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Committee on the Environment, Public Health and Food Safety

2012/0266(COD)

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AMENDMENTS
297 - 449

Draft report
Dagmar Roth-Behrendt
(PE507.972v02-00)

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

Proposal for a regulation
(COM(2012)0542 – C7-0318/2012 – 2012/0266(COD))

AM_Com_LegReport

Amendment 297
Milan Cabrnoch

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***

Or. cs

Amendment 298
Thomas Ulmer, Peter Liese

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***

Or. de

Amendment 299
Thomas Ulmer

Proposal for a regulation
Article 8 – paragraph 4 – subparagraph 2

Text proposed by the Commission	*Amendment*
Where the technical documentation is voluminous or held in different locations, the manufacturer shall provide, upon request by a competent authority, a summary technical documentation (STED) and grant access to the full technical documentation upon request.	***deleted***

Or. de

Justification

There is a need for specific clinical product standards – to be drawn up by independent experts for each category of high-risk medical products, in the form of an international compilation – on the criteria for evaluating new products, and also for recommendations as to the appropriate means of evaluating a new product before it is placed on the market.

Amendment 300
Corinne Lepage

Proposal for a regulation
Article 8 – paragraph 4 – subparagraph 2

Text proposed by the Commission	*Amendment*
Where the technical documentation is voluminous or held in different locations, the manufacturer shall provide, upon request by a competent authority, a summary technical documentation (STED) and grant access to the full technical documentation upon request.	***deleted***

Or. fr

Amendment 301
Gilles Pargneaux

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'. ***Post-market surveillance assessments and reports shall be drawn up by independent bodies.*** 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.

Or. fr

Justification

Post-market surveillance should be carried out by experienced, independent scientific experts with a view to ensuring full transparency.

Amendment 302
Marina Yannakoudakis

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'. ***Analysis and reporting of post-market surveillance shall also be conducted by independent organisations.*** 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.

Or. en

Amendment 303
Thomas Ulmer, Peter Liese

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	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.	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. ***The analysis and reporting of clinical follow-up should include reference to independent organisations.*** Where post-market clinical follow-up is not deemed necessary, this shall be duly justified and documented in the post-market surveillance plan.

Or. de

Justification

In the interests of transparency, independent scientific data should also be taken into account here.

Amendment 304
Corinne Lepage, Michèle Rivasi

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	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.	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'***, which shall be validated by the authorities responsible for granting or re-evaluating market authorisations, and be carried out by an independent authority which has in no way contributed to the device's market authorisation or the re-evaluation thereof***. 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.

Or. fr

Amendment 305
Gilles Pargneaux

Proposal for a regulation
Article 8 – paragraph 6 – subparagraph 2

Text proposed by the Commission	*Amendment*
If in the course of the post-market surveillance a need for corrective action is identified, the manufacturer shall implement the appropriate measures.	If in the course of the post-market surveillance a need for corrective action is identified, the manufacturer shall implement the appropriate measures***, including immediate notification to the European Databank on Medical Devices***

(Eudamed) established by means of Commission Decision 2010/227/EU of 19 April 2010.

Or. fr

Justification

It is important to ensure quick access to reports concerning complications or incidents caused by a device. Eudamed can be used to collect and publish all information relating to medical devices placed on the European market.

Amendment 306
Marina Yannakoudakis, Anna Rosbach

Proposal for a regulation
Article 8 – paragraph 6 – subparagraph 2

Text proposed by the Commission	*Amendment*
If in the course of the post-market surveillance a need for corrective action is identified, the manufacturer shall implement the appropriate measures.	If in the course of the post-market surveillance a need for corrective action is identified, the manufacturer shall implement the appropriate measures***, including the immediate reporting to the European databank on medical devices (Eudamed)set up by the Commission Decision 2010/227/EU***.

Or. en

Amendment 307
Nora Berra

Proposal for a regulation
Article 8 – paragraph 7

Text proposed by the Commission	*Amendment*
7. 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***	7. 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***. 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***.	language which can be easily understood by the intended user or patient***, as*** determined by the ***Member-State concerned***.

Or. en

Amendment 308
Milan Cabrnoch

Proposal for a regulation
Article 8 – paragraph 8

Text proposed by the Commission	*Amendment*
8. Manufacturers 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 take the necessary corrective action to bring that product into conformity, withdraw it or recall it, as appropriate. They shall inform the distributors and, where applicable, the authorised representative accordingly.	8. Manufacturers 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 take the necessary corrective action to bring that product into conformity, withdraw it or recall it, as appropriate. They shall inform the distributors***, the importers*** and, where applicable, the authorised representative accordingly.

Or. cs

Amendment 309
Thomas Ulmer

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	9. Manufacturers shall, in response to a reasoned request from a competent authority, ***a recognised medical institution or an association organised at European***

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.	***level,*** 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.

Or. de

Justification

Doctors are the primary users of medical devices. They should have access to all the technical and clinical data concerning a given medical device. Doctors and surgeons need such information in order to select, on criteria of efficiency and safety, the devices they want to use.

Amendment 310
Marina Yannakoudakis, Anna Rosbach

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, ***or from a legitimate health institution or association,*** 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.

Or. en

Justification

Medical doctors are the primary users of medical devices. They should have access to all technical and clinical data related to a medical device.

Amendment 311
Corinne Lepage

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***, consumers' association, patients' association or professional healthcare association,*** 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 ***or association***. ***Where this involves an 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. ***Where this involves an association, all information exchanged in respect of the request shall be notified to the competent authority.***

Or. fr

Amendment 312
Andrés Perelló Rodríguez

Proposal for a regulation
Article 8 – paragraph 9

Text proposed by the Commission	*Amendment*
9. Manufacturers shall, in response to a	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.	reasoned request from a competent authority ***or a medical association or institution***, 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 ***the applicant***. They shall cooperate with ***the competent*** 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.

Or. es

Amendment 313
Michèle Rivasi, Corinne Lepage

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 there is evidence to assume that a medical device has caused damage, the potentially harmed user, his successor in title, his compulsory health insurance or other third parties affected by the damage may also demand the information referred to in sentence 1 from the manufacturer or his authorised representative.*** ***This right to information shall also exist, subject to the conditions set forth in***

sentence 1, against the competent authorities of the Member States which are responsible for the surveillance of the respective medical device, as well as against any notified body that issued a certificate pursuant to Article 45 or was otherwise involved in the conformity assessment procedure of the medical device in question.

Or. en

Justification

In the past, users harmed by a device have lacked access to information that would demonstrate the defectiveness of the medical device that caused the damage. This new right to information would redress the balance to the benefit of users.

Amendment 314
Nora Berra

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.

Or. en

Amendment 315
Jolanta Emilia Hibner, Elżbieta Katarzyna Łukacijewska

Proposal for a regulation
Article 8 – paragraph 10 a (new)

Text proposed by the Commission	*Amendment*
	10 a. The manufacturer of the product is responsible for the product, for carrying out a conformity assessment procedure on the product prior to placing it on the market, and for placing the product on the market. If the manufacturer is not resident or established in a Member State, an authorised representative shall bear responsibility for the product. If the manufacturer has not designated an authorised representative, or if the manufacturer or authorised representative is not responsible for placing the product on the market, responsibility shall be borne by the entity that placed the product on the market.

Or. pl

Justification

Obecnie stosowana jest koncepcja, że za wyrób odpowiada wytwórca. W przypadku wytwórcy mającego swoją siedzibę w państwie trzecim, dalej jest on odpowiadzialny za wyrób, bo autoryzowany przedstawiciel zajmuje się tylko przekazywaniem informacji wytwórcy. W tej sytuacji bardzo ciężko prowadzi się postępowania wyjaśniające, nie mówiąc już o ewentualnych roszczeniach europejczyków za ewentualne szkody wyrządzone przez wyroby. Brak podmiotu odpowiedzialnego za wyrób wprowadzony do obrotu na rynku europejskim sprawia, że osoby które ucierpiały w skutek wadliwego wyrobu, nie mogą dochodzić naprawienia szkody.

Amendment 316
Nora Berra

Proposal for a regulation
Article 8 – paragraph 10 a (new)

Text proposed by the Commission	*Amendment*
	10a. Manufacturers shall have an appropriate liability insurance covering any damages that may be caused by their medical devices to patients or users. That insurance shall at least cover damage in the following cases:
	(a) in the event of the death of or injury to patient or user; or,
	(b) in the event of the death of or injury to multiple patients or users due to the use of the same medical device.

Or. en

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 317
Marina Yannakoudakis, Anna Rosbach

Proposal for a regulation
Article 8 – paragraph 10 a (new)

Text proposed by the Commission	*Amendment*
	10a. Manufacturers shall have an appropriate liability insurance covering any damages that may be caused by their medical devices to patients, users or third parties. That insurance shall at least cover

damage in the following cases:

(a) in the event of the death of or injury to a patient, user or a third party; or,

(b) in the event of the death of or injury to multiple patients or users or other third parties due to the use of the same medical device.

Or. en

Amendment 318
Michèle Rivasi, Corinne Lepage

Proposal for a regulation
Article 8 – paragraph 10 a (new)

Text proposed by the Commission	*Amendment*
	10a. A manufacturer may only place a medical device on the market if he has made sufficient provisions to ensure that he can meet its statutory obligations to provide compensation for damage that occurs due to the application of a medical device he has placed on the market. The insurance must cover the patient:
	(a) in the event of the death of or injury to a person,
	(b) in the event of the death of or injury to multiple persons due to the same medical device.
	The provision must be made in the form of taking out third party liability insurance with an insurance company authorised to do business, which is domiciled in a Member State of the European Union, in another signatory to the Agreement on the European Economic Area or in a country that is recognised as equivalent by the European Commission on the basis of Article 172 of Directive 2009/138/EC on the taking-up and pursuit of the business of Insurance

and Reinsurance (Solvency II).

Claims for damages can also be asserted directly against the insurer. Such a claim is subject to the same limitation period as the damages claim against the manufacturer based on product liability law.

Or. en

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 and of the manufacturer's insolvency, to the patients harmed by medical devices and the payers liable for the cost of treatment. In accordance with the rules in force in the area of medicinal products, the manufacturers of MD should also have to take out liability insurance with appropriate minimum sums for the coverage.

Amendment 319
Andrés Perelló Rodríguez

Proposal for a regulation
Article 8 – paragraph 10 a (new)

Text proposed by the Commission	*Amendment*
	10a. Manufacturers of medical devices must be covered by an insurance policy or equivalent financial guarantee to meet claims for health damage arising from unsafe medical devices.
	Manufacturers shall bear the cost to the health system of treatment, operations and diagnostic procedures practiced on patients as a result of defects in or malfunctioning of health devices detected by the health authorities or the manufacturers themselves.
	They shall also bear the cost of withdrawing, repairing or replacing the products involved in these situations.

Or. es

Justification

Recent incidents involving fraudulent breast implants, in which patients have had to undergo corrective surgery and other expensive treatments to monitor or diagnose their condition, have highlighted the need for a legal clause requiring manufacturers to have insurance to coverf damages to patients and the costs incurred by the health service.

Amendment 320
Pilar Ayuso, Cristina Gutiérrez-Cortines

Proposal for a regulation
Article 8 – paragraph 10 a (new)

Text proposed by the Commission	*Amendment*
	10a. Manufacturers of medical devices must be covered by an insurance policy or equivalent financial guarantee to meet claims for health damage arising from unsafe medical devices.

Or. es

Justification

Recent incidents involving fraudulent breast implants, in which patients have had to undergo corrective surgery and other expensive treatments to monitor or diagnose their condition, have highlighted the need for a legal clause requiring manufacturers to have insurance to coverf damages to patients and the costs incurred by the health service.

Amendment 321
Pilar Ayuso, Cristina Gutiérrez-Cortines

Proposal for a regulation
Article 8 – paragraph 10 b (new)

Text proposed by the Commission	*Amendment*
	10b. Manufacturers shall bear the cost to the health system of treatment, operations and diagnostic procedures practiced on patients as a result of defects in or malfunctioning of health devices detected by the health authorities or the

manufacturers themselves.

They shall also bear the cost of withdrawing, repairing or replacing the products involved in these situations.

Or. es

Justification

Recent incidents involving fraudulent breast implants, in which patients have had to undergo corrective surgery and other expensive treatments to monitor or diagnose their condition, have highlighted the need for a legal clause requiring manufacturers to have insurance to coverf damages to patients and the costs incurred by the health service.

Amendment 322
Corinne Lepage

Proposal for a regulation
Article 11 – paragraph 2 – subparagraph 1 – introductory part

Text proposed by the Commission	*Amendment*
Before placing a device on the market importers shall ensure the following:	Before placing a device on the market importers shall ensure the following:
	that the manufacturer is identifiable and has the technical, scientific and financial capacity to produce a medical device compliant with this Regulation, and that importers make available to the national authorities and on their website a report on the investigation procedures attesting to the expertise of the manufacturer.

Or. fr

Amendment 323
Nora Berra

Proposal for a regulation
Article 11 – paragraph 2 – subparagraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) that an authorised representative in	(b) ***that the manufacturer is identified and***

accordance with Article 9 has been designated by the manufacturer***;***	that an authorised representative in accordance with Article 9 has been designated by the manufacturer

Or. en

Amendment 324
Nora Berra

Proposal for a regulation
Article 11 – paragraph 2 – subparagraph 1 – 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.

Or. en

Amendment 325
Michèle Rivasi, Corinne Lepage

Proposal for a regulation
Article 11 – paragraph 2 – subparagraph 1 – point f a (new)

Text proposed by the Commission	*Amendment*
	(fa) that the manufacturer has taken out adequate insurance coverage pursuant to Article 8 paragraph 10a (new), unless the importer himself ensures coverage that meets the requirements of this provision.

Or. en

Justification

If the medical device is imported by an importer from a third country, it must likewise be guaranteed by means of liability insurance that the damage caused by defective medical

devices can actually be compensated.

Amendment 326
Milan Cabrnoch

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 his authorised representative. 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.

Or. cs

Amendment 327
Nora Berra

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	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***

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***.

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***.

Or. en

Amendment 328
Corinne Lepage

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 his authorised representative and, if appropriate, take the necessary corrective action to bring that device into conformity, withdraw or recall it. ***They*** shall also immediately inform the competent authorities of ***all*** Member States ***and EU notified bodies, specifying the identity of the manufacturer and whether it is part of a group of companies, so that the competent authorities can investigate all the products produced by the manufacturer and the group to which it belongs***.

Or. fr

Amendment 329
Milan Cabrnoch

Proposal for a regulation
Article 11 – paragraph 9

Text proposed by the Commission	*Amendment*
9. Importers shall, for the period referred to in Article 8(4), keep a copy of the EU declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation and, if applicable, a copy of the relevant certificate including any supplement, issued in accordance with Article 45, can be made available to those authorities, upon request. ***By written mandate, the importer and the authorised representative for the device in question may agree that this obligation is delegated to the authorised representative.***	9. Importers shall, for the period referred to in Article 8(4), keep a copy of the EU declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation and, if applicable, a copy of the relevant certificate including any supplement, issued in accordance with Article 45, can be made available to those authorities, upon request ***to the manufacturer or his authorised representative***.

Or. cs

Amendment 330
Milan Cabrnoch

Proposal for a regulation
Article 11 – paragraph 10

Text proposed by the Commission	*Amendment*
10. Importers shall, in response to a request from a competent national authority, ***provide it with*** all the information and documentation necessary to demonstrate the conformity of a product. This obligation shall be considered fulfilled when the authorised representative for the device in question provides the required information. Importers shall cooperate with a competent national authority, at its request, on any action taken to eliminate	10. Importers shall, in response to a request from a competent national authority, ***forward*** all the information and documentation necessary to demonstrate the conformity of a product ***from the manufacturer or his authorised representative***. This obligation shall be considered fulfilled when ***the manufacturer or, where possible,*** the authorised representative for the device in question provides the required information.

the risks posed by products which they have placed on the market.	Importers shall cooperate with a competent national authority, at its request, on any action taken to eliminate the risks posed by products which they have placed on the market.

Or. cs

Amendment 331
Anja Weisgerber, Thomas Ulmer

Proposal for a regulation
Article 12 – paragraph 2 – subparagraph 1 – introductory part

Text proposed by the Commission	*Amendment*
Before making a device available on the market distributors shall verify that the following requirements are met:	Before making a device available on the market ***for the first time,*** distributors shall verify that the following requirements are met:

Or. de

Justification

Distributors are responsible for product safety in the supply chain. Responsibility for the safety of a medical device or the completeness of the documentation in relation to it falls to manufacturers or importers.

Amendment 332
Anja Weisgerber, Thomas Ulmer

Proposal for a regulation
Article 12 – paragraph 2 – subparagraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) the product is accompanied by the information to be supplied by the manufacturer in accordance with Article 8(7);	(b) ***in the absence of a manufacturer's or importer's declaration of conformity,*** the product is accompanied by the information to be supplied by the manufacturer in accordance with Article 8(7);

Or. de

Justification

Distributors are responsible for product safety in the supply chain. Responsibility for the safety of a medical device or the completeness of the documentation in relation to it falls to manufacturers or importers.

Amendment 333
Anja Weisgerber, Thomas Ulmer

Proposal for a regulation
Article 12 – paragraph 2 – subparagraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) the manufacturer and, where applicable, the importer have complied with the requirements set out in Article 24 and Article 11(3) respectively.	(c) the manufacturer and, where applicable, the importer have complied with the requirements set out in Article 11(3).

Or. de

Justification

Distributors are responsible for product safety in the supply chain. Responsibility for the safety of a medical device or the completeness of the documentation in relation to it falls to manufacturers or importers.

Amendment 334
Holger Krahmer

Proposal for a regulation
Article 12 – paragraph 2 – subparagraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) the manufacturer and, where applicable, the importer have complied with the requirements set out in Article ***24 and Article*** 11(3) respectively.	(c) the manufacturer and, where applicable, the importer have complied with the requirements set out in Article 11(3) respectively.

Or. en

Justification

It will not be possible for most distributors (like pharmacists) to ensure that manufacturers have complied with their traceability obligations. To take one example, Article 24 (5) requires manufacturers to store device identifiers. Pharmacists could not ensure compliance with this without access to the manufacturer's database.

Amendment 335
Philippe Juvin

Proposal for a regulation
Article 12 – paragraph 2 – subparagraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) the manufacturer and, where applicable, the importer have complied with the requirements set out in Article ***24 and Article*** 11(3) ***respectively***.	(c) the manufacturer and, where applicable, the importer have complied with the requirements set out in Article 11(3) ***and whether the product in question contains a UDI, as referred to in Article 24(1)(a)***.

Or. fr

Amendment 336
Gilles Pargneaux

Proposal for a regulation
Article 12 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Distributors who consider or have reason to believe that a device which they have made available on the market is not in conformity with this Regulation shall immediately inform the manufacturer and, where applicable, his authorised representative and the importer and make sure that the necessary corrective action to bring that device into conformity, withdraw or recall it, if appropriate, is taken. Where the device presents a risk, they shall also immediately inform the competent authorities of the Member States	4. Distributors who consider or have reason to believe that a device which they have made available on the market is not in conformity with this Regulation shall immediately inform the manufacturer and, where applicable, his authorised representative and the importer and make sure***, within the scope of their respective activities,*** that the necessary corrective action to bring that device into conformity, withdraw or recall it, if appropriate, is taken. Where the device presents a risk, they shall also immediately inform the

in which they made the device available, giving details, in particular, of the non-compliance and of any corrective action taken.	competent authorities of the Member States in which they made the device available, giving details, in particular, of the non-compliance and of any corrective action taken.

Or. fr

Justification

The proposal does not distinguish between the different roles and responsibilities of actors in the supply chain for medical devices. Under the Commission text, all distributors would have the same obligations, some of which could be difficult to fulfil. This amendment has been tabled in order to forge meaningful links between the obligation and the activity carried out by the distributor, in line with the approach adopted in Article 19(2) of Regulation (EC) No 178/2002 on food security.

Amendment 337
Anja Weisgerber, Thomas Ulmer

Proposal for a regulation
Article 12 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Distributors who consider or have reason to believe that a device which they have made available on the market is not in conformity with this Regulation shall immediately inform the manufacturer and, where applicable, his authorised representative and the importer and make sure that the necessary corrective action to bring that device into conformity, withdraw or recall it, if appropriate, is taken. 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, giving details, in particular, of the non-compliance and of any corrective action taken.	4. Distributors who consider or have reason to believe that a device which they have made available on the market is not in conformity with this Regulation shall immediately inform the manufacturer and, where applicable, his authorised representative and the importer and make sure***, within their field of operations,*** that the necessary corrective action to bring that device into conformity, withdraw or recall it, if appropriate, is taken. 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, giving details, in particular, of the non-compliance and of any corrective action taken.

Or. de

Justification

Distinctions need to be drawn between the various kinds of participant in the supply chain.

Amendment 338
Holger Krahmer

Proposal for a regulation
Article 12 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Distributors who consider or have reason to believe that a device which they have made available on the market is not in conformity with this Regulation shall immediately inform the manufacturer and, where applicable, his authorised representative and the importer and make sure that the necessary corrective action to bring that device into conformity, withdraw or recall it, if appropriate, is taken. 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, giving details, in particular, of the non-compliance and of any corrective action taken.	4. Distributors who consider or have reason to believe that a device which they have made available on the market is not in conformity with this Regulation shall immediately inform the manufacturer and, where applicable, his authorised representative and the importer and make sure that***, within the limits of its respective activities,*** the necessary corrective action to bring that device into conformity, withdraw or recall it, if appropriate, is taken. 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, giving details, in particular, of the non-compliance and of any corrective action taken.

Or. en

Justification

The proposal does not distinguish between the different roles and responsibilities of the stakeholders involved in the supply chain of medical devices. All distributors would have the same obligations, some of which would be in practice unworkable, e.g. it would be impossible for distributors to organise a recall of a device. The obligation for the distributors should be linked to the activity carried out by the distributor.

Amendment 339
Marina Yannakoudakis

Proposal for a regulation
Article 12 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Distributors who consider or have reason to believe that a device which they have made available on the market is not in conformity with this Regulation shall immediately inform the manufacturer and, where applicable, his authorised representative and the importer and make sure that the necessary corrective action to bring that device into conformity, withdraw or recall it, if appropriate, is taken. 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, giving details, in particular, of the non-compliance and of any corrective action taken.	4. Distributors who consider or have reason to believe that a device which they have made available on the market is not in conformity with this Regulation shall immediately inform the manufacturer and, where applicable, his authorised representative and the importer and make sure that***, within the limits of its respective activities,*** the necessary corrective action to bring that device into conformity, withdraw or recall it, if appropriate, is taken. 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, giving details, in particular, of the non-compliance and of any corrective action taken.

Or. en

Justification

The proposal does not distinguish between the different roles and responsibilities of the stakeholders involved in the supply chain of medical devices.

Amendment 340
Philippe Juvin

Proposal for a regulation
Article 12 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Distributors who consider or have reason to believe that a device which they have made available on the market is not in conformity with this Regulation shall immediately inform the manufacturer and, where applicable, his authorised	4. Distributors who consider or have reason to believe that a device which they have made available on the market is not in conformity with this Regulation shall immediately inform the manufacturer and, where applicable, his authorised

representative ***and*** the importer ***and*** make sure that the necessary corrective action to bring that device into conformity, withdraw or recall it, if appropriate, is taken. 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, giving details, in particular, of the non-compliance and of any corrective action taken.	representative***,*** the importer ***and the notified body responsible for monitoring the product if it is a class IIa, IIb or III medical device, and the competent national authority. They shall*** make sure***, within the scope of their respective activities,*** that the necessary corrective action to bring that device into conformity, withdraw or recall it, if appropriate, is taken. 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, ***as well as the notified body responsible for evaluating the device if it is a class IIa, IIb or III product,*** giving details, in particular, of the non-compliance and of any corrective action taken.

Or. fr

Amendment 341
Milan Cabrnoch

Proposal for a regulation
Article 12 – paragraph 6

Text proposed by the Commission	*Amendment*
6. Distributors shall, in response to a request from a competent authority, ***provide it*** with all the information and documentation necessary to demonstrate the conformity of a device. This obligation shall be considered fulfilled when the authorised representative for the device in question, where applicable, provides the required information. Distributors shall cooperate with competent national authorities, at their request, on any action taken to eliminate the risks posed by devices which they have made available on the market.	6. Importers shall, in response to a request from a competent ***national*** authority, ***forward*** all the information and documentation necessary to demonstrate the conformity of a product ***from the manufacturer or his authorised representative***. This obligation shall be considered fulfilled when ***the manufacturer or, where possible,*** the authorised representative for the device in question provides the required information. Distributors shall cooperate with competent national authorities, at their request, on any action taken to eliminate the risks posed by devices which they have made available on the market.

Or. cs

Amendment 342
Holger Krahmer

Proposal for a regulation
Article 13 – title

Text proposed by the Commission	*Amendment*
Person responsible for ***regulatory*** compliance	Person responsible for compliance

Or. en

Justification

The role and responsibilities may be shared between several persons responsible for regulatory, production or quality assurance compliance.

Amendment 343
Holger Krahmer

Proposal for a regulation
Article 13 – paragraph 1 – subparagraph 1 – introductory part

Text proposed by the Commission	*Amendment*
Manufacturers shall have available within their organisation at least one ***qualified*** person who possesses ***expert knowledge*** in the field of medical devices. The ***expert knowledge*** shall be demonstrated by ***either of the following qualifications:***	Manufacturers shall have available within their organisation at least one person ***responsible for compliance*** who possesses ***expertise*** in the field of medical devices. The ***expertise*** shall be demonstrated by ***a diploma, certificate or other evidence of formal qualification awarded on completion of a university degree or of an equivalent course of study, in natural sciences, medicine, pharmacy, engineering or another relevant discipline necessary to fulfil the tasks laid down in paragraph 2 points (a) and (b) of this article.***

Or. en

Justification

These requirements would represent a major hurdle for small and medium enterprises highly represented in the medical devices sector.

Amendment 344
Thomas Ulmer

Proposal for a regulation
Article 13 – paragraph 1 – subparagraph 1 – introductory part

Text proposed by the Commission	*Amendment*
Manufacturers shall have available within their organisation at least one qualified person who possesses ***expert knowledge*** in the field of medical devices. The ***expert knowledge*** shall be demonstrated by either of the following qualifications:	Manufacturers shall have available within their organisation at least one qualified person who possesses ***the requisite expertise*** in the field of medical devices. The ***requisite expertise*** shall be demonstrated by either of the following qualifications:

Or. de

Amendment 345
Holger Krahmer

Proposal for a regulation
Article 13 – paragraph 1 – subparagraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) a diploma, certificate or other evidence of formal qualification awarded on completion of a university degree or of an equivalent course of study, in natural sciences, medicine, pharmacy, engineering or another relevant discipline, and at least two years of professional experience in regulatory affairs or in quality management systems relating to medical devices;	***deleted***

Or. en

Justification

These requirements would represent a major hurdle for small and medium enterprises highly represented in the medical devices sector.

Amendment 346
Thomas Ulmer

Proposal for a regulation
Article 13 – paragraph 1 – subparagraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) a diploma, certificate or other evidence of formal qualification awarded on completion of a university degree or of an equivalent course of study, in natural sciences, medicine, pharmacy, engineering or another relevant discipline, and at least two years of professional experience in regulatory affairs or in quality management systems relating to medical devices;	***deleted***

Or. de

Amendment 347
Anna Rosbach

Proposal for a regulation
Article 13 – paragraph 1 – subparagraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) a diploma, certificate or other evidence of formal qualification awarded on completion of a university degree or of an equivalent course of study, in natural sciences, medicine, pharmacy, engineering or another relevant discipline, and at least ***two*** years of professional experience in regulatory affairs or in quality management	(a) a diploma, certificate or other evidence of formal qualification awarded on completion of a university degree or of an equivalent course of study ***at university level***, in natural sciences, medicine, pharmacy, engineering or another relevant discipline, and at least ***five*** years of professional experience in regulatory

systems relating to medical devices;	affairs or in quality management systems relating to medical devices;

Or. en

Justification

It must be ensured that the diploma or certificate of the qualified person is on a sufficiently high level. Furthermore two years of industry experience does not guarantee a sufficient level of "expert knowledge".

Amendment 348
Thomas Ulmer

Proposal for a regulation
Article 13 – paragraph 1 – subparagraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) ***a diploma, certificate or other evidence of formal qualification awarded on completion of a university degree or of an equivalent course of study, in natural sciences, medicine, pharmacy, engineering or another relevant discipline, and at least two years of professional experience in regulatory affairs or in quality management systems relating to medical devices;***	(a) ***a certificate awarded on completion of a university degree in natural sciences, medicine or technology, or***

Or. de

Amendment 349
Peter Liese

Proposal for a regulation
Article 13 – paragraph 1 – subparagraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) a diploma, certificate or other evidence of formal qualification awarded on completion of a university degree or of an	(a) a diploma, certificate or other evidence of formal qualification awarded on completion of a university degree or of an

equivalent course of study, in natural sciences, medicine, pharmacy, engineering or another relevant discipline***, and at least two years of professional experience in regulatory affairs or in quality management systems relating to medical devices***;	equivalent course of study, in natural sciences, medicine, pharmacy, engineering or another relevant discipline;

Or. en

Justification

The institution of a qualified person doesn't exist in the current directive. It imposes new burden for companies, especially for SMEs. This is necessary but we should not go further than the situation in the more advanced member states.

Amendment 350
Holger Krahmer

Proposal for a regulation
Article 13 – paragraph 1 – subparagraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) five years of professional experience in regulatory affairs or in quality management systems relating to medical devices.	***deleted***

Or. en

Justification

These requirements would represent a major hurdle for small and medium enterprises highly represented in the medical devices sector.

Amendment 351
Thomas Ulmer

Proposal for a regulation
Article 13 – paragraph 1 – subparagraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) five years of professional experience in regulatory affairs or in quality management systems relating to medical devices.	***deleted***

Or. de

Amendment 352
Anna Rosbach

Proposal for a regulation
Article 13 – paragraph 1 – subparagraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) ***five*** years of professional experience in regulatory affairs or in quality management systems relating to medical devices.	(b) ***ten*** years of professional experience in regulatory affairs or in quality management systems relating to medical devices ***as well as a proven in-depth knowledge of both the therapeutic area and the product type(s) concerned***.

Or. en

Amendment 353
Thomas Ulmer

Proposal for a regulation
Article 13 – paragraph 1 – subparagraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) ***five years of*** professional experience ***in regulatory affairs or in quality management systems relating to medical devices***.	(b) ***an educational qualification attesting to competence to perform the tasks listed in paragraph 2 and at least two years' professional experience. Proof of expertise must be supplied on request to the authorities responsible.***

Or. de

Amendment 354
Peter Liese

Proposal for a regulation
Article 13 – paragraph 1 – subparagraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) ***five*** years of professional experience in regulatory affairs or in quality management systems relating to medical devices.	(b) ***two*** years of professional experience in regulatory affairs or in quality management systems relating to medical devices.

Or. en

Justification

The institution of a qualified person doesn't exist in the current directive. It imposes new burden for companies, especially for SMEs. This is necessary but we should not go further than the situation in the more advanced member states.

Amendment 355
Pat the Cope Gallagher

Proposal for a regulation
Article 13 – paragraph 1 – subparagraph 1 – point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) a recognised professional title awarded following successful assessment of competence to practice the profession of engineering in the field of medical device or production.

Or. en

Justification

The inclusion of a professional registered title provides greater assurances to make sure that the qualified person is suitably competent as the expert required within the legislation. One example of this professional registration would be the achievement by the qualified person of the national requirements for Eur Ing designation, the EU wide professional registered engineering qualification.

Amendment 356
Marina Yannakoudakis

Proposal for a regulation
Article 13 – paragraph 1 – subparagraph 1 – point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) An agreed set of skills and competencies decided by competent national authorities, which are relevant to the product area in which the qualified person is operating.

Or. en

Amendment 357
Holger Krahmer

Proposal for a regulation
Article 13 – paragraph 1 – subparagraph 2

Text proposed by the Commission	*Amendment*
Without prejudice to national provisions regarding professional qualifications, manufacturers of custom-made devices may demonstrate their expert knowledge referred to in the first subparagraph by at least two years of professional experience within the relevant field of manufacture.	Without prejudice to national provisions regarding professional qualifications, manufacturers of custom-made devices may demonstrate their expert knowledge referred to in the first subparagraph by at least two years of professional experience within the relevant field of manufacture. ***Gaining a qualification to run a business and to train apprentices shall, in particular, be deemed to constitute proof of professional experience.***

Or. de

Justification

With regard to the requisite level of qualification under the rules concerning persons responsible, it should be specified that persons who have gained a master craftsman's diploma for health professionals shall continue to be entitled to open and run a business as a

manufacturer of custom-made devices without being subject to further requirements.

Amendment 358
Thomas Ulmer

Proposal for a regulation
Article 13 – paragraph 1 – subparagraph 2

Text proposed by the Commission	*Amendment*
Without prejudice to national provisions regarding professional qualifications, manufacturers of custom-made devices may demonstrate their ***expert knowledge*** referred to in the first ***subparagraph*** by at least two years of professional experience within the relevant field of manufacture.	Without prejudice to national provisions regarding professional qualifications, manufacturers of custom-made devices may demonstrate their ***expertise*** referred to in the first ***sentence*** by at least two years of professional experience within the relevant field of manufacture.

Or. de

Amendment 359
Marina Yannakoudakis

Proposal for a regulation
Article 13 – paragraph 1 – subparagraph 3

Text proposed by the Commission	*Amendment*
This paragraph shall not apply to manufacturers of custom-made devices who are micro-enterprises as defined by Commission Recommendation 2003/361/EC**.**	This paragraph shall not apply to manufacturers of custom-made devices who are ***registered pharmacies, or*** micro-enterprises as defined by Commission Recommendation 2003/361/EC

Or. en

Amendment 360
Holger Krahmer

Proposal for a regulation
Article 13 – paragraph 1 – subparagraph 3

Text proposed by the Commission	*Amendment*
This paragraph shall not apply to manufacturers of custom-made devices who are micro-enterprises as defined by Commission Recommendation 2003/361/EC.	This paragraph shall not apply to manufacturers of custom-made devices who are ***registered pharmacies, or*** micro-enterprises as defined by Commission Recommendation 2003/361/EC.

Or. en

Justification

Pharmacies manufacture some custom made medical devices such some creams, powders and plasters. They undergo extensive training in pharmaceutical preparation during their formal education followed by application of this knowledge during the obligatory training period. The two year experience requirement is excessive, and may reduce the capacity of pharmacies to undertake this essential activity.

Amendment 361
Holger Krahmer

Proposal for a regulation
Article 13 – paragraph 2 – introductory part

Text proposed by the Commission	*Amendment*
2. The ***qualified person*** shall at least be responsible for ensuring the following matters:	2. The ***person responsible for compliance*** shall at least be responsible for ensuring the following matters:

Or. en

Justification

The role and responsibilities may be shared between several persons responsible for regulatory, production or quality assurance compliance.

Amendment 362
Holger Krahmer

Proposal for a regulation
Article 13 – paragraph 2 – point b

Text proposed by the Commission	*Amendment*
(b) that the technical documentation and the declaration of conformity are drawn up and kept up-to-date;	***deleted***

Or. en

Justification

The technical documentation and the declaration of conformity are part of the general obligations of the manufacturer.

Amendment 363
Thomas Ulmer

Proposal for a regulation
Article 13 – paragraph 2 – point b

Text proposed by the Commission	*Amendment*
(b) that the ***technical documentation and the declaration of conformity are drawn up and kept up-to-date***;	(b) that the ***reporting obligations in accordance with Articles 61 to 66 are fulfilled***;

Or. de

Amendment 364
Anna Rosbach

Proposal for a regulation
Article 13 – paragraph 2 – point c

Text proposed by the Commission	*Amendment*
(c) that the reporting obligations in accordance with Articles 61 to 66 are fulfilled;	(c) that the reporting obligations in accordance with Articles ***59 and*** 61 to 66 are fulfilled;

Or. en

Justification

This will include responsibilities on reporting serious adverse events

Amendment 365
Thomas Ulmer

Proposal for a regulation
Article 13 – paragraph 2 – point d

Text proposed by the Commission	*Amendment*
(d) in the case of investigational devices, that the statement referred to in point 4.1 of Chapter II of Annex XIV is issued.	***deleted***

Or. de

Amendment 366
Holger Krahmer

Proposal for a regulation
Article 13 – paragraph 2 – point d

Text proposed by the Commission	*Amendment*
(d) ***in the case of investigational devices, that the statement referred to in*** point ***4.1 of Chapter II of Annex XIV is issued***.	(d) ***Where more than one person responsible for compliance is responsible for ensuring the matters pursuant to*** point ***(a) of this paragraph, the corresponding duties shall be recorded in a written form***.

Or. en

Justification

The technical documentation and the declaration of conformity are part of the general obligations of the manufacturer.

Amendment 367
Anna Rosbach, Marina Yannakoudakis

Proposal for a regulation
Article 13 – paragraph 2 – point d

Text proposed by the Commission	*Amendment*
(d) in the case of investigational devices, that the statement referred to in point 4.1 of Chapter II of Annex XIV is issued.	(d) in the case of investigational devices, that the statement referred to in point 4.1 of Chapter II of Annex XIV is issued ***and the obligations on Serious Adverse Events reporting are fulfilled***.

Or. en

Amendment 368
Thomas Ulmer

Proposal for a regulation
Article 13 – paragraph 2 – subparagraph 1 (new)

Text proposed by the Commission	*Amendment*
	If a number of qualified persons are jointly responsible in respect of the provision in the first sentence, their respective areas of responsibility shall be stipulated in writing.

Or. de

Amendment 369
Holger Krahmer

Proposal for a regulation
Article 13 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The ***qualified*** person shall suffer no disadvantage within the manufacturer's organisation in relation to the proper fulfilment of his duties.	3. The person ***responsible for compliance*** shall suffer no disadvantage within the manufacturer's organisation in relation to the proper fulfilment of his duties.

Or. en

Justification

The role and responsibilities may be shared between several persons responsible for regulatory, production or quality assurance compliance.

Amendment 370
Holger Krahmer

Proposal for a regulation
Article 13 – paragraph 4 – introductory part

Text proposed by the Commission	*Amendment*
4. Authorised representatives shall have available within their organisation at least one ***qualified*** person who possesses ***expert knowledge*** regarding the ***regulatory*** requirements for medical devices in the Union. The ***expert knowledge*** shall be demonstrated by ***either of the following qualifications:***	4. Authorised representatives shall have available within their organisation at least one person ***responsible for compliance*** who possesses ***expertise*** regarding the requirements for medical devices in the Union. The ***expertise*** shall be demonstrated by ***a diploma, certificate or other evidence of formal qualification awarded on completion of a university degree or of an equivalent course of study, in natural sciences, medicine, pharmacy, engineering or another relevant discipline necessary to fulfil the tasks laid down in paragraph 2 points (a) and (b) of this article.***

Or. en

Justification

The role and responsibilities may be shared between several persons responsible for regulatory, production, or quality assurance compliance.

Amendment 371
Holger Krahmer

Proposal for a regulation
Article 13 – paragraph 4 – point a

Text proposed by the Commission	*Amendment*
(a) a diploma, certificate or other evidence of formal qualification awarded on completion of a university degree or of an equivalent course of study, in law, natural sciences, medicine, pharmacy, engineering or another relevant discipline, and at least two years of professional experience in regulatory affairs or in quality management systems relating to medical devices;	***deleted***

Or. en

Justification

The role and responsibilities may be shared between several persons responsible for regulatory, production, or quality assurance compliance.

Amendment 372
Anna Rosbach

Proposal for a regulation
Article 13 – paragraph 4 – point a

Text proposed by the Commission	*Amendment*
(a) a diploma, certificate or other evidence of formal qualification awarded on completion of a university degree or of an equivalent course of study, in law, natural sciences, medicine, pharmacy, engineering or another relevant discipline, and at least ***two*** years of professional experience in regulatory affairs or in quality management systems relating to medical devices;	(a) a diploma, certificate or other evidence of formal qualification awarded on completion of a university degree or of an equivalent course of study ***at university level***, in law, natural sciences, medicine, pharmacy, engineering or another relevant discipline, and at least ***five*** years of professional experience in regulatory affairs or in quality management systems relating to medical devices;

Or. en

Amendment 373
Holger Krahmer

Proposal for a regulation
Article 13 – paragraph 4 – point b

Text proposed by the Commission	*Amendment*
(b) five years of professional experience in regulatory affairs or in quality management systems relating to medical devices.	***deleted***

Or. en

Justification

The role and responsibilities may be shared between several persons responsible for regulatory, production, or quality assurance compliance.

Amendment 374
Anna Rosbach

Proposal for a regulation
Article 13 – paragraph 4 – point b

Text proposed by the Commission	*Amendment*
(b) ***five*** years of professional experience in regulatory affairs or in quality management systems relating to medical devices.	(b) ***ten*** years of professional experience in regulatory affairs or in quality management systems relating to medical devices ***as well as a proven in-depth knowledge of both the therapeutic area and the product(s) concerned***.

Or. en

Amendment 375
Pat the Cope Gallagher

Proposal for a regulation
Article 13 – paragraph 4 – point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) a recognised professional title awarded following successful assessment of competence to practice the profession of engineering in the field of medical device or production.

Or. en

Justification

The inclusion of a professional registered title provides greater assurances to make sure that the qualified person is suitably competent as the expert required within the legislation. One example of this professional registration would be the achievement by the qualified person of the national requirements for Eur Ing designation, the EU wide professional registered engineering qualification.

Amendment 376
Marina Yannakoudakis, Anna Rosbach

Proposal for a regulation
Article 14 – paragraph 1 – subparagraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) modifies a device already placed on the market or put into service in such a way that compliance with the applicable requirements may be affected.	(c) modifies a device already placed on the market or put into service in such a way that compliance with the applicable requirements may be affected***; this includes the reuse of a device outside of the specifications set out in the manufacturer's instructions for use***.

Or. en

Amendment 377
Holger Krahmer

Proposal for a regulation
Article 14 – paragraph 1 – subparagraph 2

Text proposed by the Commission	*Amendment*
The first subparagraph shall not apply to any person who, while not considered a manufacturer as defined in number (19) of Article 2(1), assembles or adapts a device already on the market to its intended purpose for an individual patient.	***A distributor, importer or other natural or legal person shall assume the obligations incumbent on the manufacturer under paragraph 1(a) only if the device in question was manufactured outside the European Union. In the case of devices manufactured within the EU, the manufacturer's proof of compliance with the provisions of this Regulation shall suffice.*** The first subparagraph shall not apply to any person who, while not considered a manufacturer as defined in number (19) of Article 2(1), assembles or adapts a device already on the market to its intended purpose for an individual patient.

Or. de

Justification

Article 14(1)(a) concerns firms which engage in own-branding – buying hearing aids or spectacles from the manufacturers and then placing them on the market under their own name. Under the Commission's proposal, these firms would have the same obligations as the actual manufacturers. In the case of devices that originate in the EU, this is disproportionate because manufacturers here already have a comprehensive set of obligations.

Amendment 378
Mairead McGuinness

Proposal for a regulation
Article 14 – paragraph 1 – subparagraph 2

Text proposed by the Commission	*Amendment*
The first subparagraph shall not apply to any person who, while not considered a manufacturer as defined in number (19) of Article 2(1), assembles or adapts a device already on the market to its intended purpose for an individual patient.	The first subparagraph shall not apply to any person who, while not considered a manufacturer as defined in number (19) of Article 2(1), assembles or adapts a device already on the market to its intended purpose for an individual patient.

Or. en

Amendment 379
Milan Cabrnoch

Proposal for a regulation
Article 14 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Prior to making the relabelled or repackaged device available, the distributor or importer referred to in paragraph 3 shall inform the manufacturer and the competent authority of the Member State where he plans to make the device available and, upon request, shall provide them with a sample ***or a mock-up*** of the relabelled or repackaged device, including any translated label and instructions for use. He shall submit to the competent authority a certificate, issued by a notified body referred to in Article 29, designated for the type of devices that are subject to activities mentioned in points (a) and (b) of paragraph 2, attesting that the quality management system complies with the requirements laid down in paragraph 3.	4. ***At least 28 calendar days*** prior to making the relabelled or repackaged device available, the distributor or importer referred to in paragraph 3 shall inform the manufacturer and the competent authority of the Member State where he plans to make the device available and, upon request, shall provide them with a sample of the relabelled or repackaged device, including any translated label and instructions for use. ***Within the same period of 28 calendar days,*** he shall submit to the competent authority a certificate, issued by a notified body referred to in Article 29, designated for the type of devices that are subject to activities mentioned in points (a) and (b) of paragraph 2, attesting that the quality management system complies with the requirements laid down in paragraph 3.

Or. cs

Amendment 380
Corinne Lepage

Proposal for a regulation
Article 15

Text proposed by the Commission	*Amendment*
[...]	***deleted***

Or. fr

Amendment 381
Nora Berra

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

Or. en

Amendment 382
Milan Cabrnoch

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 a single-use device to make it suitable for further use within the Union***, provided that the device does not feature on the list of devices that are unsuitable for reprocessing,*** shall be considered to be the manufacturer of the reprocessed device and shall assume the obligations incumbent on manufacturers laid down in this Regulation.

Or. cs

Amendment 383
Nora Berra

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.

Or. en

Amendment 384
Thomas Ulmer

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 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. ***Hospitals that reprocess single-use devices in house shall not be deemed to be manufacturers. They must, however, demonstrate that they have the requisite technical expertise for in-house reprocessing and must possess liability insurance covering them in the event of problems with the reprocessing.***

Or. de

Amendment 385
Anna Rosbach, Christofer Fjellner, Zofija Mazej Kukovič, Marina Yannakoudakis

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***, including health institutions as specified at Art. 4.4,*** 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.

Or. en

Justification

Patient safety need to be ensured equally regardless of who reprocesses a single use device. Therefore it must be made clear that all reprocessors, including hospitals and other health institutions, must live up to the same safety and performance requirements as applicable for originally manufactured device.

Amendment 386
Christel Schaldemose

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 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. ***This requirement shall also apply to hospitals and other health institutions as defined in Article 2(1)(24).***

Or. da

Amendment 387
Rebecca Taylor

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 a single-use device to make it suitable for further use within the Union shall ***comply with guidelines*** to be ***set out by the Commission by means of implementing acts, to ensure the safety of the reprocessing***

Or. en

Justification

Reprocessing should be subject to safety requirements, but these should be set out via implementing Acts

Amendment 388
Anna Rosbach

Proposal for a regulation
Article 15 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Only single-use devices that 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.	2. Only single-use devices that 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***, and only if this allowed under national legislation as well as can be proved by the reprocessor to be safe for the patient***.

Or. en

Amendment 389
Nora Berra

Proposal for a regulation
Article 15 – paragraph 2

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

Or. en

Amendment 390
Horst Schnellhardt

Proposal for a regulation
Article 15 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. The Commission, by means of implementing acts, shall lay down guidelines on the reprocessing of medical devices, with stipulations on standardisable, reproducible and effective cleaning, disinfection and sterilisation processes in line with the risk assessment for the respective devices, as well as requirements in relation to systems for hygiene, infection-prevention, quality management and documentation applicable to the natural or legal persons reprocessing the medical devices. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).

Or. de

Justification

The reprocessing of medical devices in the EU single market should be carried out in accordance with common guidelines in order to ensure a uniform level of safety. Existing national texts can be used as a basis for compiling such guidelines.

Amendment 391
Françoise Grossetête

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. ***Reprocessing*** of ***implantable*** single-use devices ***and surgically invasive single-use devices shall*** be ***prohibited***.

Or. fr

Amendment 392
Thomas Ulmer

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 single-use devices for critical use, only reprocessing that is considered safe according to the latest scientific evidence may be carried out***; the hygiene requirements for the reprocessing of medical devices recommended by the Commission for Hospital Hygiene and the Prevention of Infection (KRINKO), attached to the Robert Koch Institute (RKI) and the German Federal Institute for Drugs and Medical Devices (BfArM) should serve as examples of practice in this regard***.

Or. de

Justification

The reprocessing of medical devices is a practice carried out to good effect in many Member States. It must have a scientific basis and proceed within an appropriate framework. The recommendations referred to afford such a framework.

Amendment 393
Marina Yannakoudakis

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 single-use devices for critical use, only reprocessing that is considered safe according to the latest scientific evidence may be carried out. ***Scientific evidence also needs to take account of cases where the situation is critical due to the severity of the disease that is being treated.***

Or. en

Justification

For example adrenaline injectors for patients with allergies.

Amendment 394
Anna Rosbach

Proposal for a regulation
Article 15 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. In case of reprocessing of single-use medical devices the legal or natural person referred to in paragraph 1 shall ensure the traceability of each

reprocessed device, including clear indications for how many times the device has already been reprocessed.

Or. en

Amendment 395
Anna Rosbach, Zofija Mazej Kukovič

Proposal for a regulation
Article 15 – paragraph 3 b (new)

Text proposed by the Commission	*Amendment*
	3b. The legal or natural person referred to in paragraph 1 shall establish a maximum number of times a single-use device can be reprocessed and shall ensure that the device is not reprocessed more times than this level.

Or. en

Amendment 396
Milan Cabrnoch

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 and groups of single-use devices that may not be reprocessed owing to a genuine risk to safety. Those delegated acts shall be adopted in accordance with Article 89.***
	The Commission, by means of delegated 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 ***delegated*** acts shall be adopted in accordance with Article ***89***.

Or. cs

Amendment 397
Nora Berra

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***.

Or. en

Amendment 398
Horst Schnellhardt

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 implementing acts, shall establish a list of categories or groups of single-use devices for critical use which may be reprocessed in accordance with paragraph 3. ***The list shall also include requirements in relation to systems for hygiene, infection-prevention, quality management and documentation applicable to the natural or legal persons reprocessing these***

particularly sensitive devices. It will be regularly updated. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).

Or. de

Justification

Specific requirements in respect of re-processors' expertise and equipment are essential for ensuring the safe reprocessing of devices for use in particularly sensitive fields. These requirements should be laid down by the Commission so as to establish a uniform level of protection throughout the EU.

Amendment 399
Nora Berra

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.

Or. en

Amendment 400
Horst Schnellhardt

Proposal for a regulation
Article 15 – paragraph 6

Text proposed by the Commission	*Amendment*
6. A Member State may maintain or introduce national provisions prohibiting, within its territory, on grounds of protection of public health specific to that	***deleted***

Member State the following:

(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;

(b) the making available of reprocessed single-use devices.

Member States shall notify the Commission and the other Member States of the national provisions and the grounds for introducing them. The Commission shall keep the information publicly available.

Or. de

Justification

Article 72 of the Commission proposal provides for a procedure for dealing with compliant devices presenting a risk to health and safety. In the interests of the single market, this procedure should also apply in respect of reprocessed products.

Amendment 401
Anna Rosbach

Proposal for a regulation
Article 15 – paragraph 6 a (new)

Text proposed by the Commission	*Amendment*
	6a. Patients shall always be informed when reprocessed single-use devices are used.

Or. en

Amendment 402
Antonyia Parvanova

Proposal for a regulation
Article 15 – paragraph 6 a (new)

Text proposed by the Commission	*Amendment*
	6a. The Commission shall, by means of implementing acts, and in collaboration with the International medical devices regulatory forum and international standardisation bodies, define a clear set of high quality and safety standards for reprocessing of single use devices, including specific requirements for the manufacturers of reprocessed devices.

Or. en

Amendment 403
Nora Berra

Proposal for a regulation
Article 15 – paragraph 6 – subparagraph 1 – 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;

Or. en

Amendment 404
Nora Berra

Proposal for a regulation
Article 15 – paragraph 6 – subparagraph 1 – 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.

Or. en

Amendment 405
Corinne Lepage

Proposal for a regulation
Article 15 a (new)

Text proposed by the Commission	*Amendment*
	Article 15 a
	Single-use devices and their reprocessing
	Single-use devices may not be reprocessed for the purposes of reuse on the European market.

Or. fr

Amendment 406
Mairead McGuinness

Proposal for a regulation
Article 16 – title

Text proposed by the Commission	*Amendment*
Implant card	***Information about implantable devices and implant*** card

Or. en

Amendment 407
Marian Harkin

Proposal for a regulation
Article 16 – title

Text proposed by the Commission	*Amendment*
Implant card	***Information about implantable devices***

Or. en

Justification

In the interest of patient safety and transparency, relevant information about implantable devices should be shared with the patient who has been implanted with the device in a way that will ensure that the information is not lost and can be easily accessed when needed. Information about implantable devices should not be kept on a physical card which could be mislaid or lost but should be recorded and kept in the patient's medical records. In addition to the responsibility of the manufacturer, the healthcare professional implanting the device should have particular responsibility towards the patient to provide him with the information about the implantable device and to record the information in the patient's medical records.

Amendment 408
Nora Berra

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 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. ***This paragraph shall not apply to clips, sutures and dental fillings.***

Or. fr

Amendment 409
Nora Berra

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 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***.

Or. en

Amendment 410
Thomas Ulmer

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 device ***in sterile packaging*** shall provide ***in advance to the relevant health professional,*** together with the device**,** an implant card which shall be made available to the particular patient who has been implanted with the device. ***The implanter shall be responsible for making the card available to the patient and entering the data in the relevant database.*** ***The following types of implant shall be exempt: stitches, clips, screws, plates and accessories to orthopaedic implants.*** ***The Commission, by means of implementing acts, shall regularly review and update this list of exempted implants. Those implementing acts shall be adopted in accordance with Article 88(3).***

Or. de

Justification

It must de ensured that the data are also forwarded to the European Databank on Medical Devices (Eudamed).

Amendment 411
Mairead McGuinness

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 device shall provide together with the device an implant card which shall be made available to the ***healthcare professional implanting the device who shall:***

Or. en

Amendment 412
Marina Yannakoudakis

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 ***Commission shall be empowered to adopt delegated acts in accordance with Article 89 identifying for which*** implantable ***devices the manufacturer*** shall provide together with the device an implant card***, which can be provided by electronic form or other means containing the information referred to in paragraph 2*** which shall be made available to the particular patient who has been implanted with the device.

Or. en

Justification

It is necessary that there is delineation between implantable devices that require such implant cards, for example in the case of implantable medical devices such as sutures, surgical clips, pins, screws and dental fillers.

Amendment 413
Linda McAvan

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 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. ***The implant card shall also be made available in an electronic format, and Member States shall ensure that hospitals and clinics keep an electronic version on record, so that it can be easily forwarded at the request of a patient.***

Or. en

Justification

As recommended by the European Parliament's resolution of 14 June 2012 on defective silicone gel breast implants made by French company PIP.

Amendment 414
Marian Harkin

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 device shall provide together with the device ***information*** which shall be ***submitted to the healthcare professional implanting the device who will be responsible for:*** ***- submitting this information*** to the patient***; and*** ***- recording this information in the patient's medical records***.

Or. en

Justification

In the interest of patient safety and transparency, relevant information about implantable devices should be shared with the patient who has been implanted with the device in a way that will ensure that the information is not lost and can be easily accessed when needed. Information about implantable devices should not be kept on a physical card which could be mislaid or lost but should be recorded and kept in the patient's medical records. In addition to the responsibility of the manufacturer, the healthcare professional implanting the device should have particular responsibility towards the patient to provide him with the information about the implantable device and to record the information in the patient's medical records.

Amendment 415
Michèle Rivasi, Corinne Lepage

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 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. ***An electronic version of this information shall be kept and made available to the patient upon request by the manufacturer as long as the device is implanted in the patient.***

Or. en

Amendment 416
Mairead McGuinness

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

Text proposed by the Commission	*Amendment*
	- record all the information contained on the card in the patient's medical records

Or. en

Amendment 417
Mairead McGuinness

Proposal for a regulation
Article 16 – paragraph 1 – indent 2 (new)

Text proposed by the Commission	*Amendment*
	- handover the card to the patient

Or. en

Amendment 418
Antonyia Parvanova

Proposal for a regulation
Article 16 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. Member States may introduce national provisions requiring that the implant card includes also information on post-operative follow-up care measures and that is signed by both the patient and the surgeon responsible for the surgery.

Or. en

Amendment 419
Marian Harkin

Proposal for a regulation
Article 16 – paragraph 2 – subparagraph 1 – introductory part

Text proposed by the Commission	*Amendment*
This ***card*** shall contain the following:	This ***information*** shall contain the following:

Or. en

Justification

In the interest of patient safety and transparency, relevant information about implantable devices should be shared with the patient who has been implanted with the device in a way that will ensure that the information is not lost and can be easily accessed when needed. Information about implantable devices should not be kept on a physical card which could be mislaid or lost but should be recorded and kept in the patient's medical records. In addition to the responsibility of the manufacturer, the healthcare professional implanting the device should have particular responsibility towards the patient to provide him with the information about the implantable device and to record the information in the patient's medical records.

Amendment 420
Linda McAvan

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

Text proposed by the Commission	*Amendment*
	(ba) Information about the special characteristics of the device and any potential adverse effects

Or. en

Justification

As recommended by the European Parliament's resolution of 14 June 2012 on defective silicone gel breast implants made by French company PIP.

Amendment 421
Antonyia Parvanova

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;

Or. en

Amendment 422
Linda McAvan

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

Text proposed by the Commission	*Amendment*
	(ca) A space for signature for the surgeon and the patient, so that the card can be used as a consent form for the operation.

Or. en

Justification

As recommended by the European Parliament's resolution of 14 June 2012 on defective silicone gel breast implants made by French company PIP.

Amendment 423
Antonyia Parvanova

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.

Or. en

Amendment 424
Michèle Rivasi, Corinne Lepage

Proposal for a regulation
Article 16 – paragraph 2 – subparagraph 2

Text proposed by the Commission	*Amendment*
The information shall be written in a way	The information shall be written in a way

that is readily understood by a lay person.	that is readily understood by a lay person. ***This information shall be supplied to the patient at the time of consent, before the device is implanted. The patients need to know that implants are not permanent and may need to be replaced or removed; patients also need to be informed about the quality of implants and the potential risks associated with them.***

Or. en

Justification

This is stated in the European Parliament resolution on defective silicone gel breast implants made by French company PIP (2012/2621(RSP)).

Amendment 425
Milan Cabrnoch

Proposal for a regulation
Article 17 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The EU declaration of conformity shall state that fulfilment of the requirements specified in this Regulation has been demonstrated. It shall be continuously updated. The minimum content of the EU declaration of conformity is set out in Annex III. It shall be ***translated into the official Union language or languages required by the Member State(s) in which the device is made available***.	1. The EU declaration of conformity shall state that fulfilment of the requirements specified in this Regulation has been demonstrated. It shall be continuously updated. The minimum content of the EU declaration of conformity is set out in Annex III. It shall be ***drafted in an official Union language that is acceptable to the notified body processing the declaration of conformity in accordance with Article 42.***

Or. cs

Amendment 426
Thomas Ulmer

Proposal for a regulation
Article 17 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The EU declaration of conformity shall state that fulfilment of the requirements specified in this Regulation has been demonstrated. It shall be continuously updated. The minimum content of the EU declaration of conformity is set out in Annex III. It shall be ***translated into the*** official Union language ***or languages*** required by the Member State(s) in which the device is made available.	1. The EU declaration of conformity shall state that fulfilment of the requirements specified in this Regulation has been demonstrated. It shall be continuously updated. The minimum content of the EU declaration of conformity is set out in Annex III. It shall be ***issued in an EU*** official Union language required by the Member State(s) in which the device is ***placed on the market, and also in English if the device is*** made available ***in other Member States***.

Or. de

Amendment 427
Marina Yannakoudakis

Proposal for a regulation
Article 17 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The EU declaration of conformity shall state that fulfilment of the requirements specified in this Regulation has been demonstrated. It shall be continuously updated. The minimum content of the EU declaration of conformity is set out in Annex III. It shall be translated into ***the official Union language or languages required by*** the Member State(***s***) ***in which the device is made available***.	1. The EU declaration of conformity shall state that fulfilment of the requirements specified in this Regulation has been demonstrated. It shall be continuously updated. The minimum content of the EU declaration of conformity is set out in Annex III. It shall be translated into ***English in addition to a version in the language of*** the member state (***if required***) ***where the manufacturer or authorized representative has their registered place of business***.

Or. en

Justification

The declaration of conformity is addressed to notified bodies and authorities - not patients. Having to provide translations of the EU declaration of conformity for all EU countries where the products are made available will increase costs for small businesses.

Amendment 428
Richard Seeber

Proposal for a regulation
Article 17 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The EU declaration of conformity shall state that fulfilment of the requirements specified in this Regulation has been demonstrated. It shall be continuously updated. The minimum content of the EU declaration of conformity is set out in Annex III. It shall be ***translated into the*** official Union language ***or languages required by the Member State(s) in which the device is made available***.	1. The EU declaration of conformity shall state that fulfilment of the requirements specified in this Regulation has been demonstrated. It shall be continuously updated. The minimum content of the EU declaration of conformity is set out in Annex III. It shall be ***available in one*** official Union language.

Or. en

Justification

Translation of the EU Declarations to multiple languages is burdensome and considered unnecessary.

Amendment 429
Milan Cabrnoch

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	***deleted***

of conformity set out in Annex III in the light of technical progress.

Or. cs

Amendment 430
Thomas Ulmer, Peter Liese

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***

Or. de

Amendment 431
Michèle Rivasi, Corinne Lepage

Proposal for a regulation
Article 18 – paragraph 5

Text proposed by the Commission	*Amendment*
5. Where applicable, the CE marking shall be followed by the identification number of the notified body responsible for the conformity assessment procedures set out in Article 42. The identification number shall also be indicated in any promotional material which mentions that a device fulfils the legal requirements for CE marking.	5. Where applicable, the CE marking shall be followed by the identification number of the notified body responsible for the conformity assessment procedures set out in Article 42. The identification number ***and contact information of the notified body responsible*** shall also be indicated in any promotional material which mentions that a device fulfils the legal requirements for CE marking.

Or. en

Amendment 432
Nora Berra

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.

Or. en

Amendment 433
Sirpa Pietikäinen

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 significantly changing its performance or safety characteristics, shall ensure that the article does not adversely affect the safety and performance of the device. ***For devices composed of more than one implantable part, it shall also be ensured that the article does not require the replacement of the whole device due to***

incompatibility with the functioning part of the device. Substantiating evidence shall be kept available to the competent authorities of the Member States.

Or. en

Amendment 434
Richard Seeber

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.

Or. en

Amendment 435
Thomas Ulmer

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 must meet the***

requirements laid down in this Regulation.

Or. de

Amendment 436
Thomas Ulmer

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

Text proposed by the Commission	*Amendment*
	2a. Any natural or legal person who reprocesses a device in accordance with the manufacturer's recommendations must ensure that he does not adversely affect the characteristics or the safety of the device.

Or. de

Amendment 437
Thomas Ulmer

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

Text proposed by the Commission	*Amendment*
	2b. Any natural or legal person who reprocesses a device without reference to the manufacturer's recommendations on reprocessing or who disregards or violates those recommendations shall be considered as a manufacturer within the meaning of this Regulation.

Or. de

Amendment 438
Michèle Rivasi

Proposal for a regulation
Article 22 a (new)

Text proposed by the Commission	*Amendment*
	Article 22 a
	Responsibility in case of damage caused to the patient by a class IIb or class III medical device
	The manufacturer will be held as legally responsible for the damage caused by a class IIb or class III medical device to the patient, unless he can prove the damage was caused by improper application by the healthcare professional or the patient, where relevant.

Or. en

Justification

It should be clear who bears the responsibility in case of damage to the patient.

Amendment 439
Milan Cabrnoch

Proposal for a regulation
Article 23 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
For devices, other than custom-made or investigational devices, economic operators shall be able to identify the following, for ***the*** period ***referred to in Article 8(4)***:	For devices, other than custom-made or investigational devices, economic operators shall be able to identify the following, for ***a*** period ***of 10 years***:

Or. cs

Amendment 440
Thomas Ulmer

Proposal for a regulation
Article 24 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. For devices, other than custom-made and investigational devices, a system for Unique Device Identification shall be put in place in the Union. The UDI system shall allow the identification and traceability of devices and shall consist of the following:	1. For ***class II*** devices, other than custom-made and investigational devices, a system for Unique Device Identification shall be put in place in the Union. The UDI system shall allow the identification and traceability of devices and shall consist of the following:

Or. de

Amendment 441
Marina Yannakoudakis

Proposal for a regulation
Article 24 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. For devices, other than custom-made and investigational devices, a system for Unique Device Identification shall be put in place in the Union. The UDI system shall allow the identification and traceability of devices and shall consist of the following:	1. For devices, other than custom-made and investigational devices, a ***single*** system for Unique Device Identification shall be put in place in the Union. The UDI system shall allow the identification and traceability of devices***, be coherent if possible with the global regulatory approach for UDI in medical devices,*** and shall consist of the following:

Or. en

Justification

The word "single" needs to be inserted to ensure that we have a unique and harmonised approach to UDI in Europe and where possible globally.

Amendment 442
Rebecca Taylor

Proposal for a regulation
Article 24 – paragraph 2 – point e – point i

Text proposed by the Commission	*Amendment*
(i) to operate its system for the assignment of UDIs for the period to be determined in the designation which shall at least be ***three*** years after its designation;	(i) to operate its system for the assignment of UDIs for the period to be determined in the designation which shall at least be ***five*** years after its designation;

Or. en

Justification

The UDI System is a vital component of the new Regulatory system, and providers of UDIs should ensure a greater degree of permanence to their role

Amendment 443
Marian Harkin

Proposal for a regulation
Article 24 – paragraph 7 – point a

Text proposed by the Commission	*Amendment*
(a) determining the devices, categories or groups of devices whose identification shall be based on the UDI system as set out in paragraphs 1 to 6, and the timelines for implementing this. Following a risk-based approach, implementation of the UDI system shall be ***gradual, starting with*** devices falling in the highest risk class;	(a) determining the devices, categories or groups of devices whose identification shall be based on the UDI system as set out in paragraphs 1 to 6, and the timelines for implementing this. Following a risk-based approach, implementation of the UDI system shall be ***restricted to*** devices falling in the highest risk class;

Or. en

Justification

The mandatory obligations under the future Unique Device Identification (UDI) System should be restricted to highest risk devices to avoid creating excessive administrative and financial burden in healthcare without corresponding improvements in patient safety.

Amendment 444
Marian Harkin

Proposal for a regulation
Article 24 – paragraph 7 – point b

Text proposed by the Commission	*Amendment*
(b) specifying the data to be included in the production identifier ***which, following a risk based approach, may vary depending on the risk class of the device***;	(b) specifying the data to be included in the production identifier;

Or. en

Justification

The mandatory obligations under the future Unique Device Identification (UDI) System should be restricted to highest risk devices to avoid creating excessive administrative and financial burden in healthcare without corresponding improvements in patient safety.

Amendment 445
Anja Weisgerber, Thomas Ulmer

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

Text proposed by the Commission	*Amendment*
	(ea) compatibility with identification systems for medical devices already on the market.

Or. de

Justification

In the interests of smooth operability, it is important that traceability systems should be technically compatible.

Amendment 446
Holger Krahmer

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

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

Or. en

Justification

It is likely an electronic medicine authentication system will be out in place pursuant to Falsified Medicines Directive. It is important that the systems for medical devices and medicines are compatible, otherwise this will bring a significant and possibly unmanageable burden for the agents in the supply chain working with both kinds of products.

Amendment 447
Peter Liese

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

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

Or. en

Justification

It is likely an electronic medicine authentication system will be out in place pursuant to Falsified Medicines Directive. It is important that the systems for medical devices and medicines are compatible, otherwise this will bring a significant and possibly unmanageable burden for the agents of the supply chain working with both kinds of products.

Amendment 448
Françoise Grossetête

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

Text proposed by the Commission	*Amendment*
	(ea) the compatibility of the UDI systems with the safety features established under Directive 2011/62/EU amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products.

Or. fr

Amendment 449
Gilles Pargneaux

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

Text proposed by the Commission	*Amendment*
	(ea) the compatibility with the other traceability systems used by actors working in the field of medical devices.

Or. fr

Justification

An electronic authentication system for medicinal products should be established in the light of the directive on falsified medicines. The systems for medical devices and medicinal products should be compatible so as not to impose a substantial burden on actors in the supply chain who work with both types of product.