies and to manufacturers relating to information about their own devices. The data referred to in points (a) to (e) of Article 62(1) shall not be considered commercially confidential information unless the MDCG issues a contrary opinion***.

Justification

Access to clinical data is essential to preserve system's transparency and for analysis by independent academics and professional medical organizations. No intellectual property or commercially sensitive information is implicated in such clinical data.

Amendment 115
Proposal for a regulation
Article 62 – paragraph 5 a (new)

Text proposed by the Commission	*Amendment*
	5a.The reports and information referred to in Article 62(5), shall also be automatically transmitted as regards the device in question via the electronic system to the notified body that issued the certificate in accordance with Article 45.

Justification

The integration of the notified bodies in the exchange of information of the market surveillance authorities must be extended and clearly defined. Particularly, the notified bodies need - within the framework of automated, harmonized communication procedures - consolidated information in order to recognize developments, take new information immediately into account and react promptly and appropriately to occurrences and incidents.

Amendment 116

Proposal for a regulation
Article 62 – paragraph 5 a (new)

Text proposed by the Commission	*Amendment*
	5a. It shall be ensured that besides the European reporting no national reporting in individual Members States can additionally be required.

Amendment 117
Proposal for a regulation
Article 63 – paragraph 1 – subparagraph 2

Text proposed by the Commission	*Amendment*
If in the case of reports received in accordance with Article 61(3) the competent authority ascertains that the reports relate to ***a serious*** incident it shall notify without delay those reports to the electronic system referred to in Article 62, ***unless the same incident has already been reported by the manufacturer***	If in the case of reports received in accordance with Article 61(3) the competent authority ascertains that the reports relate to ***an*** incident it shall notify without delay those reports to the electronic system referred to in Article 62,

Justification

Reports should be notified to the electronic system in any case, especially to ensure the circulation of all information.

Amendment 118
Proposal for a regulation
Article 63 a (new)

Text proposed by the Commission	*Amendment*
	Article 63a
	Periodic safety update reports
	1. Manufacturers of medical devices classified as class III shall report to the electronic system referred to in Article 62:
	(a) summaries of data relevant to the benefits and risks of the medical devices, including results of all studies with a consideration of their potential impact on the certification;
	(b) a scientific evaluation of the risk-benefit ratio of the medical device;
	(c) all data relating to the volume of sales of the medical devices including an estimate of the population exposed to the medical device.
	2. The frequency with which the manufacturers shall make the report referred to in the paragraph 1 shall be specified in the MDCG scientific assessment referred to in Article 44.

Manufacturers shall submit periodic safety update reports to the competent authorities immediately upon request or at least once a year during the first 2 years following initial placing on the market of that medical device.

3. The MDCG shall assess periodic safety update reports to determine whether there are new risks or whether risks have changed, or whether there are changes to the risk-benefit ratio of the medical device.

4. Following the assessment of periodic safety update reports, the MDCG shall consider whether any action regarding the medical device concerned is necessary. The MDCG shall inform the notified body in case of unfavourable scientific assessment. In this case, the notified body shall maintain, vary, suspend or revoke the authorisation as appropriate.

Justification

It is important in the framework of the vigilance system to introduce an obligation for the manufacturers to report periodically for medical devices class III on safety data and volume of sales.

Amendment 119
Proposal for a regulation
Article 67 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The competent authorities shall perform appropriate checks on the characteristics and performance of devices including, where appropriate, review of documentation and physical or laboratory checks on the basis of adequate samples. They shall take account of established principles regarding risk assessment and risk management, vigilance data and complaints. The competent authorities may require economic operators to make available the documentation and	1. The competent authorities shall perform appropriate checks on the characteristics and performance of devices including, where appropriate, review of documentation and physical or laboratory checks on the basis of adequate samples. They shall take account of established principles regarding risk assessment and risk management, vigilance data and complaints. The competent authorities may require economic operators to make available the documentation and

information necessary for the purpose of carrying out their activities and, ***where necessary and justified***, enter the premises of economic operators and take the necessary samples of devices. They may destroy or otherwise render inoperable devices presenting a serious risk where they deem it necessary.	information necessary for the purpose of carrying out their activities and enter the premises of economic operators and take the necessary samples of devices ***for analysis by an official laboratory. They may destroy or otherwise render inoperable devices presenting a serious risk where they deem it necessary.***

Justification

Competent authorities should not have to justify any inspection

Amendment 120

Proposal for a regulation
Article 67 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. Unannounced inspections, in terms of their nature and extent, may be counted as regular inspections, with offsetting of economic operators' costs resulting from unannounced inspections, provided that no significant non-conformities are recorded during unannounced inspections. Account must be taken at all times, when ordering unannounced inspections and carrying them out, of the proportionality principle, with due regard, in particular, for the risk potential of each individual product.

Amendment 121
Proposal for a regulation
Article 67 – paragraph 5 a (new)

Text proposed by the Commission	*Amendment*
	5a. Without prejudice to any international agreements concluded between the Union and third countries, checks as referred in paragraph 1 can also take place in the premises of an economic operator located in a third country, if the device is intended

to be made available on the Union market.

Justification

Inspections by the competent authorities of the Member States should be possible in premises established in third countries when placing devices on the EU market.

Amendment 122
Proposal for a regulation
Article 67 – paragraph 5 b (new)

Text proposed by the Commission	*Amendment*
	5b. After every check, as referred in paragraph 1, the concerned competent authority shall report to the inspected economic operator on the level of compliance with this Regulation. Before adopting the report, the competent authority shall give the inspected economic operator the possibility to submit comments.

Justification

It is important that the inspected entity is informed on the outcome of the inspection and has the possibility to make comments

Amendment 123
Proposal for a regulation
Article 67 – paragraph 5 c (new)

Text proposed by the Commission	*Amendment*
	5c. The Commission shall establish detailed guidelines on the principles for carrying out the checks referred to in this Article including in particular on the qualifications of inspectors, and on inspection arrangements and access to data and information held by economic operators.

Justification

Establishment of guidelines should create a harmonised approach of control activities in the

Union

Amendment 124
Proposal for a regulation
Article 78 – paragraph 7 a (new)

Text proposed by the Commission	*Amendment*
	7a. The MDCG shall establish a stakeholder dialogue group made up of stakeholders representatives organised at Union level. Such group shall act in parallel and work with the Medical Device Coordination Group (MDCG), advising the Commission and Member States on various aspects of medical technology and implementation of the Regulation.

Justification

It is important to maintain a stakeholder dialogue group allowing patients, healthcare professionals and industry to communicate with regulators.

Amendment 125
Proposal for a regulation
Article 80 – point b

Text proposed by the Commission	*Amendment*
(b) to ***contribute to the scrutiny of certain conformity assessments*** pursuant to Article 44;	(b) to ***provide a scientific assessment on certain types of medical devices*** pursuant to Article 44;

Justification

In accordance with Article 44.

Amendment 126
Proposal for a regulation
Article 80 a (new)

Text proposed by the Commission	*Amendment*
	Article 80a

Scientific Advisory Board

1. The Commission shall set up and provide the logistic support for a Scientific Advisory Board made up of not more than 15 scientific and/or clinical experts in the field of medical devices, appointed in their personal capacity by the MDCG.

2. When appointing these experts, the Commission shall ensure a broad, appropriate and balanced coverage of the medical disciplines relevant for medical devices, the publication of any interests which might affect the conduct of their work and the signature of a confidentiality clause. The Scientific Advisory Board may establish under its responsibility expert panels for specific medical disciplines. The Commission or the MDCG may request the Scientific Advisory Board to provide scientific advice on any issue related to the implementation of this Regulation

3. The Scientific Advisory Board shall appoint one chairperson and one vice chairperson from among its members for a term of three years, renewable once. In duly justified situations, the majority of its members may request the chairperson and/or vice-chairperson to resign.

4. The Scientific Advisory Board shall establish its rules of procedure which shall, in particular, lay down procedures for:

a) the functioning of expert panel;

b) the appointment and replacement of its chairperson and vice-chairperson,

c) the scientific assessment foreseen in Article 44, including in cases of urgency,

The rules of procedure shall enter into force after receiving a favourable opinion from the Commission.

Justification

The MDCG scientific assessment on clinical evaluation foreseen in art 44 should relies on an experts board. These experts will contribute to establish guidelines and common technical specifications addressed to manufacturers and accredited bodies for clinical evaluation and post-market follow-up in order to harmonize practices.

Amendment 127

Proposal for a regulation
Article 82 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Members of the MDCG and staff of the EU reference laboratories shall not have financial or other interests in the medical device industry which could affect their impartiality. They shall undertake to act in the public interest and in an independent manner. They shall declare any direct and indirect interests they may have in the medical device industry and update this declaration whenever a relevant change occurs. ***Upon request,*** the declaration of interests shall be ***accessible to the public. This Article shall not apply to the representatives of stakeholder organisations participating in the sub-groups of the MDCG***.	1. Members of the MDCG***, of the advisory panels to the MDCG*** and staff of the EU reference laboratories shall not have financial or other interests in the medical device industry which could affect their impartiality. They shall undertake to act in the public interest and in an independent manner. They shall declare any direct and indirect interests they may have in the medical device industry and update this declaration whenever a relevant change occurs. The declaration of interests shall be ***made publicly available on the European Commission web site***.

Amendment 128

Proposal for a regulation
Article 82 – paragraph 2

Text proposed by the Commission	*Amendment*
2. ***Experts and other third parties invited by the MDCG on a case-by-case basis*** shall be ***requested to declare their interests in the issue in question***.	2. ***Representative of stakeholder organizations participating in the sub-groups of the MDCG shall declare any direct and indirect interests they may have in the medical device industry and update***

this declaration whenever a relevant change occurs. The declaration of interests shall be ***made publicly available on the European Commission web site. This shall not apply to representatives of the medical devices industry***.

Amendment 129
Proposal for a regulation
Article 82 a (new)

Text proposed by the Commission	*Amendment*
	Article 82a
	Scientific advice
	1. The Commission shall facilitate the access of manufacturers of innovative devices concerned by the scientific assessment laid down in Article 44 to scientific advice provided by the Scientific Advisory Board or by an EU reference laboratory to information concerning the criteria for an appropriate assessment of the conformity of a device, in particular with regard to the clinical data required for the clinical evaluation.
	2. The scientific advice provided by the Scientific Advisory Board or by an EU reference laboratory shall not be binding.
	3. The Commission shall publish summaries of the scientific advice referred to in paragraph 1, providing that all information of commercial confidential nature have been deleted.

Justification

This advice should notably help manufacturers to conduct clinical evaluation in accordance with the state of the art and latest recommendations from the European experts group.

Amendment 130

Proposal for a regulation

Annex I – part II – point 7 – point 7.1 – point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) the physical compatibility where appropriate, between equivalent articles of the devices which consist of more than one implantable part;

Amendment 131

Proposal for a regulation
Annex I – part II – point 7 – point 7.4 – introductory part

Text proposed by the Commission	*Amendment*
7.4. The devices shall be designed and manufactured in such a way as to reduce as far as possible and appropriate the risks posed by substances that may leach or leak from the device. ***Special attention shall be given to*** substances which are carcinogenic, mutagenic or toxic to reproduction, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, ***and to*** substances having endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) .	7.4. The devices shall be designed and manufactured in such a way as to reduce as far as possible and appropriate the risks posed by substances that may leach or leak from the device. Substances which are carcinogenic, mutagenic or toxic to reproduction, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, ***shall be phased out within 8 years from the entry into force of this Regulation, unless no safer alternative substances are available. In the case that no safer alternatives exist, the manufacturer shall provide a specific justification for the use of these substances with regard to compliance with the general safety and performance requirements, within the technical documentation and, within the instructions for use, information on residual risks for these patient groups and, if applicable, on appropriate precautionary measures. Devices containing*** substances having endocrine

disrupting properties ***that come into contact with the body of patients and*** for which there is scientific evidence of probable serious effects to human health and which are identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) ***and in accordance with the endocrine disrupting substances' criteria set out in the report of the Endocrine Disrupters Expert Advisory Group shall be phased out within 8 years from the entry into force of this Regulation, unless no safer alternative substances are available. In the case that no safer alternatives exist, the manufacturer shall provide a specific justification for the use of these substances with regard to compliance with the general safety and performance requirements, within the technical documentation and, within the instructions for use, information on residual risks for these patient groups and, if applicable, on appropriate precautionary measures***.

Amendment 132

Proposal for a regulation
Annex I – part II – point 7 – point 7.4 – paragraph 1 – indent 3 – paragraph 1

Text proposed by the Commission	*Amendment*
contain, in a concentration of 0.1% by mass of the plasticised material or above, phthalates ***which are classified as carcinogenic, mutagenic or toxic to reproduction of category 1A or 1B in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008***, these ***devices*** shall be ***labelled on the device itself and/or on the packaging for each***	contain, in a concentration of 0.1% by mass of the plasticised material or above, phthalates, these ***substances*** shall be ***phased out within 8 years from the entry into force of this Regulation, unless no safer alternatives are available. In the case that no safer alternatives exist***, the manufacturer shall provide a specific justification for the use of these substances

unit or, where appropriate, on the sales packaging as devices containing phthalates. If the intended use of such devices includes treatment of children or treatment of pregnant or nursing women, the manufacturer shall provide a specific justification for the use of these substances with regard to compliance with the general safety and performance requirements, in particular of this paragraph, within the technical documentation and, within the instructions for use, information on residual risks for these patient groups and, if applicable, on appropriate precautionary measures.	with regard to compliance with the general safety and performance requirements, in particular of this paragraph, within the technical documentation and, within the instructions for use, information on residual risks for these patient groups and, if applicable, on appropriate precautionary measures. ***If the intended use of such devices includes treatment of children or treatment of pregnant or nursing women, phthalates should be banned as of 1st January 2020, unless the manufacturer can show that there are no suitable safer substances or devices without these substances. Where the manufacturer can show that there are no suitable safer substances or devices without these substances, these substances shall be labelled on the device itself and/or on the packaging for each unit as devices containing substances which are classified as CMRs 1A or 1B or as EDCs.***

Amendment 133
Proposal for a regulation
Annex I – section 19.2 – point a a (new)

Text proposed by the Commission	*Amendment*
	(aa) the mention "This product is a medical device".

Justification

A medical product should be clearly indentified as such on its label.

Amendment 134
Proposal for a regulation
Annex I – section 19.2 – point b

Text proposed by the Commission	*Amendment*
(b) The details strictly necessary for a user to identify the device, the contents of the packaging and, where it is not obvious for	(b) The details strictly necessary for a user to identify the device, the contents of the packaging and, where it is not obvious for

the user, the intended purpose of the device.	the user, the intended purpose of the device and ***where applicable that the device is only to be used during a single procedure.***

Justification

It should be clearly stated on the label if a device is of single use only.

Amendment 135

Proposal for a regulation
Annex IV – point 1 – introductory part

Text proposed by the Commission	*Amendment*
1. The CE marking shall consist of the initials ***'CE'*** taking the following form:	1. The CE marking shall consist of the initials ***'CE' accompanied by the term "Medical Device"*** taking the following form:

Amendment 136
Proposal for a regulation
Annex VI – Title

Text proposed by the Commission	*Amendment*
MINIMUM REQUIREMENTS TO BE MET BY NOTIFIED BODIES	REQUIREMENTS TO BE MET BY NOTIFIED BODIES

Amendment 137

Proposal for a regulation
Annex VII – part III – point 4 – point 4.2 – paragraph 1 – indent 1

Text proposed by the Commission	*Amendment*
– are intended to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in class III,	– are ***active devices*** intended ***specifically*** to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in class III,

Amendment 138

Proposal for a regulation
Annex VII – part III – point 4 – point 4.2 – paragraph 1 – indent 3

Text proposed by the Commission	*Amendment*
– are intended specifically ***for use in direct contact with*** the central nervous system, in which case they are in class III,	– are ***active devices*** intended specifically ***to control, diagnose, monitor or correct a defect of*** the central nervous system ***through direct contact with these parts of the body***, in which case they are in class III,

Amendment 139

Proposal for a regulation
Annex VII – part III – point 4 – point 4.3 – paragraph 1 – indent 1

Text proposed by the Commission	*Amendment*
– are intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in class III,	– are ***active devices*** intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in class III,

Amendment 140

Proposal for a regulation
Annex VII – part III – point 4 – point 4.3 – paragraph 1 – indent 2

Text proposed by the Commission	*Amendment*
– are intended specifically for use in direct contact with the central nervous system, in which case they are in class III,	– are ***active devices*** intended specifically for use in direct contact with the central nervous system, in which case they are in class III,

Amendment 141

Proposal for a regulation
Annex VII – part III – point 4 – point 4.4 – paragraph 1 – indent 8

Text proposed by the Commission	*Amendment*
– are spinal disc replacement implants ***and implantable devices that come into contact with the spinal column***, in which case they are in class III.	– are spinal disc replacement implants, in which case they are in class III.

Amendment 142
Proposal for a regulation
Annex VII – section 6.7

Text proposed by the Commission	*Amendment*
All devices incorporating or consisting of nanomaterial *are in* class III ***unless the nanomaterial is encapsulated or bound in such a manner that it cannot be released into the patient's or user's body when the device is used within its intended purpose.***	All devices incorporating or consisting of nanomaterial ***intended to be intentionally released in the human body*** are *classified as* class III.

Justification

The risk of the use of nanomaterials shall be taken into account in the risk assessment process. However, too many products with no serious concern for health may fall under this rule. Then the up-classification in Class III shall be made only when the use of nanomaterials is intentional and part of the intended use of the product.

Amendment 143

Proposal for a regulation
Annex VII – part III – point 6 – point 6.9 – paragraph 1

Text proposed by the Commission	*Amendment*
Devices that are composed of substances or combination of substances intended to be ingested, inhaled or administered rectally or vaginally and that are absorbed by ***or*** dispersed in the human body are in	Devices that are composed of substances or combination of substances ***primarily*** intended to be ingested, inhaled or administered rectally or vaginally and that are absorbed by ***and*** dispersed in the

class III.	human body ***in order to achieve their intended purpose*** are in class III.

Amendment 144
Proposal for a regulation
Annex VIII – section 3.2 - point d – indent 2

Text proposed by the Commission	*Amendment*
- the product identification procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture;	- the product identification ***and traceability*** procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture;

Justification

The traceability of the product and parts or components thereof within the development and production process is an integral part of the functioning of the quality assurance system and therefore of its evaluation.

Amendment 145
Proposal for a regulation
Annex VIII – section 4.4 – paragraph 1

Text proposed by the Commission	*Amendment*
The notified body shall randomly perform unannounced ***factory*** inspections ***to the manufacturer*** and, if appropriate***, at*** the manufacturer's suppliers and/or subcontractors, ***which may be combined with the periodic surveillance assessment referred to in Section 4.3. or be performed in addition to this surveillance assessment.*** The notified body shall establish a plan for the unannounced inspections which must not be disclosed to the manufacturer.	The notified body shall randomly perform ***at least once every five years and for each manufacturer and generic device group*** unannounced inspections ***at the relevant manufacturing sites*** and, if appropriate, at the manufacturer's suppliers and/or subcontractors, The notified body shall establish a plan for the unannounced inspections which ***shall not take a periodicity lower than one inspection per year and*** must not be disclosed to the manufacturer. ***At the time of such inspections, the notified body shall carry out the tests or ask to carry them in order to check that the quality management system is working properly. It shall provide the manufacturer with an***

inspection report and with a test report.

Justification

The number of unannounced inspections in section 4.4 has to be clearly defined in order to strengthen the necessary controls and to guarantee unannounced inspections at the same level and frequency in all member states. Therefore unannounced inspections should be performed at least once in a certification cycle and for each manufacturer and generic device group. Because of the vital importance of this instrument, the scope and procedures of the unannounced inspections should be stated in the Regulation itself instead of in down streamed rules such as an implementing act.

Amendment 146
Proposal for a regulation
Annex VIII – section 5.3 – paragraph 1

Text proposed by the Commission	*Amendment*
The notified body shall examine the application employing staff with proven knowledge and experience regarding the technology concerned. The notified body may require the application to be completed by further tests or other evidence to allow assessment of conformity with the requirements of the Regulation. The notified body shall carry out adequate physical or laboratory tests in relation to the device or request the manufacturer to carry out such tests.	The notified body shall examine the application employing staff with proven knowledge and experience regarding the technology concerned. ***The notified body shall ensure that the manufacturer's application adequately describes the design, manufacture and performance of the device, allowing assessment of whether the product conforms with the requirements set out in this Regulation. The notified bodies shall comment on the conformity of the following:*** ***- general description of the product,*** ***- design specifications, including a description of the solutions adopted to fulfil the essential requirements,*** ***- systematic procedures used for the design process and techniques used to control, monitor and verify the design of the device.*** The notified body may require the application to be completed by further tests or other evidence to allow assessment of conformity with the requirements of the Regulation. The notified body shall carry

	out adequate physical or laboratory tests in relation to the device or request the manufacturer to carry out such tests.

Justification

The requirements on the conformity assessment based on design dossier examination should be concretized and amended by taking over the already existing requirements regarding assessment of the application by the manufacturer describe in the voluntary code of conduct of Notify Bodies.

Amendment 147
Proposal for a regulation
Annex XIII – part A – point 5

Text proposed by the Commission	*Amendment*
5. In the case of implantable devices and devices falling within class III, clinical investigations shall be performed unless it is duly justified to rely on existing clinical data alone. Demonstration of equivalence in accordance with Section 4 ***shall generally*** not be considered as sufficient justification within the meaning of the first sentence of this paragraph.	5. In the case of implantable devices and devices falling within class III, clinical investigations shall be performed unless it is duly justified to rely on existing clinical data alone. ***For novel products,*** demonstration of equivalence in accordance with Section 4 ***shall*** not be considered as sufficient justification within the meaning of the first sentence of this paragraph. ***However, for iteration of devices already on the market and for which clinical data are available and for which the data from the post-market surveillance are not indicating any safety concerns, demonstration of equivalence may be considered as a sufficient justification. For devices submitted to the scientific assessment foreseen in this Regulation, demonstration of equivalence shall be assessed by the MDCG.***

Justification

The formulation "shall generally" is too vague. Cases where equivalence could be justified should be clarified in the text. However with the introduction in Article 44 of a systematic assessment on clinical data, it will be the responsibility of European experts to determine if equivalence is demonstrated or if clinical investigation is necessary.

Amendment 148

Proposal for a regulation
Annex XIII – part B – point 1

Text proposed by the Commission	*Amendment*
1. Post-market clinical follow-up, hereinafter: PMCF, is a continuous process to update the clinical evaluation referred to in Article 49 and Part A of this Annex and shall be part of the manufacturer's post-market surveillance plan. To this end, the manufacturer shall proactively collect and evaluate clinical data from the use in or on humans of a device which is authorised to bear the CE marking, within its intended purpose as referred to in the relevant conformity assessment procedure, with the aim of confirming the safety and performance throughout the expected lifetime of the device, the continued acceptability of identified risks and to detect emerging risks on the basis of factual evidence.	1. Post-market clinical follow-up, hereinafter: PMCF, is a continuous process to update the clinical evaluation referred to in Article 49 and Part A of this Annex and shall be part of the manufacturer's post-market surveillance plan. To this end, the manufacturer shall proactively collect***, register in the electronic system on vigilance referred to in Article 62*** and evaluate clinical data from the use in or on humans of a device which is authorised to bear the CE marking, within its intended purpose as referred to in the relevant conformity assessment procedure, with the aim of confirming the safety and performance throughout the expected lifetime of the device, the continued acceptability of identified risks and to detect emerging risks on the basis of factual evidence.

Amendment 149

Proposal for a regulation
Annex XIII – part B – point 3

Text proposed by the Commission	*Amendment*
3. The manufacturer shall analyse the findings of the PMCF and document the results in a PMCF evaluation report that shall be part of the technical documentation.	3. The manufacturer shall analyse the findings of the PMCF and document the results in a PMCF evaluation report that shall be part of the technical documentation ***and be sent periodically to the concerned Member States***.

Amendment 150

Proposal for a regulation
Annex XIII – part B – point 4

Text proposed by the Commission	*Amendment*
4. The conclusions of the PMCF evaluation report shall be taken into account for the clinical evaluation referred to in Article 49 and Part A of this Annex and in the risk management referred to in Section 2 of Annex I. If through the PMCF the need for corrective measures has been identified, the manufacturer shall implement them.	4. The conclusions of the PMCF evaluation report shall be taken into account for the clinical evaluation referred to in Article 49 and Part A of this Annex and in the risk management referred to in Section 2 of Annex I. If through the PMCF the need for corrective measures has been identified, the manufacturer shall implement them ***and inform the concerned Member States***.

Amendment 151

Proposal for a regulation
Annex XIV – part I – point 1 – paragraph 1

Text proposed by the Commission	*Amendment*
Every step in the clinical investigation, from first consideration of the need and justification of the study to the publication of the results, shall be carried out in accordance with recognised ethical principles, as for example those laid down in the World Medical Association Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects, adopted by the 18th World Medical Association General Assembly in Helsinki, Finland, in 1964, and last amended by the 59th World Medical Association General Assembly in Seoul, Korea, in 2008.	Every step in the clinical investigation, from first consideration of the need and justification of the study to the publication of the results, shall be carried out in accordance with recognised ethical principles, as for example those laid down in the World Medical Association Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects, adopted by the 18th World Medical Association General Assembly in Helsinki, Finland, in 1964, and last amended by the 59th World Medical Association General Assembly in Seoul, Korea, in 2008. ***Conformity with the above principles shall be granted after an examination by the concerned Ethics Committee.***

Amendment 152

Proposal for a regulation
Annex XIV – part I – point 2 – point 2.7

Text proposed by the Commission	*Amendment*
2.7. The clinical investigation report, signed by the medical practitioner or other authorised person responsible, shall contain ***a critical evaluation of all the*** data collected during the clinical investigation, including negative findings.	2.7. The clinical investigation report, signed by the medical practitioner or other authorised person responsible, shall contain ***all clinical*** data collected during the clinical investigation ***and a critical evaluation of such data***, including negative findings.

Amendment 153

Proposal for a regulation
Annex XV – point 4

Text proposed by the Commission	*Amendment*
4. Equipment for liposuction;	4. Equipment for liposuction ***and lipolysis***;

PROCEDURE

Title	Regulation on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009
References	COM(2012)0542 – C7-0318/2012 – 2012/0266(COD)
Committee responsible Date announced in plenary	ENVI 22.10.2012
Opinion by Date announced in plenary	IMCO 22.10.2012
Rapporteur Date appointed	Nora Berra 10.10.2012
Discussed in committee	20.3.2013 25.4.2013 29.5.2013
Date adopted	18.6.2013
Result of final vote	+: 32 –: 0 0: 4
Members present for the final vote	Claudette Abela Baldacchino, Pablo Arias Echeverría, Preslav Borissov, Jorgo Chatzimarkakis, Sergio Gaetano Cofferati, Birgit Collin-Langen, Lara Comi, Anna Maria Corazza Bildt, António Fernando Correia de Campos, Christian Engström, Evelyne Gebhardt, Małgorzata Handzlik, Malcolm Harbour, Toine Manders, Sirpa Pietikäinen, Phil Prendergast, Zuzana Roithová, Heide Rühle, Matteo Salvini, Christel Schaldemose, Andreas Schwab, Catherine Stihler, Róża Gräfin von Thun und Hohenstein, Gino Trematerra, Emilie Turunen, Bernadette Vergnaud, Barbara Weiler
Substitute(s) present for the final vote	Raffaele Baldassarre, Nora Berra, Jürgen Creutzmann, María Irigoyen Pérez, Roberta Metsola, Olle Schmidt, Marc Tarabella, Sabine Verheyen
Substitute(s) under Rule 187(2) present for the final vote	Marek Józef Gróbarczyk