

3. *Upon request by a competent authority, the natural or legal person offering a device in accordance with paragraph 1 or providing a service in accordance with paragraph 2 shall make available a copy of the EU declaration of conformity of the device concerned.*
4. *A Member State may, on grounds of protection of public health, ~~may require from the~~ a provider of information society services as defined in Article 1(2) of Directive 98/34/EC to cease its activity.*

#### *Article 6*

##### *Harmonised standards*

1. Devices which are in conformity with the relevant harmonised standards, or parts thereof, the references of which have been published in the Official Journal of the European Union shall be presumed to be in conformity with the requirements of this Regulation covered by those standards or parts thereof.
- ~~2.~~ The first subparagraph shall also apply to system or process requirements to be fulfilled by economic operators or sponsors in accordance with this Regulation, including those related to the quality management system, risk management, the post-market surveillance plan, clinical investigations, clinical evaluation or post-market clinical follow-up.
2. Reference to harmonised standards also includes the monographs of the European Pharmacopoeia adopted in accordance with the Convention on the Elaboration of a European Pharmacopoeia, notably on surgical sutures and on interaction between medicinal products and materials used in devices containing such medicinal products, ~~the provided references of which~~ *to those monographs have been published in the Official Journal of the European Union.*

## Article 7

### *Common technical specifications*

1. ~~Where~~ ***Without prejudice to Article 1(1a) and the deadline laid down therein, where*** no harmonized standards exist or where relevant harmonised standards are not sufficient, the Commission, ***after having consulted the MDCG, shall be empowered to*** ~~may~~ adopt common technical specifications (ETS CS) in respect of the general safety and performance requirements set out in Annex I, the technical documentation set out in Annex II ~~or~~, the clinical evaluation and post-market clinical follow-up set out in Annex XIII ***or the requirements regarding clinical investigation set out in Annex XIV***. The ETS CS shall be adopted by means of implementing acts in accordance with the examination procedure referred to in Article 88(3).
2. Devices which are in conformity with the ETS CS referred to in paragraph 1 shall be presumed to be in conformity with the requirements of this Regulation covered by those ETS CS or parts thereof.
3. Manufacturers shall comply with the ETS CS unless they can duly justify that they have adopted solutions ensuring a level of safety and performance that is at least equivalent thereto.
4. ***Notwithstanding paragraph 3, manufacturers of products listed in Annex XV shall comply with the relevant common specifications for those products.***

## Article 8

### *General obligations of the manufacturer*

1. When placing their devices on the market or putting them into service, manufacturers shall ensure that they have been designed and manufactured in accordance with the requirements of this Regulation.

**1a. Manufacturers shall establish, execute, maintain and document a system for Risk Management as described in Section 1.2 in Annex I.**

**1b. Manufacturers shall conduct a clinical evaluation in accordance with the principles set out in Article 49 and Annex XIII, including post-market clinical follow-up.**

2. Manufacturers shall draw up **and keep up to date** the technical documentation which shall allow assessment of the conformity of the device with the requirements of this Regulation. The technical documentation shall include the elements set out in Annex II.

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.

3. Where compliance of a device with the applicable requirements has been demonstrated following the applicable conformity assessment procedure, manufacturers of devices, other than custom-made or investigational devices, shall draw up an EU declaration of conformity in accordance with Article 17, and affix the CE marking of conformity in accordance with Article 18.

**3b. Manufacturers shall comply with the obligations related to the UDI system referred to in Articles 24 and with the registration obligations referred to in Article 25.**

4. Manufacturers shall keep the technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificate including any ~~supplement~~ **amendments and supplements**, issued in accordance with Article 45, available to the competent authorities for a period of at least five years after the last device covered by the declaration of conformity has been placed on the market. In the case of implantable devices, the period shall be at least 15 years after the last device has been placed on the market.

~~Upon~~ Where the technical documentation is voluminous or held in different locations, the manufacturer shall provide, upon request by a competent authority, **the manufacturer shall provide the full technical documentation or** a summary technical documentation (STED) and ~~grant access to the full technical documentation upon~~ **as indicated in the** request.

**A manufacturer with registered place of business outside the Union shall, in order to allow the authorised representative to fulfil the tasks mentioned in Article 9, paragraph 3 shall ensure that the authorised representative has to the necessary documentation permanently available.**

5. Manufacturers shall ensure that procedures are in place to keep series production in conformity with the requirements of this Regulation. Changes in product design or characteristics and changes in the harmonised standards or ~~ETS CS~~ **CS** by reference to which conformity of a product is declared shall be adequately taken into account **in a timely manner**. Proportionate to the risk class and the type of device, manufacturers of devices, other than ~~custom-made or~~ investigational devices, shall ~~institute~~ **establish, document, implement, maintain,** and keep up to date **and continually improve** a quality management system that shall **ensure compliance with this regulation in the most effective manner**.

**The QMS consists of all parts and components of a manufacturer's organisation dealing with the quality of processes, procedures and devices. It is managing the structure, responsibilities, procedures, processes and management resources to implement the needed principles and actions to achieve compliance with the provisions of this regulation.**

**The quality management system shall** address at least the following aspects:

- (aa) **a strategy for regulatory compliance, including compliance with conformity assessment procedures and management change;**
- (ab) **identification of applicable general safety and performance requirements and exploration of options to address these;**

- (a) the responsibility of the management;
- (b) resource management, including selection and control of suppliers and sub-contractors;
- (ba) risk management according to section I.2 of Annex I;**
- (bc) clinical evaluation, according to Article 49 and Annex XIII, including post-market clinical follow-up;**
- (c) product realisation, *including planning, design, development, production and service provision*;
- (ca) control of the UDI-Code assignments to all relevant devices ensuring consistency of information provided according to article 25;**
- (cb) setting-up, implementation and maintenance of a systematic post-market surveillance plan according to Article 60a;**
- (cc) handling communication with competent authorities, notified bodies, other economic operators, customers and/or other stakeholders;**
- (cd) processes for reporting of serious incidents and field safety corrective actions in the context of vigilance;**
- (ce) management of corrective and preventive actions and verification of their effectiveness;**
- (d) processes for monitoring and measurement of output, data analysis and product improvement.

6. Proportionate to the risk class and the type of device, manufacturers of devices, ~~other than custom-made devices, shall institute~~ **implement** and keep up to date ~~the 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'~~ **system referred to in Chapter VII, Section 0, Article 60a**. ~~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.~~

~~If in the course of the post-market surveillance a need for corrective action is identified, the manufacturer shall implement the appropriate measures.~~

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 language(s) ~~which can be easily understood by the intended user or patient~~ **determined by the concerned Member State**. 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. The particulars on the label shall be easily legible, clearly comprehensible and indelible.

8. Manufacturers who consider or have reason to believe that a device which they have placed on the market *or put into service* 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 ~~accordingly~~ the distributors and, where applicable, the authorised representative ~~accordingly~~ *and the importers accordingly*.

*Where the device presents a serious risk, manufacturers shall immediately inform the competent authorities of the Member States in which they made the device available and, where applicable, the notified body that issued a certificate for the device in accordance with Article 45, in particular, of the non-compliance and of any corrective action taken.*

- 8a. *Manufacturers shall have a system for reporting of incidents and field safety corrective actions as described in Article 61.*

9. Manufacturers shall, ~~in response to a~~ *upon* 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~~ *determined by the Member State concerned*. ~~They~~ *The competent authority where the manufacturer has his registered place of business may require that the manufacturer provide samples of the device free of charge or, where impracticable, grant access to the device. Manufacturers shall cooperate with that a 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.*

*If the manufacturer fails to cooperate or the information and documentation provided is incomplete or incorrect, the competent authority may suspend the involved device until its demonstration of conformity to the essential requirements.*

10. Where manufacturers have their devices designed and manufactured by another legal or natural person the information on the identity of that person shall be part of the information to be submitted in accordance with Article 25.

13. ***Natural or legal persons may claim compensation for damage caused by a defective device in accordance with applicable Union and national law.***

***To this end, manufacturers shall consider taking out appropriate insurance or arranging for an equivalent financial guarantee, to cover the costs associated with defective devices.***

#### ***Article 9***

##### ***Authorised representative***

1. ***A ~~Where the~~ manufacturer of a device is not established in any Member State, that is the device may only be placed on the Union market, or bears the CE marking without being placed on the Union market, who does not have a registered place of business in a Member State or does not carry out relevant activities at a registered place of business in a Member State, shall if the manufacturer*** designates a single authorised representative.
2. The designation shall ***constitute the authorised representative's mandate, it shall*** be valid only when accepted in writing by the authorised representative and shall be effective at least for all devices of the same generic device group.
3. The authorised representative shall perform the tasks specified in the mandate agreed between the manufacturer and the authorised representative. ***The authorised representative shall provide a copy of the mandate to the competent authority, upon request.***

The mandate shall allow and require the authorised representative to perform at least the following tasks in relation to the devices that it covers:

- (aa) ***verify that the EU declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the manufacturer;***

- (a) keep *a copy of* the technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificate including any *amendments and supplements* issued in accordance with Article 45 at the disposal of competent authorities for the period referred to in Article 8(4);
- (ab) comply with the registration obligations laid down in Article 25a(1), (4) and (5);*
- (b) in response to a ~~reasoned~~ request from a competent authority, provide that competent authority with all the information and documentation necessary to demonstrate the conformity of a device *in a language determined by the Member State concerned;*
- (ba) forward to the manufacturer any request by a competent authority where he has his registered place of business for samples, or access to a device and verify that the competent authority receives the samples or gets access to the device;*
- (c) cooperate with the competent authorities on any corrective action taken to eliminate the risks posed by devices;
- (d) immediately inform the manufacturer about complaints and reports from healthcare professionals, patients and users about suspected incidents related to a device for which they have been designated;
- (e) terminate the mandate if the manufacturer acts contrary to his obligations under this Regulation.

~~To allow the authorised representative to fulfil the tasks mentioned in this paragraph, the manufacturer shall at least ensure that the authorised representative has permanent immediate access to the necessary documentation in one of the official Union languages.~~

- 4. The mandate referred to in paragraph 3 shall not include the delegation of the manufacturer's obligations laid down in Article 8(1), (2), *(3), (3a)*, (5), (6), (7) and (8).
- 4a. Without prejudice to paragraph 4, where the manufacturer is not established in any Member State, and has not complied with the obligations laid down in Article 8, the authorised representative shall be legally liable for defective devices in accordance with Article 8(13).*

5. An authorised representative who terminates the mandate on the grounds referred to in point (e) of paragraph 3 shall immediately inform the competent authority of the Member State in which he is established and, where applicable, the notified body that was involved in the conformity assessment for the device of the termination of the mandate and the reasons therefor.
6. Any reference in this Regulation to the competent authority of the Member State where the manufacturer has his registered place of business shall be understood as a reference to the competent authority of the Member State where the authorised representative, designated by a manufacturer referred to in paragraph 1, has his registered place of business.

#### *Article 10*

##### *Change of authorised representative*

The modalities of a change of authorised representative shall be clearly defined in an agreement between the manufacturer, **where practicable** the outgoing authorised representative and the incoming authorised representative. This agreement shall address at least the following aspects:

- (a) the date of termination of the mandate with the outgoing authorised representative and date of beginning of the mandate with the incoming authorised representative;
- (b) the date until which the outgoing authorised representative may be indicated in the information supplied by the manufacturer, including any promotional material;
- (c) the transfer of documents, including confidentiality aspects and property rights;
- (d) the obligation of the outgoing authorised representative after the end of the mandate to forward to the manufacturer or incoming authorised representative any complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device for which he had been designated as authorised representative.

## Article 11

### General obligations of importers

1. Importers shall place on the Union market only devices that are in conformity with this Regulation.
2. ~~Before placing~~ ***In order to place*** a device on the market importers shall ~~ensure~~ ***verify*** the following:
  - (a) that the ***device has been CE marked and that the declaration of appropriate conformity of the device has been drawn up*** ~~assessment procedure has been carried out by the manufacturer;~~
  - (b) that an authorised representative in accordance with Article 9 has been designated by the manufacturer;
  - (c) ~~that the EU declaration of conformity and the technical documentation has been drawn up by the manufacturer;~~
  - (d) ~~that the device bears the required CE marking of conformity;~~
  - (e) that the device is labelled in accordance with this Regulation and accompanied by the required instructions for use ~~and EU declaration of conformity;~~
  - (f) that, where applicable, a Unique Device Identification has been assigned by the manufacturer in accordance with Article 24.

Where an importer considers or has reason to believe that a device is not in conformity with the requirements of this Regulation, he shall not place the device on the market until it has been brought into conformity. ~~Where the device presents a risk, the importer~~ ***and*** shall inform the manufacturer and his authorised representative. ~~to that effect, as well as~~ ***Where the importer considers or has reason to believe that the device presents a serious risk or is falsified, he shall also inform*** the competent authority of the Member State in which he is established.

3. Importers shall indicate their name, registered trade name or registered trade mark and the address of their registered place of business at which they can be contacted and their location can be established on the device or on its packaging or in a document accompanying the device. They shall ensure that any additional label does not obscure any information on the label provided by the manufacturer.
4. Importers shall **ensure verify** that the device is registered in the electronic system in accordance with Article 25(2) **and shall add their details to that registration. Importers shall also verify that the registration includes details on the authorised representative and, if appropriate, inform the authorised representative or the manufacturer.**
5. Importers shall ensure that, while a device is under their responsibility, storage or transport conditions do not jeopardise its compliance with the general safety and performance requirements set out in Annex I **and shall comply with the conditions set by the manufacturer, where available.**
6. ~~When deemed appropriate with regard to the risks presented by a device, importers shall, in order to protect the health and safety of patients and users, carry out sample testing of marketed products, investigate complaints and~~ **Importers shall** keep a register of complaints, of non-conforming products and of product recalls and withdrawals, and ~~shall keep provide~~ **provide** the manufacturer, authorised representative and distributors ~~informed of such monitoring~~ **with any information requested by them, in order to allow them to investigate complaints.**

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~~ ***Importers shall cooperate with the manufacturer, his authorised representative and the competent authorities to ensure that*** the necessary corrective action to bring that device into conformity, withdraw or recall it ***is taken***. Where the device presents a ***serious*** 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.
8. Importers who have received complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device which they have placed on the market shall immediately forward this information to the manufacturer and his 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. 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.~~

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 **authorities**, at **their** its request, on any action taken to eliminate the risks posed by devices which they have placed on the market. **Importers, upon request of a competent authority where the importer has his registered place of business, shall provide samples of the device free of charge or, where impracticable, grant access to the device.**

## Article 12

### *General obligations of distributors*

1. ~~When~~ **In the context of their activities, when** making a device available on the market, distributors shall act with due care in relation to the requirements applicable.

2. Before making a device available on the market distributors shall verify that the following requirements are met:
- (a) ~~the product *device* bears the required CE marking of conformity~~ *has been CE marked and that the declaration of conformity of the device has been drawn up;*
  - (b) the product is accompanied by the information to be supplied by the manufacturer in accordance with Article 8(7);
  - (c) ~~the manufacturer and, where applicable, the importer have~~ *has* complied with the requirements set out in ~~Article 24 and Article 11(3) respectively.~~
  - (d) *that, where applicable, a Unique Device Identification has been assigned by the manufacturer.*

*In order to meet the requirements referred to in subparagraphs (a) and (b) the distributor may apply a sampling method representative of products supplied by that distributor.*

Where a distributor considers or has reason to believe that a device is not in conformity with the requirements of this Regulation, he shall not make the device available on the market until it has been brought into conformity ~~Where the device presents a risk, the distributor shall~~ *and* inform the manufacturer and, where applicable, his authorised representative, and the importer. ~~to that effect, as well as~~ *Where the distributor consider or has reason to believe that the device presents a serious risk or is falsified, he shall also inform* the competent authority of the Member State in which he is established.

3. Distributors shall ensure that, while a *the* device is under their responsibility, storage or transport conditions ~~do not jeopardise its compliance with the general safety and performance requirements set out in Annex I~~ *comply with the conditions set by the manufacturer.*

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~~ ***Distributors shall co-operate with the manufacturer and, where applicable his authorised representative and the importer, and with any competent authorities to ensure*** that the necessary corrective action to bring that device into conformity, withdraw or recall it, if appropriate, is taken. Where ***the distributor considers or has reason to believe that*** the device presents a ***serious*** risk, ~~they~~ ***he*** shall also immediately inform the competent authorities of the Member States in which ~~they~~ ***he*** made the device available, ***and, where applicable, the notified body that issued a certificate for the device in accordance with Article 45*** giving details, in particular, of the non-compliance and of any corrective action taken.
  
5. Distributors who have received complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device they have made available, shall immediately forward this information to the manufacturer and, where applicable, his authorised representative. ***They shall keep a register of complaints, of non-conforming products and of product recalls and withdrawals, and keep the manufacturer and, where available, the authorised representative informed of such monitoring and provide them with any information upon their request.***
  
6. Distributors shall, in response to a request from a competent authority, provide it with all the information and documentation ***that is at its disposal and is*** 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. ***Distributors, upon request of the competent authority where he has his registered place of business, shall provide free samples of the device or, where impracticable, grant access to the device.***

Article 13

*Person responsible for regulatory compliance*

1. Manufacturers shall have available within their organisation, at least one ~~qualified~~ person ***responsible for regulatory compliance activities*** who possesses expert knowledge in the field of medical devices. The expert knowledge shall be demonstrated by either of the following qualifications:
  - (a) a diploma, certificate or other evidence of formal qualification awarded on completion of a university degree or of ~~an~~ ***a course of study recognized as equivalent course of study, in natural sciences, by the Member States concerned, in*** medicine, pharmacy, engineering or another relevant discipline ***of sciences***, and at least two years of professional experience in regulatory affairs or in quality management systems relating to ~~medical~~ devices;
  - (b) five years of professional experience in regulatory affairs ~~or~~ ***related to devices including experience*** in quality management systems ~~relating to medical devices~~.

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.

- ~~1a. This paragraph shall not apply to manufacturers of custom-made devices who are micro-enterprises as defined by *Micro and small enterprises within the meaning of* Commission Recommendation 2003/361/EC ***are not required to have the person responsible for regulatory compliance within their organisation but shall have such person permanently and continuously at their disposal.***~~

2. The ~~qualified~~ person ***responsible for regulatory compliance activities*** shall at least be responsible for ensuring the following matters:
  - (a) that the conformity of the devices is appropriately assessed ***checked in accordance with the quality management system under which these devices are manufactured*** before a ***product batch*** is released;

- (b) that the technical documentation and the declaration of conformity are drawn up and kept up-to-date;
  - (ba) **that the post-market surveillance obligations in accordance with Article 8(7) are complied with;**
  - (c) that the reporting obligations in accordance with Articles 61 to 66 are fulfilled;
  - (d) in the case of investigational devices, that the statement referred to in point 4.1 of Chapter II of Annex XIV is issued.
3. The ~~qualified~~ person **responsible for regulatory compliance** shall suffer no disadvantage within the manufacturer's organisation in relation to the proper fulfilment of his duties.
4. Authorised representatives shall have ~~available within~~ **permanently and continuously at their organisation disposal** at least one ~~qualified~~ person **in charge for regulatory compliance activities** 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:
- (a) a diploma, certificate or other evidence of formal qualification awarded on completion of a university degree or of ~~an~~ **a course of study recognised as equivalent by the Member States concerned**, ~~course of study, in law, natural sciences, medicine, pharmacy, engineering or another relevant discipline~~ **sciences**, and at least two years of professional experience in regulatory affairs or in quality management systems relating to medical devices;
  - (b) five years of professional experience in regulatory affairs or in quality management systems relating to medical devices.

## Article 14

### *Cases in which obligations of manufacturers apply to importers, distributors or other persons*

1. A distributor, importer or other natural or legal person shall assume the obligations incumbent on manufacturers if he does any of the following:
  - (a) makes available on the market a device under his name, registered trade name or registered trade mark, ***except in cases where a distributor or importer enters into an agreement with a manufacturer whereby the manufacturer is identified as such on the label and is responsible for meeting the requirements placed on manufacturers in this Regulation;***
  - (b) changes the intended purpose of a device already placed on the market or put into service;
  - (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.

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.

2. For the purposes of point (c) of paragraph 1, the following shall not be considered to be a modification of a device that could affect its compliance with the applicable requirements:
  - (a) provision, including translation, of the information supplied by the manufacturer in accordance with Section 19 of Annex I relating to a device already placed on the market and of further information which is necessary in order to market the product in the relevant Member State;
  - (b) changes to the outer packaging of a device already placed on the market, including a change of pack size, if the repackaging is necessary in order to market the product in the relevant Member State and if it is carried out in such conditions that the original condition of the device cannot be affected by it. In the case of devices placed on the market in sterile condition, it shall be presumed that the original condition of the device is adversely affected if the package that shall ensure the sterile condition is opened, damaged or otherwise negatively affected by the repackaging.

3. A distributor or importer who carries out any of the activities mentioned in points (a) and (b) of paragraph 2 shall indicate the activity carried out together with his name, registered trade name or registered trade mark and the address at which he can be contacted and his location can be established on the device or, where ~~that is not possible~~ **impracticable**, on its packaging or in a document accompanying the device.

He shall ensure that he has in place a quality management system that includes procedures which ensure that the translation of information is accurate and up-to-date, and that the activities mentioned in points (a) and (b) of paragraph 2 are performed by means and under conditions that preserve the original condition of the device and that the packaging of the repackaged device is not defective, of poor quality or untidy. Part of the quality management system shall be procedures ensuring that the distributor or importer is informed of any corrective action taken by the manufacturer in relation to the device in question in order to respond to safety issues or to bring it in conformity with this Regulation.

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.

#### *Article 15*

##### *Single-use devices and their reprocessing*

0. ***Reprocessing and further use of single-use devices may only take place where permitted by national law and ~~Save where prohibited by Member States under national law, the reprocessing and further use of single-use devices shall be permitted only in accordance with this article.~~***