

25. Devices which are in conformity with the CTS referred to in paragraph 1 shall be presumed to be in conformity with the requirements of this Regulation covered by those CTS or parts thereof.
26. Manufacturers shall comply with the CTS unless they can duly justify that they have adopted solutions ensuring a level of safety and performance that is at least equivalent thereto.

Article 8
General obligations of the manufacturer

27. 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.
28. Manufacturers shall draw up 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.

29. 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.
30. Manufacturers shall keep the technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificate including any supplement, 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.

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.

31. 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 CTS by reference to which conformity of a product is declared shall be adequately taken into account. Proportionate to the risk class and the type of device, manufacturers of devices, other than custom-made or investigational devices, shall institute and keep up to date a quality management system that shall address at least the following aspects:

(a) the responsibility of the management;

- (b) resource management, including selection and control of suppliers and sub-contractors;
 - (c) product realisation;
 - (d) processes for monitoring and measurement of output, data analysis and product improvement.
32. 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.
- If in the course of the post-market surveillance a need for corrective action is identified, the manufacturer shall implement the appropriate measures.
33. Manufacturers shall ensure that the device is accompanied by the information to be supplied in accordance with Section 19 of Annex I in an official Union language which can be easily understood by the intended user or patient. The language(s) of the information to be supplied by the manufacturer may be determined by the law of the Member State where the device is made available to the user or patient.
34. 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.
35. 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.
36. 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.

Article 9
Authorised representative

37. A manufacturer of a device that is 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 designate a single authorised representative.
38. The designation 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.
39. The authorised representative shall perform the tasks specified in the mandate agreed between the manufacturer and the authorised representative.

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

- (e) keep the technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificate including any supplement issued in accordance with Article 45 at the disposal of competent authorities for the period referred to in Article 8(4);
- (f) 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;
- (g) cooperate with the competent authorities on any corrective action taken to eliminate the risks posed by devices;
- (h) 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;
- (i) 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.

40. The mandate referred to in paragraph 3 shall not include the delegation of the manufacturer's obligations laid down in Article 8(1), (2), (5), (6), (7) and (8).
41. 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.

42. 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, the outgoing authorised representative and the incoming authorised representative. This agreement shall address at least the following aspects:

- (j) the date of termination of the mandate with the outgoing authorised representative and date of beginning of the mandate with the incoming authorised representative;
- (k) the date until which the outgoing authorised representative may be indicated in the information supplied by the manufacturer, including any promotional material;
- (l) the transfer of documents, including confidentiality aspects and property rights;
- (m) 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

43. Importers shall place on the Union market only devices that are in conformity with this Regulation.
44. Before placing a device on the market importers shall ensure the following:
- (n) that the appropriate conformity assessment procedure has been carried out by the manufacturer;
 - (o) that an authorised representative in accordance with Article 9 has been designated by the manufacturer;
 - (p) that the EU declaration of conformity and the technical documentation has been drawn up by the manufacturer;
 - (q) that the device bears the required CE marking of conformity;
 - (r) that the device is labelled in accordance with this Regulation and accompanied by the required instructions for use and EU declaration of conformity;

- (s) 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 shall inform the manufacturer and his authorised representative to that effect, as well as the competent authority of the Member State in which he is established.

45. 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.
46. Importers shall ensure that the device is registered in the electronic system in accordance with Article 25(2).
47. 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.
48. 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 keep a register of complaints, of non-conforming products and of product recalls and withdrawals, and shall keep the manufacturer, authorised representative and distributors informed of such monitoring.
49. 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.
50. 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.
51. 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.

52. 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 the risks posed by products which they have placed on the market.

Article 12

General obligations of distributors

1. 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 bears the required CE marking of conformity;
 - (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 complied with the requirements set out in Article 24 and Article 11(3) respectively.

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 inform the manufacturer and, where applicable, his authorised representative and the importer to that effect, as well as the competent authority of the Member State in which he is established.

3. Distributors 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.
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.
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.

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.

Article 13

Person responsible for regulatory compliance

1. 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:
 - (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;
 - (b) five years of professional experience in regulatory affairs or 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.

This paragraph shall not apply to manufacturers of custom-made devices who are micro-enterprises as defined by Commission Recommendation 2003/361/EC⁵⁴.

2. The qualified person shall at least be responsible for ensuring the following matters:
 - (a) that the conformity of the devices is appropriately assessed before a batch is released;
 - (b) that the technical documentation and the declaration of conformity are drawn up and kept up-to-date;
 - (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 shall suffer no disadvantage within the manufacturer's organisation in relation to the proper fulfilment of his duties.

⁵⁴ OJ L 124, 20.5.2003, p. 36

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:
- (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;
 - (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;
 - (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, 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

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.
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.
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.
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).
5. The name and address of the legal or natural person referred to in paragraph 1 and the other relevant information in accordance with Section 19 of Annex I shall be indicated on the label and, where applicable, in the instructions for use of the reprocessed device.

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.

6. A Member State may maintain or introduce national provisions prohibiting, within its territory, on grounds of protection of public health specific to that 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.

Article 16 *Implant card*

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.
2. This card shall contain the following:
 - (a) the information allowing identification of the device, including the Unique Device Identification;
 - (b) any warnings, precautions or measures to be taken by the patient or a healthcare professional with regard to reciprocal interference with reasonably foreseeable external influences or environmental conditions;
 - (c) any information about the expected lifetime of the device and any necessary follow-up.

The information shall be written in a way that is readily understood by a lay person.

Article 17 *EU declaration of conformity*

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.
2. Where, concerning aspects not covered by this Regulation, devices are subject to other Union legislation which also requires a declaration of conformity by the manufacturer that fulfilment of the requirements of that legislation has been demonstrated, a single EU declaration of conformity shall be drawn up in respect of

all Union acts applicable to the device containing all information required for identification of the Union legislation to which the declaration relates.

3. By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for compliance with the requirements of this Regulation and all other Union legislation applicable to the device.
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.

Article 18

CE marking of conformity

1. Devices, other than custom-made or investigational devices, considered to be in conformity with the requirements of this Regulation shall bear the CE marking of conformity, as presented in Annex IV.
2. The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.
3. The CE marking shall be affixed visibly, legibly and indelibly to the device or its sterile pack. Where that is not possible or not warranted on account of the nature of the device, it shall be affixed to the packaging. The CE marking shall also appear in the instructions for use and on the sales packaging where those are provided.
4. The CE marking shall be affixed before the device is placed on the market. It may be followed by a pictogram or any other mark indicating a special risk or use.
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.
6. Where devices are subject to other Union legislation concerning other aspects which also provide for the affixing of the CE marking, the CE marking shall indicate that the devices also fulfil the provisions of the other legislation.

Article 19

Devices for special purposes

1. Member States shall not create any obstacle to the following devices:
 - (a) investigational devices which are supplied to a doctor of medicine, a dental practitioner or an authorised person for the purpose of clinical investigation if they meet the conditions laid down in Articles 50 to 60 and in Annex XIV;
 - (b) custom-made devices which are made available on the market if they comply with Article 42(7) and Annex XI.

Those devices shall not bear the CE marking, with the exception of the devices referred to in Article 54.

2. Custom-made devices shall be accompanied by the statement referred to in Annex XI which shall be made available to the particular patient or user identified by name, an acronym or a numerical code.

Member States may require that the manufacturer of a custom-made device submit to the competent authority a list of such devices which have been made available in their territory.

3. At trade fairs, exhibitions, demonstrations or similar events, Member States shall not create any obstacle to the showing of devices which do not comply with this Regulation, provided a visible sign clearly indicates that such devices are intended for presentation or demonstration purposes only and cannot be made available until they have been made to comply with this Regulation.

Article 20

Systems and procedure packs

1. Any natural or legal person shall draw up a statement referred to in paragraph 2 if he puts devices bearing the CE marking together with the following other devices or products, in accordance with the intended purpose of the devices or other products and within the limits of use specified by their manufacturers, in order to place them on the market as a system or procedure pack:
 - other devices bearing the CE marking;
 - *in vitro* diagnostic medical devices bearing the CE marking in conformity with Regulation (EU) [.../...];
 - other products which are in conformity with the legislation applicable to those products.
2. In the statement, the person referred to in paragraph 1 shall declare the following:
 - (a) that he verified the mutual compatibility of the devices and, if applicable other products, in accordance with the manufacturers' instructions and has carried out his operations in accordance with those instructions;
 - (b) that he packaged the system or procedure pack and supplied relevant information to users incorporating the information to be supplied by the manufacturers of the devices or other products which have been put together;
 - (c) that the activity of putting devices and, if applicable, other products together as a system or procedure pack was subject to appropriate methods of internal monitoring, verification and validation.
3. Any natural or legal person who sterilises systems or procedure packs referred to in paragraph 1 for the purpose of placing them on the market shall, at his choice, follow one of the procedures referred to in Annex VIII or in Part A of Annex X. The

application of those Annexes and the involvement of the notified body shall be limited to the aspects of the procedure relating to ensuring sterility until the sterile package is opened or damaged. The person shall draw up a statement declaring that sterilisation has been carried out in accordance with the manufacturer's instructions.

4. Where the system or procedure pack incorporate devices which do not bear the CE marking or where the chosen combination of devices is not compatible in view of their original intended purpose, the system or procedure pack shall be treated as a device in its own right and shall be subjected to the relevant conformity assessment procedure pursuant to Article 42.
5. The systems or procedure packs referred to in paragraph 1 shall not themselves bear an additional CE marking but they shall bear the name, registered trade name or registered trade mark of the person referred to in paragraph 1 as well as the address at which he can be contacted and his location can be established. Systems or procedure packs shall be accompanied by the information referred to in Section 19 of Annex I. The statement referred to in paragraph 2 of this Article shall be kept at the disposal of the competent authorities, after the system or procedure pack has been put together, for the period that is applicable to the devices put together in accordance with Article 8(4). Where these periods differ, the longest period shall apply.

Article 21

Parts and components

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.
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.

Article 22

Free movement

Member States shall not refuse, prohibit or restrict the making available or putting into service within their territory of devices which comply with the requirements of this Regulation.

Chapter III

Identification and traceability of devices, registration of devices and of economic operators, summary of safety and clinical performance, European databank on medical devices

Article 23 *Identification within the supply chain*

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):

- (a) any economic operator to whom they have supplied a device;
- (b) any economic operator who has supplied them with a device;
- (c) any health institution or healthcare professional to whom they have supplied a device.

Upon request, they shall inform the competent authorities thereof.

Article 24 *Unique Device Identification system*

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:
 - (a) production of a UDI that comprises the following:
 - (i) a device identifier specific to a manufacturer and a device model, providing access to the information laid down in Part B of Annex V;
 - (ii) a production identifier that identifies data related to the unit of device production;
 - (b) placement of the UDI on the label of the device;
 - (c) storage of the UDI by the economic operators and the health institutions through electronic means;
 - (d) establishment of an electronic system on UDI.
2. The Commission shall designate one or several entities that operate a system for assignment of UDIs pursuant to this Regulation and that satisfy all of the following criteria:
 - (a) the entity is an organisation with legal personality;

- (b) its system for the assignment of UDIs is adequate to identify a device through its distribution and use in accordance with the requirements of this Regulation;
 - (c) its system for the assignment of UDIs conforms to the relevant international standards;
 - (d) the entity gives access to its system for the assignment of UDIs to all interested users according to a set of predetermined and transparent terms and conditions;
 - (e) the entity undertakes the following:
 - (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;
 - (ii) to make available to the Commission and to the Member States, upon request, information concerning its system for the assignment of UDIs and concerning manufacturers that place an UDI on the label of their device in accordance with the entity's system;
 - (iii) to remain in compliance with the criteria for designation and the terms of designation during the period for which it is designated.
3. Before placing a device on the market, the manufacturer shall assign to the device a UDI provided by an entity designated by the Commission in accordance with paragraph 2, if that device belongs to the devices, categories or groups of devices determined by a measure referred to in point (a) of paragraph 7.
4. The UDI shall be placed on the label of the device, in accordance with the conditions laid down by a measure referred to in point (c) of paragraph 7. It shall be used for reporting serious incidents and field safety corrective actions in accordance with Article 61 and shall be included in the implant card referred to in Article 16. The device identifier shall appear on the EU declaration of conformity referred to in Article 17 and in the technical documentation referred to in Annex II.
5. Economic operators and health institutions shall store and keep, by electronic means, the device identifier and the production identifier of the devices which they have supplied or they have been supplied with, if they belong to the devices, categories or groups of devices determined by a measure referred to in point (a) of paragraph 7.
6. The Commission, in cooperation with the Member States, shall set up and manage an electronic system on UDI to collate and process the information mentioned in Part B of Annex V. This information shall be accessible to the public.
7. The Commission shall be empowered to adopt delegated acts in accordance with Article 89:
- (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;

- (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;
 - (c) defining the obligations of economic operators, of health institutions and of professional users, in particular regarding allocation of the numeric or alphanumeric characters, placement of the UDI on the label, storage of information in the electronic system on UDI and use of the UDI in documentation and reporting related to the device provided for in this Regulation;
 - (d) amending or supplementing the list of information set out in Part B of Annex V in the light of technical progress.
8. When adopting the measures referred to in paragraph 7, the Commission shall take into account the following:
- (a) the protection of personal data;
 - (b) the legitimate interest in protecting commercially sensitive information;
 - (c) the risk-based approach;
 - (d) the cost-effectiveness of the measures;
 - (e) the convergence of UDI systems developed at international level.

Article 25

Electronic system on registration of devices and economic operators

1. The Commission, in collaboration with the Member States, shall set up and manage an electronic system to collate and process information that is necessary and proportionate to describe and identify the device and to identify the manufacturer and, where applicable, the authorised representative and the importer. The details regarding the information to be submitted by the economic operators are laid down in Part A of Annex V.
2. Before a device, other than a custom-made or investigational device, is placed on the market the manufacturer or his authorised representative shall submit to the electronic system the information referred to in paragraph 1.
3. Within one week after placing a device, other than a custom-made or investigational device, on the market, importers shall submit to the electronic system the information referred to in paragraph 1.
4. Within one week of any change occurring in relation to the information referred to in paragraph 1, the relevant economic operator shall update the data in the electronic system.
5. Not later than two years after submission of the information in accordance with paragraphs 2 and 3, and then every second year, the relevant economic operator shall confirm the accuracy of the data. In the event of failure to confirm within six months

of the due date, any Member State may take measures to suspend or otherwise restrict the making available of the device in question within its territory until the obligation referred to in this paragraph is complied with.

6. The data contained in the electronic system shall be accessible to the public.
7. The Commission shall be empowered to adopt delegated acts in accordance with Article 89 amending the list of information to be submitted as set out in Part A of Annex V in the light of technical progress.

Article 26

Summary of safety and clinical performance

1. In the case of devices classified as class III and implantable devices, other than custom-made or investigational devices, the manufacturer shall draw up a summary of safety and clinical performance. It shall be written in a way that is clear to the intended user. The draft of this summary shall be part of the documentation to be submitted to the notified body involved in the conformity assessment in accordance with Article 42 and shall be validated by that body.
2. The Commission may, by means of implementing acts, set out the form and the presentation of the data elements to be included in the summary of safety and clinical performance. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 88(2).

Article 27

European databank

1. The Commission shall develop and manage the European databank on medical devices (Eudamed) for the following purposes:
 - (a) to enable the public to be adequately informed about devices placed on the market, about the corresponding certificates issued by notified bodies and about the relevant economic operators;
 - (b) to enable traceability of devices within the internal market;
 - (c) to enable the public to be adequately informed about clinical investigations and to enable sponsors of clinical investigations to be conducted in more than one Member State to comply with information obligations under Articles 50 to 60;
 - (d) to enable manufacturers to comply with information obligations under Articles 61 to 66;
 - (e) to enable the competent authorities of the Member States and the Commission to carry out their tasks relating to this Regulation on a well informed basis and to enhance the cooperation between them.
2. Eudamed shall include the following as integral parts:
 - (a) the electronic system on UDI referred to in Article 24;

- (b) the electronic system on registration of devices and economic operators referred to in Article 25;
 - (c) the electronic system on information on certificates referred to in Article 45(4);
 - (d) the electronic system on clinical investigations referred to in Article 53,
 - (e) the electronic system on vigilance referred to in Article 62;
 - (f) the electronic system on market surveillance referred to in Article 68.
3. The data shall be entered into Eudamed by the Member States, notified bodies, economic operators and sponsors as specified in the provisions concerning the electronic systems referred to in paragraph 2.
 4. All the information collated and processed by Eudamed shall be accessible to the Member States and to the Commission. The information shall be accessible to notified bodies, economic operators, sponsors and the public to the extent defined in the provisions referred to in paragraph 2.
 5. Eudamed shall contain personal data only insofar as this is necessary for the electronic systems referred to in paragraph 2 to collate and process the information in accordance with this Regulation. Personal data shall be kept in a form which permits identification of the data subjects for no longer than the periods referred to in Article 8(4).
 6. The Commission and the Member States shall ensure that the data subjects may effectively exercise their rights to information, to access, to rectify and to object in accordance with Regulation (EC) No 45/2001 and Directive 95/46/EC, respectively. They shall ensure that the data subjects may effectively exercise the right of access to data relating to them, and the right to have inaccurate or incomplete data corrected and erased. Within their respective responsibilities, the Commission and the Member States shall ensure that inaccurate and unlawfully processed data is deleted, in accordance with the applicable legislation. Corrections and deletions shall be carried out as soon as possible, but no later than within 60 days after a request is made by a data subject.
 7. The Commission shall, by means of implementing acts, lay down the modalities necessary for the development and management of Eudamed. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).
 8. In relation to its responsibilities under this Article and the processing of personal data involved therein, the Commission shall be considered controller of Eudamed and its electronic systems.

Chapter IV

Notified bodies

Article 28

National authorities responsible for notified bodies

1. A Member State that intends to designate a conformity assessment body as a notified body, or has designated a notified body, to carry out third-party conformity assessment tasks under this Regulation shall designate an authority that shall be responsible for setting up and carrying out the necessary procedures for the assessment, designation and notification of conformity assessment bodies and for the monitoring of notified bodies, including subcontractors or subsidiaries of those bodies, hereinafter referred to as the 'national authority responsible for notified bodies'.
2. The national authority responsible for notified bodies shall be established, organised and operated so as to safeguard the objectivity and impartiality of its activities and to avoid any conflicts of interests with conformity assessment bodies.
3. It shall be organised so that each decision relating to notification of a conformity assessment body is taken by personnel different from those who carried out the assessment of the conformity assessment body.
4. It shall not perform any activities that conformity assessment bodies perform nor provide consultancy services on a commercial or competitive basis.
5. The national authority responsible for notified bodies shall safeguard the confidentiality of the information it obtains. However, it shall exchange information on a notified body with other Member States and the Commission.
6. The national authority responsible for notified bodies shall have a sufficient number of competent personnel at its disposal for the proper performance of its tasks.

Without prejudice to Article 33(3), where a national authority is responsible for the designation of notified bodies in the field of products other than medical devices, the competent authority for medical devices shall be consulted on all aspects specifically related to medical devices.

7. Member States shall provide the Commission and the other Member States with information on their procedures for the assessment, designation and notification of conformity assessment bodies and for the monitoring of notified bodies, and of any changes thereto.
8. The national authority responsible for notified bodies shall be peer-reviewed every second year. The peer-review shall include an on-site visit to a conformity assessment body or a notified body under the responsibility of the reviewed authority. In the case referred to in the second subparagraph of paragraph 6, the competent authority for medical devices shall participate in the peer-review.

The Member States shall draw up the annual plan for the peer-review, ensuring an appropriate rotation in respect of reviewing and reviewed authorities, and submit it to the Commission. The Commission may participate in the review. The outcome of the peer-review shall be communicated to all Member States and to the Commission and a summary of the outcome shall be made publicly available.

Article 29

Requirements relating to notified bodies

1. Notified bodies shall satisfy the organisational and general requirements and the quality management, resource and process requirements that are necessary to fulfil their tasks for which they are designated in accordance with this Regulation. Minimum requirements to be met by notified bodies are set out in Annex VI.
2. The Commission shall be empowered to adopt delegated acts in accordance with Article 89 amending or supplementing the minimum requirements in Annex VI, in the light of technical progress and considering the minimum requirements needed for the assessment of specific devices, or categories or groups of devices.

Article 30

Subsidiaries and subcontracting

1. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary for specific tasks connected with conformity assessment, it shall verify that the subcontractor or the subsidiary meets the relevant requirements set out in Annex VI and shall inform the national authority responsible for notified bodies accordingly.
2. Notified bodies shall take full responsibility for the tasks performed on their behalf by subcontractors or subsidiaries.
3. Conformity assessment activities may be subcontracted or carried out by a subsidiary only with the agreement of the legal or natural person that applied for conformity assessment.
4. Notified bodies shall keep at the disposal of the national authority responsible for notified bodies the relevant documents concerning the verification of the qualifications of the subcontractor or the subsidiary and the work carried out by them under this Regulation.

Article 31

Application by a conformity assessment body for notification

1. A conformity assessment body shall submit an application for notification to the national authority responsible for notified bodies of the Member State in which it is established.
2. The application shall specify the conformity assessment activities, the conformity assessment procedures and the devices for which the body claims to be competent,