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.

1a. By way of derogation from paragraph 1, as regards single-use devices that are reprocessed and used within a health institution ~~or reprocessed at the request of a health institution provided that exactly the same device is returned to that health institution~~, Member States may decide not to apply all ~~certain~~ rules relating to manufacturers' obligations laid down in this Regulation provided that they ensure that:

(a) the safety and performance of the reprocessed device is equivalent to that of the original device and the requirements in Article 4(4a) (a), (c), (d) and ~~to~~ (e), are ~~observed~~ complied with;

(b) the reprocessing is performed according to common specifications ~~or national provisions as appropriate,~~ detailing the requirements:

- *on risk management, including the analysis of the construction and material, related properties of the device (reverse engineering) and procedures to detect changes in the design of the original product as well as of its planned application after reprocessing,*
- *on the validation of procedures for the entire process, including cleaning steps,*
- *on the product release and performance testing, and*
- *on the quality management system.*

Member States shall notify the Commission and the other Member States of the national provisions, introduced pursuant to this paragraph and the grounds for introducing them. The Commission shall keep the information publicly available.

1b. Member States may choose to apply provisions referred to in paragraph 1a also as regards single-use devices that are reprocessed by an external reprocessor at the request of a health institution provided that the reprocessed device in its entirety is returned to that health institution and the reprocessor complies with the requirements referred to in paragraph 1a (a) and (b).

1~~b~~c. The Commission shall adopt the necessary Common Specifications referred to in paragraph 1a(b) ~~as soon as possible~~ by the date of application of this regulation. In case Common Specifications are not adopted by the date of application of this regulation, reprocessing shall be performed according to relevant harmonized standards and national provisions that ensure compliance with the requirements outlined in paragraph 1a(b). The compliance with the common specifications or, in the absence of common specifications, the relevant harmonized standards and the national provisions, shall be certified by a notified body.

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. ***Only*** ~~In the case of reprocessing of single-use devices for critical use, only~~ reprocessing ***of single-use devices*** 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 ***cannot be reprocessed safely and therefore*** may ***under no circumstances*** 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 ***that permits reprocessing of single-use devices*** may maintain or introduce ***stricter*** national provisions ***restricting or*** prohibiting, within its territory, ~~on grounds of protection of public health~~ 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 ~~***and***~~ ***or further use*** 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*~~ ***Information to be supplied to the patient with an implanted device***

1. The manufacturer of an implantable device shall provide together with the device ~~an implant card~~ ***the following:***

(a) information allowing the identification of the device, including the device name, serial number, batch code or lot number, the Unique Device Identification, as well as the name, address and the URL of the website of the manufacturer;

(c) 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, medical examinations or environmental conditions;

(d) any information about the expected lifetime of the device and any necessary follow-up;

(e) any other information to assure a safe use of the device by the patient, including the information in Annex I, Section 19.3. Point (ob).

1a. ***The above mentioned information*** ~~which~~ shall be made available ~~to~~ ***for*** the particular patient who has been implanted with the device ***by any means that can allow a rapid access to the information and stated in the language(s) determined by the concerned Member State. The information shall be written in a way that is readily understood by a lay person. The information mentioned in this article must be updated where appropriate and updates should be available to the patient via the URL for the website mentioned in paragraph 1 point (a).***

1aa. ***Member states shall require health institutions to make the information mentioned in this article available to patients who have been implanted.***

1b. ***The Commission shall, by means of implementing acts,*** ~~shall~~ ***establish a list of categories or groups of devices to which this Article shall not apply. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88 (3).***

~~2. This card shall contain the following:~~

~~(a) the information allowing identification of the device, including the Unique Device Identification, as well as the name and address of the manufacturer;~~

~~(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~~ ***an*** 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:

(a)- other devices bearing the CE marking;

(b)- *in vitro* diagnostic medical devices bearing the CE marking in conformity with Regulation (EU) [.../...];

(c)- other products which are in conformity with the legislation applicable to those products ***only when they are used within the medical procedure or their presence in the system or procedure pack is justified.***

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, ***or where the sterilisation has not been carried out in accordance with the manufacturer's instructions*** 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***and 3*** 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~~ ***Supporting*** 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

Except where otherwise provided in this regulation, 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

1. ***Distributors and importers shall co-operate with the manufacturer or authorized representative to achieve an appropriate level of ~~care professionals and health institutions to store and keep,~~ traceability of devices.***

2. ***Economic*** ~~For devices, other than custom-made or investigational devices, economic~~ operators shall be able to identify the following ***to the competent authority***, 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.~~

3. ***For systems and procedure packs, this provision shall also apply to the natural or legal person referred to in Article 20(1).***

Article 23a

Medical devices nomenclature

To facilitate the functioning of the European Databank on medical devices (Eudamed) established pursuant to Article 27 and the UDI database established pursuant to Article 24a the Commission shall ensure that a medical devices nomenclature shall be available free of charge to manufacturers, natural or legal persons required to use nomenclature for the purpose of this regulation. The Commission shall also endeavour to ensure that that nomenclature is available to other stakeholders free of charge, where reasonably practicable.

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 ***Unique Device Identification (***UDI***)*** system shall allow the identification and ***facilitate the*** traceability of devices***, other than custom-made and investigational devices,*** and shall consist of the following:
   (a) production of a UDI that comprises the following:
      (i) a device identifier ***(DI)*** 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 ***(PI)*** that identifies ***the produced device's unit and if applicable the packaged devices as specified in Annex V Part C*** ~~data related to the unit of device production~~;
   (b) ~~placement~~ ***application*** of the UDI on the label of the device ***or on its package***;
   ~~(c) storage of the UDI by the economic operators and the health institutions through electronic means;~~
   (d) establishment of an electronic system on UDI ***(UDI database) according to Article 24a***.

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~~ ***a*** 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~~ ***ten*** 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~~.

In exercising its powers under this paragraph the Commission shall endeavour to promote interoperability between different UDI assigning entity systems with a view to minimising financial and administrative burdens for economic operators and health institutions.

3. Before placing a device on the market, the manufacturer shall assign to the device ***and – if applicable – to all higher levels of packaging*** a UDI ***created in compliance with the rules of*** ~~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 ***carrier*** shall be placed on the label of the device ***and on all higher levels of packaging. Higher levels of packaging do not include shipping containers.*** ~~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.~~

4a. The UDI shall be used for reporting serious incidents and field safety corrective actions in accordance with Article 61 and shall be included in the information to be provided to a patient implanted with a medical device referred to in Article 16.

4b. The Basic UDI device identifier (Basic UDI-DI as defined in Annex V Part C) of the device shall appear on the EU declaration of conformity referred to in Article 17.

4c. The manufacturer has to keep up-to-date a list of all applied UDI as part of the technical documentation referred to in Annex II.

5. Economic operators ~~and health institutions~~ shall store and keep, ***preferably*** by electronic means, the ***UDI*** ~~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.

5a. Member States shall encourage, and may require, health care professionals and health institutions to store and keep, preferably by electronic means, the UDI of the devices which they have been supplied with. With a view to ensuring a uniform approach to the manner in which the UDI of devices, categories or groups of devices which health institutions have been supplied with is to be stored, the Commission may adopt implementing acts pursuant to point (aa) 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~~ ***may, by means of*** ~~adopt delegated~~ ***implementing*** acts, ***specify the modalities and the procedural aspects with a view to ensuring harmonised application of the Unique Device Identification System for any of the following aspects*** ~~in accordance with Article 89(3)~~:

(a) ~~determining~~ ***the determination of*** the devices, categories or groups of devices ~~whose identification shall be based on the~~ ***to which the obligation laid down in paragraph 5*** ~~UDI~~ ***shall apply*** ~~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~~;

(aa) the determination of the devices, categories or groups of devices to which paragraph 5a shall apply;

(b) ~~specifying~~ ***the specification of*** the data to be included in the ***UDI*** production identifier ***(UDI-PI) of specific devices or device groups*** ~~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;~~

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).

~~(d)~~*7a. The Commission shall be empowered to adopt delegated acts in accordance with Article 89:*

(a) amending or supplementing the list of information set out in Part B of Annex V in the light of technical progress*; and*

(b) amending or supplementing ~~of~~ Annex V in the light of international development in the field of unique device identification.

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*;*

(f) the need to avoid duplications in the UDI system;

(g) the needs of the health care systems of the Member States.

Article 24a

Electronic system on UDI (UDI database)

1. The Commission, after consulting the MDCG shall set up and manage an electronic system on UDI (UDI database) to validate, collate, process and make available to the public the information mentioned in Part B of Annex V.

1a. When designing the UDI database the Commission shall consider the general principles on the UDI database as described in Annex V Part C section 6. The design shall, inter alia, be such that:

- *No UDI Production Identifiers are included in the UDI database;*
- *No commercially confidential product information shall be included in the UDI database.*

1b. The core data elements in the UDI database shall be accessible to the public free of charge.

2. *The technical design of the electronic system must ensure permanent accessibility on information stored in the UDI database and allow multi user access and automatic up and downloads of these information. The Commission shall provide for proper technical and administrative support to manufacturers and other users of the UDI database.*

3. *Before a device, other than a custom-made or investigational device, is placed on the market the manufacturer or his authorised representative must ensure that the information referred to in Part B of Annex V of the device in question are correctly submitted and transferred to the UDI database.*

Article 24b

Process for registration of devices

1. *Before placing on the market the manufacturer of a device, other than custom made or investigational devices shall assign in compliance with the rules of the designated issuing entities to the device a Basic UDI-DI as defined in Annex V Part C.*

1a. *Before placing on the market a system or procedure pack according to article 20 (1), other than custom made or investigational devices, the responsible natural or legal person shall assign in compliance with the rules of the designated issuing entities to the system or procedure pack a Basic UDI-DI as defined in Annex V Part C 6.3 and submit to the UDI database this Basic UDI-DI and the linked information referred to in Part B of Annex V.*

2. *Where a manufacturer of a device, other than custom made or investigational devices, applies a conformity assessment procedure according to Article 42 paragraph 3 first sentence, paragraph 4 or paragraph 5 the manufacturer shall submit to the UDI database the Basic UDI-DI and the linked information referred to in Part B of Annex V before placing the device on the market.*

3. ***Where a manufacturer of devices, other than custom made or investigational devices, applies a conformity assessment procedure according to Article 42 paragraph 2 second sentence or paragraph 3 third sentence (EU technical documentation assessment and EU type-examination) the manufacturer shall assign the Basic UDI-DI (Annex V Part C) to the device before applying for a conformity assessment procedure by a notified body. The Notified Body shall reference the Basic UDI-DI on the certificate issued (Annex XII I 4.a)). After the issuing of the relevant certificate and before placing the device on the market the manufacturer or his authorised representative shall submit to the UDI database the Basic UDI-DI and the linked information referred to in Part B of Annex V.***

Article 25

Electronic system on registration of ~~devices and~~ economic operators

1. The Commission, ~~in collaboration with the Member States~~ ***after consulting the MDCG***, shall set up and manage an electronic system to ***create the single registration number referred to in Article 25a and 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.

1b. Member States may maintain or introduce national provisions on registration of distributors and importers of a devices which have been made available in their territory.

~~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~~ *two* weeks after placing a device, other than a custom-made or investigational device *for performance evaluation*, on the market, importers shall ~~submit to~~ ***verify that the manufacturer or authorised representative has uploaded to*** the electronic system the information referred to in paragraph 1 ***and shall add their details to the relevant entry/entries.***

Where applicable, importers shall also verify that the registration includes the details of the authorised representative and, if these details are not included, shall inform the relevant authorised representative.

Article 25a

Process for registration of manufacturers and Authorised Representatives, Single registration number

1. ***The manufacturer or his authorised representative, who has not been registered before according to this article shall submit to the electronic system the information referred to in Annex V Part A before placing a device, other than a custom-made or investigational device, on the market. In cases where the conformity assessment procedure requires the involvement of a notified body the information referred to in Annex V part A shall be submitted to the electronic system before applying to a notified body.***

2. ***After having verified the data entered by the manufacturer or his authorised representative the competent authority shall procure from the electronic system referred to in Article 25 a single registration number (SRN) and issue it to the manufacturer or his authorised representative.***

3. ***The manufacturer shall use the single registration number when applying to a notified body for certification according to Article 43 and for entering the electronic system on UDI (in order to fulfil their obligations according to Article 24a(3) and Article 24b(2) and (3)).***

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~~ ***one*** years after submission of the information in accordance with paragraphs ~~2 and 3~~ ***1***, and then every second year ***thereafter***, the relevant economic operator shall confirm the accuracy of the data. ***Without prejudice to the economic operator's responsibility for the data, the competent authority shall verify the confirmed data referred to in points 1-4a of Part A of Annex V.*** In the event of failure to confirm within six months of the due date, any Member State may take ***appropriate corrective*** 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.~~

7a. The competent authority may use the data to administer a charge or fee to the manufacturer or the authorised representative pursuant to Article 86.

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 ***and, if relevant, to the patient and shall be available to the public via Eudamed***. 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. ***After validation the notified body shall upload this summary report to Eudamed. The manufacturer shall mention on the label or instructions for use where the summary report is available.***

1a. The summary of safety and clinical performance shall include at least the following aspects:

(a) the identification of the device and the manufacturer, including the basic UDI-DI and the single registration number;

(b) the intended purpose of the device, including indications, contra-indications and target populations;

(c) a description of the device, including a reference to previous generation(s) or variants if such exist, and the description of the differences, as well as a description of the accessories, other medical devices and other products that are not medical devices, which are intended to be used in combination with the medical device;

(d) suggested position in treatment options;

(e) reference to harmonized standards and common specifications;

(f) the summary of the clinical evaluation report as referred to in annex XIII, and relevant information on the post-market clinical follow up;

(g) suggested profile and training for users;

(h) information on any residual risks and any undesirable effects, warnings and precautions.

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*, after consulting the MDCG,* 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 *unique identification and to facilitate* traceability of devices within the internal market;