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From:	Presidency
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Subject:	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards simplifying and reducing the burden of the rules on medical devices and in vitro diagnostic medical devices, and amending Regulation (EU) 2022/123 as regards the support of the European Medicines Agency for the expert panels on medical devices and Regulation (EU) 2024/1689 as regards the list of Union harmonisation legislation referred to in its Annex I *- Exchange of views*

Delegations will find in Annex the first Presidency compromise text on Cluster 1 (Scope, UDI and EUDAMED, international cooperation) to be discussed at the meeting of Working Party on Pharmaceuticals and Medical Devices on 2 July 2026.

Changes compared to the Commission proposal are indicated in ~~strikethrough~~ for deletions and **bold** for new text. Text from the MDR or IVDR not included in the Commission proposal and added to this compromise text is indicated in *italics*. Changes to that text are indicated in ~~*strikethrough*~~ for deletions and ***bold*** *for new text*.

ANNEX

Scope

(**New recital, in support of changes being made to MDR Article 1(7)**):
For integral products combining a medical device and an in vitro diagnostic medical device, the determination of whether the action of one component is principal or ancillary should be based on objective criteria, including the primary intended purpose of the product, the relevance of the component for clinical decision-making, and its functional contribution to the overall safety and performance of the integral product.

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Amendments to Regulation (EU) 2017/745

Regulation (EU) 2017/745 is amended as follows:

(1) Article 1 is amended as follows:

(a) ~~in~~ paragraph 2~~, the first sentence~~ is replaced by the following:

'This Regulation shall also apply, as from the date of application of common ~~—~~specifications~~-~~ adopted pursuant to Article 9, to the groups of products without an intended medical purpose that are listed in Annex XVI, and their accessories, taking into account the state of the art, and in particular existing harmonised standards for analogous devices with a medical purpose, based on similar technology. *The common specifications for each of the groups of products listed in Annex XVI shall address, at least, application of risk management as set out in Annex I for the group of products in question* ***and, where relevant, for their accessories*** *and, where necessary, clinical evaluation regarding safety*.;'

(b) paragraph 4 is replaced by the following:

'4. For the purposes of this Regulation, medical devices, accessories for medical devices, and products listed in Annex XVI and their accessories, to which this Regulation applies pursuant to paragraph 2 shall hereinafter be referred to as 'devices'.';'

(c) in paragraph 6, point ~~(g)~~**(a)** is replaced by the following:

'(a) *in vitro diagnostic medical devices covered by Regulation (EU) 2017/746,* ***without affecting paragraph 7;'***

(ca) in paragraph 6, point (b) is replaced by the following:

'medicinal products as defined in point 2 of Article 1 of Directive 2001/83/EC. In deciding whether a product falls under Directive 2001/83/EC or under this Regulation, particular account shall be taken of the principal mode of action of the product, ***without affecting paragraph 7;'***

(cb) in paragraph 6, point (c) is replaced by the following:

'(c) advanced therapy medicinal products covered by Regulation (EC) No 1394/2007, ***without affecting paragraph 7;'***

(cc) in paragraph 6, point (g) is replaced by the following:

'(g) ~~organs intended for transplantation falling within the scope of Directive 2010/53/EU~~ **any of the** ~~European Parliament and of the Council* or substances of human origin falling within the scope of Regulation (EU) 2024/1938 of the European Parliament and of the Council**, or their derivatives, or products containing or consisting of them; however, this Regulation does apply to devices manufactured utilising derivatives of substances of human origin which are non-viable or are rendered non-viable;~~**following**:

- organs intended for transplantation falling within the scope of Directive 2010/53/EU of the European Parliament and of the Council* or
- substances of human origin as defined in Article 3(1) of Regulation (EU) 2024/1938 of the European Parliament and of the Council** , or their derivatives, or products containing or consisting of them.

However, this Regulation does apply to devices manufactured utilising derivatives of substances of human origin which are non-viable or are rendered non-viable.

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* Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024 on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC (OJ L, 2024/1938, 17.7.2024, ELI: http://data.europa.eu/eli/reg/2024/1938/oj).

** Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation (OJ L 207, 6.8.2010, p. 14, ELI: http://data.europa.eu/eli/dir/2010/53/oj).;'

(d) paragraph 7 is replaced by the following:

'7. Any device which, when placed on the market or put into service, incorporates as an integral part an in vitro diagnostic medical device as defined in Article 2, point (2), of Regulation (EU) 2017/746 that has an action ancillary to that of the device in which it is incorporated, shall be governed by this Regulation. In that case, the relevant general safety and performance requirements set out in Annex I to Regulation (EU) 2017/746 shall apply with regard to the safety and performance of the in vitro diagnostic medical device part.

However, if the action of the in vitro diagnostic medical device is principal and not ancillary to that of the device in which it is incorporated, the integral product shall be governed by Regulation (EU) 2017/746. In that case, the relevant general safety and performance requirements set out in Annex I to this Regulation shall apply with regard to the safety and performance of the device part.**'**;'

(e) paragraph 10 is amended as follows:

(i) the first subparagraph is replaced by the following:

'Any device which, when placed on the market or put into service, incorporates, as an integral part, non-viable substances of human origin**,** or their derivatives**,** that have an action ancillary to that of the device in which they are incorporated shall be assessed and authorised in accordance with this Regulation**, without prejudice to Article 2(8) of Regulation 2024/1938**.;'

(ii) ~~in~~ the second subparagraph, first sentence, ~~the reference to 'Directive 2004/23/EC'~~ is replaced by ~~a reference to 'Regulation (EU) 2024/1938';~~ **the following:**

'However, if the action of those substances of human origin, or their derivatives is principal and not ancillary to that of the device and the product is not governed by Regulation (EC) No 1394/2007, the product shall be governed by 'Regulation (EU) 2024/1938.'

(2) Article 2 is amended as follows:

(a) in point (1), the second subparagraph is replaced by the following:

'The following products shall also be deemed to be medical devices:

- devices for the control or support of conception;
- products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4).;'

Amendments to Regulation (EU) 2017/746

Regulation (EU) 2017/746 is amended as follows:

(1) Article 1(4) is replaced by the following:

'4. Any device which, when placed on the market or put into service, incorporates, as an integral part, a medical device as defined in Article 2, point (1), of Regulation (EU) 2017/745 that has an action ancillary to that of the in vitro diagnostic medical device, the integral product shall be governed by this Regulation. In that case, the relevant general safety and performance requirements set out in Annex I to Regulation (EU) 2017/745 shall apply as far as the safety and performance of the medical device part are concerned.

However, if the action of the medical device is principal and not ancillary to that of the in vitro diagnostic medical device, the integral product shall be governed by Regulation (EU) 2017/745. In that case, the relevant general safety and performance requirements set out in Annex I to this Regulation shall apply as far as the safety and performance of the in vitro diagnostic medical device part are concerned.;'

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Definitions

Amendments to Regulation (EU) 2017/745

(2) Article 2 is amended as follows:

(b) point (7) is replaced by the following:

'(7) 'generic device group' means a set of devices having the same or similar intended purposes and a commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics;~~;~~'

(c) points (18), (19), (20) and (21) are deleted;

(e) the following points (72), (73), (74), (75) and (76) are added:

'(72) 'well-established technology device' means a device that ~~belongs to a generic device group, which~~ fulfils **all** the following criteria:

(a) it ~~has~~ **is** simple **in its design, with a**~~, common and~~ stable ~~design~~ **manufacturing process and is characterised by a relative ease of use and operation by the intended user**;

(b) it ~~has not been associated with safety issues in the past;~~ **is part of a generic device group that is characterised by all the following:**

- **it has a stable, acceptable, and well understood risk profile, with a demonstrable, favourable track record of safety;**
- **the clinical performance characteristics of the generic device group are acceptable, well-understood, and sufficiently documented based on relevant clinical and post-market surveillance data, taking into account the expected lifetime of the device and the state of the art;**

- **devices in the generic device group have been continuously made available on the Union market for at least ten years; and**
- **the characteristics of devices in the generic device group are stable, as demonstrated by no significant changes to the design or intended purpose over the past ten years.**

~~(c) it has well-known clinical performance characteristics and comprises standard of care devices with little evolution in indications and the state of the art;~~

~~(d) it has a long history on the Union market;';'~~

(…)

(3) Articles 3 and 4 are replaced by the following:

'Article 3

Amendment and implementation of certain definitions

1. The Commission is empowered to adopt delegated acts in accordance with Article 115 in order to amend the definition of well-established technology device set out in Article 2, point (72), in the light of technical and scientific progress and taking into account definitions agreed at Union and international level.

2. The Commission ~~may, by means of implementing acts, draw up non-exhaustive lists of devices that fall under, or of devices that do not fall~~ **shall, in consultation with the MDCG, develop dedicated guidelines to support national authorities in the determination of whether a device falls** under the definition of well-established technology device **as referred to** in Article 2, point (72). **Those guidelines shall include at least an indicative, non-exhaustive list of devices that are deemed to fall under the definition, and may include an indicative, non-exhaustive list of devices that are not deemed to fall under that definition. Those guidelines shall be published by [one year after publication of this Regulation in OJEU], and shall be assessed and updated regularly, as appropriate.**

~~Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3). '~~

(…)

Amendments to Regulation (EU) 2017/746

(2) Article 2 is amended as follows:

(a) in point (2), first subparagraph, point (f) is replaced by the following:

'(f) to define or monitor therapeutic measures.;'

(…)

(c) point (8) is replaced by the following:

'(8) 'generic device group' means a set of devices having the same or similar intended purposes and a commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics;';

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Amendments to Regulation (EU) 2017/745

(19) Article 27 is amended as follows:

~~(a) in paragraph 1, after point (b) the following point (ba) is inserted:~~

~~'(ba) a Basic UDI-DI, as defined in Part C of Annex VI;;'~~

(b) paragraph 2 is amended as follows:

(i) point (d) is replaced by the following:

'(d) the entity gives access to its system for the assignment of UDIs to all interested users in accordance with a set of predetermined and transparent terms and conditions that take into account the interests of micro, small and medium-sized enterprises within the meaning of Recommendation 2003/361/EC;~~;~~'

(ii) in point (e), the following point (iv) is added:

'(iv) offer its system for the assignment of UDIs to manufacturers that are micro and small enterprises within the meaning of Recommendation 2003/361/EC under preferential conditions **on access, fees and support,** that take into account the specific needs of such enterprises and are proportionate to their size.;'

(c) paragraph 3 is replaced by the following:

'3. Before placing a device, other than a custom-made device**,** or investigational device, on the market, the manufacturer shall, in accordance with the rules of the issuing entity designated by the Commission in accordance with paragraph 2, assign to the device a Basic UDI-DI and a UDI as defined in Part C of Annex VI. If applicable, the manufacturer shall assign a ~~UDI-DI~~**UDI** to all higher levels of packaging.~~;~~'

(d) the following paragraphs 3a**, 3b and 9a** ~~and 3b~~ are inserted:

'3a. Before placing on the market a system or procedure pack pursuant to Article 22(1) and (3), the natural or legal person responsible shall assign to the system or procedure pack, in accordance with the rules of the issuing entity designated by the Commission in accordance with paragraph 2, a Basic UDI-DI and UDI as defined in Part C of Annex VI.

3b. For devices that are the subject of a conformity assessment as referred to in Article 52(3) and in Article 52(4), second and third subparagraphs, **the manufacturer shall assign** a Basic UDI-DI referred to in paragraph 1 of this Article ~~shall be assigned~~ before the manufacturer applies to a notified body for that assessment.;

9a. Requirements laid down in this Article, Article 29 and Annex VI Part C, as applicable, shall not apply to those devices, categories or groups of devices that are highly individualised, or in view of their risk class, the number of devices placed on the market and the financial and administrative burden related to the assignment of UDI, provided that such exemptions remain proportionate and do not compromise traceability. '

(e) in paragraph 10, points (a) and (b) are replaced by the following:

'(a) amending the list of information set out in Parts A and B of Annex VI in the light of technical progress;

(b) amending Annex VI in the light of experience obtained from the implementation of the UDI system, or in the light of international developments and technical progress in the field of Unique Device Identification.;'

(ea) in paragraph 11, the following point (ab) is added:

'(ab) determining the devices to which paragraph 9a applies;'

~~(f) in paragraph 11, the following point (c) is added:~~

~~'(c) determining the UDI related obligations laid down in this Article, Article 29 and Annex VI Part C that shall not apply to certain devices, categories or groups of~~ devices ~~in view of the highly individualised characterisation of those devices, or in view of their risk class, the number of devices placed on the market and the financial and administrative burden related to the assignment of UDI '~~

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(20) Article 28 is amended as follows:

(a) paragraph 3, is replaced by the following:

'3. The core data elements to be provided to the UDI database, referred to in Part B of Annex VI, shall be accessible to the public, except the element referred to in point ~~13~~**9** of that Part. **Such access shall remain free of charge**.'

(21) Article 29 is replaced by the following:

'Article 29

Registration of devices and systems or procedure packs

1. Before placing a device, other than a custom-made device or investigational device, on the market, the manufacturer shall**,** provide the Basic UDI-DI to the UDI database together with the other core data elements referred to in Part B of Annex VI related to that device~~, as applicable~~. The manufacturer shall keep the information provided to the UDI database updated **and shall update any changes without undue delay, and in any event no later than 30 days after the change occurs**.

2. Before placing on the market a system or procedure pack as referred to in Article 22(1) and (3), the natural or legal person responsible shall provide the Basic UDI-DI to the UDI database together with the other core data elements referred to in Part B of Annex VI related to that system or procedure pack. The natural or legal person referred to in Article 22(1) shall keep up to date the information provided to the UDI database **within 30 days from any change that occurred**.

3. For devices that are the subject of a conformity assessment as referred to in Article 52(3) and in Article 52(4), second and third subparagraphs, the notified body shall confirm in Eudamed that the information referred to in **Point 2 of** Part B of Annex VI is correct.~~;~~'

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(22) Article 30 is amended as follows:

(a) paragraph 1 is replaced by the following:

‘1. The Commission, after consulting the MDCG, shall set up and manage an electronic system to create the single registration number referred to in Article 31(2) and to collate and process information that is necessary and proportionate to identify the manufacturer and, where applicable, the authorised representative~~,~~ the importer and the person referred to in Article 22(1). The details regarding the information to be provided to that electronic system by the economic operators are laid down in Part A, Section 1, of Annex VI.;’

(b) in paragraph 2, the following sentence is added:

‘Where national distributor databases require information on devices**, where feasible**, such databases shall allow for the retrieval of the device information from the electronic systems referred to in Article 33(2), points (a) and (b).;’

(23) Article 31 is amended as follows:

(a) the title is replaced by the following:

‘Registration of economic operators;’

(b) paragraphs 1 and 2 are replaced by the following:

‘1. Before placing a device, other than a custom-made device, on the market, manufacturers, authorised representatives, importers and persons referred to in Article 22(1) of this Regulation- shall, in order to- register, submit to the electronic system referred to in Article 30 the information referred to in Part A of Annex VI, provided that they have not already registered in accordance with this Article. In cases where the conformity assessment procedure requires the involvement of a notified body pursuant to Article 52, the information referred to in Part A of Annex VI shall be provided to that electronic system before applying to the notified body.

2. Without undue delay, the competent authority shall verify the data entered pursuant to paragraph 1, obtain a single registration number (‘SRN’) from the electronic system referred to in Article 30 and issue it to the manufacturer, the authorised representative, the importer or the person referred to in Article 22(1).;’

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(c) in paragraph 4, the words ‘one week’ are replaced by the words ‘two weeks’;

(d) paragraph 6 is deleted;

(e) paragraph 7 is replaced by the following:

‘7. The data entered pursuant to paragraph 1 of this Article in the electronic system referred to in Article 30 shall be accessible to the public, except the information regarding the person responsible for regulatory compliance referred to in Part A, point 1.4, of Annex VI.;’

(f) paragraph 8 is replaced by the following:

‘8. The competent authority may use the data to charge the manufacturer, the authorised representative, the importer or the person referred to in Article 22(1) a fee pursuant to Article 111.;’

(25) Article 33 is amended as follows:

~~(a) in paragraph 2, the following subparagraph is inserted:~~

~~‘By way of derogation from the first subparagraph, the Commission may decide that one or more of the electronic systems referred to in that subparagraph are not to be included in Eudamed. In that case, the Commission shall ensure that those electronic systems are interoperable with Eudamed.;’~~

(b) paragraph 3 is replaced by the following:

‘3. When designing ~~Eudamed and, where applicable, any of the electronic systems that are not included in~~ Eudamed, the Commission shall give due consideration to compatibility with national databases and national web-interfaces to allow for import and export of data.;’

(c) paragraph 4 is replaced by the following:

‘4. The data shall be entered into ~~Eudamed and, where applicable, any of the electronic systems that are not included in~~ Eudamed by the Member States, notified bodies, economic operators and sponsors as specified in the provisions on the electronic systems referred to in paragraph 2. The Commission shall provide for technical and administrative support to users of Eudamed ~~and, where applicable, any of the electronic systems that are not included in Eudamed~~.;’

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(d) paragraph 5 is replaced by the following:

‘5. All the information collated and processed by Eudamed ~~and, where applicable, any of the electronic systems that are not included in 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 specified in the provisions on the electronic systems referred to in paragraph 2.

The Commission shall ensure that public parts of Eudamed ~~and, where applicable, any of the electronic systems that are not included in Eudamed,~~ are presented in a user-friendly and easily-searchable format.;’

(e) paragraph 6 is replaced by the following:

‘6. Eudamed ~~and, where applicable, any of the electronic systems that are not included in Eudamed,~~ shall contain personal data only insofar as necessary for the electronic systems to collate and process information in accordance with this Regulation. Personal data shall be kept in a form which permits identification of data subjects for periods no longer than those referred to in Article 10(8).;’

(ea) paragraph 7 is replaced by the following:

‘7. ***The Commission shall ensure that personal data processed within EUDAMED is protected in accordance with Union law.*** *Within their respective responsibilities, the Commission and the Member States shall ensure that inaccurate and unlawfully processed data are deleted, in accordance with the applicable legislation. Corrections and deletions shall be carried out as soon as possible, but no later than 60 days after a request is made by a data subject.’*

(f) Paragraph 8 is replaced by the following:

‘8. The Commission shall, by means of implementing acts, lay down the detailed arrangements necessary for the setting up and maintenance of ~~Eudamed and, where applicable, any of the electronic systems that are not included in~~ Eudamed. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3). When adopting those implementing acts, the Commission shall ensure that, as far as possible, the systems are developed in such a way as to avoid having to enter the same information twice within the same electronic system or in different electronic systems.;’

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(g) paragraph 9 is replaced by the following:

'9. In relation to its responsibilities under this Article and the processing of personal data involved therein, the Commission shall be considered to be the controller of Eudamed and its electronic systems ~~as well as, where applicable, any of the electronic systems that are not included in Eudamed~~.;'

(26) Article 34(1) is replaced by the following:

'1. The Commission shall, in collaboration with the MDCG, draw up the functional specifications for Eudamed ~~and, where applicable, any of the electronic systems that are not included in Eudamed~~.'

(…)

(97) in Article 123(3), point (d), the following third subparagraph is added:

'After the date of application of the provisions referred to in the first subparagraph of this point, where Member States maintain national databases, the relevant information available in Eudamed for those national databases shall be retrieved from Eudamed. **This shall be without prejudice to the possibility for Member States to maintain or develop complementary national functionalities and data elements necessary for national market surveillance or other regulatory tasks, provided that duplication of core Union data is avoided.**;'

(…)

(4) Annex VI is amended as follows:

(a) Parts A and B are replaced by the following:

'PART A

INFORMATION TO BE SUBMITTED UPON THE REGISTRATION OF ECONOMIC OPERATORS IN ACCORDANCE WITH ARTICLE 31

Manufacturers and where applicable, authorised representatives, and, where applicable, importers and, where applicable the persons referred to in Article 22(1) shall submit the following information relating to the economic operator:

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1. type of economic operator (manufacturer, authorised representative, importer or the person referred to in Article 22(1)),
2. name, address and contact details, including the digital contact, of the economic operator,
3. where submission of information is carried out by another person on behalf of any of the economic operators mentioned under Section 1.1, the name, address and contact details, including the digital contact, of that person,
4. name, address and contact details, including the digital contact, of the person or persons responsible for regulatory compliance referred to in Article 15.

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PART B

CORE DATA ELEMENTS TO BE PROVIDED TO THE UDI DATABASE IN ACCORDANCE WITH ARTICLES 28 AND 29

The manufacturer shall provide to the UDI database the following information relating to the manufacturer and the device:

1. Basic UDI-DI as referred to in Article 27 and any additional UDI-DIs,
2. For devices referred to in Article 120(3), type, number and expiry date of the certificate issued by the notified body and the name or identification number of that notified body and the link to the information that appears on the certificate and was entered by the notified body in the electronic system on notified bodies and certificates,
3. Member State in which the device is to be or has been placed on the market in the Union,
4. Member States where the device is or is to be made available,
5. risk class of the device,
6. presence of a substance which, if used separately, may be considered to be a medicinal product and name of that substance,
7. presence of a substance which, if used separately, may be considered to be a medicinal product derived from human blood or human plasma and name of this substance,
8. presence of tissues or cells of human origin, or their derivatives (y/n),

9. presence of tissues or cells of animal origin, or their derivatives, as referred to in Regulation (EU) No 722/2012 or any subsequent implementing rules adopted pursuant to that Regulation (y/n),
10. where applicable, the single identification number of the clinical investigation or investigations conducted in relation to the device or a link to the clinical investigation registration in the electronic system on clinical investigations,
11. in the case of devices listed in Annex XVI, specification as to whether the intended purpose of the device is other than a medical purpose,
12. in the case of devices designed and manufactured by another legal or natural person as referred in Article 10(15), the name, address and contact details, including the digital contact, of that legal or natural person,
13. where applicable, the summary of safety and clinical performance,
14. status of the device (placed on the market, no longer placed on the market, recalled, field safety corrective action initiated).
15. quantity per package configuration,
16. the manner in which production of the device is controlled (expiry date or manufacturing date, lot number, serial number),
17. if applicable, the unit of use UDI-DI (where a UDI is not labelled on the device at the level of its unit of use, a 'unit of use' DI shall be assigned so as to associate the use of a device with a patient),
18. name and address of the manufacturer (as indicated on the label),
19. the SRN issued in accordance with Article 31(2),
20. if applicable, name and address of the authorised representative (as indicated on the label),
21. the medical device nomenclature code as provided for in Article 26,
22. if applicable, name or trade name, and if applicable additional trade names,
23. if applicable, device model, reference, or catalogue number,
24. if applicable, clinical size (including volume, length, gauge, diameter),
25. additional product description (optional),
26. if applicable, storage and/or handling conditions (as indicated on the label or in the instructions for use),
27. labelled as a single-use device (y/n),

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28. if applicable, the maximum number of reuses,
29. device labelled sterile (y/n),
30. need for sterilisation before use (y/n),
31. containing latex (y/n),
32. where applicable, information labelled in accordance with Section 10.4.5 of Annex I,
33. if applicable, the instructions for use, or where available, the URL of the website where the instructions for use are made available,
34. if applicable, critical warnings or contra-indications.'

(b) Part C is amended as follows:

(i) in Section 1, the definition of 'Basic UDI-DI' is replaced by the following:

'Basic UDI-DI

The Basic UDI-DI is the primary identifier of a device model. The Basic UDI-DI is the main key in the database and relevant documentation (e.g. certificates, declaration of conformity, technical documentation and summary of safety and clinical performance) to connect devices with the same intended purpose, risk class and essential design and manufacturing characteristics. It is the main key for records in the UDI database and is referenced in relevant certificates and EU declarations of conformity.;'

(ii) in Section 4.10, the second sentence is replaced by the following:

'The UDI carrier for reusable devices that require cleaning, disinfection, sterilisation or refurbishing between patient uses shall be permanent and readable after each process performed to make the device ready for the subsequent use throughout the intended lifetime of the device, unless the device is intended to be reused exclusively by or for the same patient.;'

Amendments to Regulation (EU) 2017/746

(17) the heading of Chapter III is replaced by the following:

'IDENTIFICATION AND TRACEABILITY OF DEVICES, REGISTRATION OF DEVICES AND OF ECONOMIC OPERATORS, SUMMARY OF SAFETY AND PERFORMANCE, EUROPEAN DATABASE ON MEDICAL DEVICES';

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(18) Article 24 is amended as follows:

~~(a) in paragraph 1, the following point (ba) is inserted:~~

~~'(ba) a Basic UDI-DI, as defined in Part C of Annex VI;;'~~

(b) paragraph 2 is amended as follows:

(i) point (d) is replaced by the following:

'(d) the entity gives access to its system for the assignment of UDIs to all interested users in accordance with a set of predetermined and transparent terms and conditions taking into consideration the interests of micro, small and medium-sized enterprises within the meaning of Recommendation 2003/361/EC;~~;~~'

(ii) in point (e), the following subpoint (iv) is added:

'(iv) offers its system for the assignment of UDIs to manufacturers that are micro and small enterprises within the meaning of Recommendation 2003/361/EC under preferential conditions **on access, fees and support** that take into account the specific needs of such enterprises and are proportionate to their size.;'

(c) paragraph 3 is replaced by the following:

'3. Before placing a device, other than a device for performance study, on the market, the manufacturer shall, in accordance with the rules of the issuing entity designated by the Commission in accordance with paragraph 2, assign to the device, a Basic UDI-DI and UDI as defined in Part C of Annex VI. If applicable, the manufacturer shall assign a ~~UDI-DI~~**UDI** to all higher levels of packaging.;'

(d) the following paragraph 3a is inserted:

'3a. For devices that are the subject of a conformity assessment as referred to in Article 48(3) and (4), Article 48(7), second subparagraph, Article 48(8), and Article 48(9), second subparagraph, the assignment of a Basic UDI-DI referred to in paragraph 1 of this Article shall be done before the manufacturer applies to a notified body for that assessment.;'

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(e) in paragraph 10, points (a) and (b) are replaced by the following:

'(a) amending the list of information set out in Parts A and B of Annex VI in the light of technical progress; and

(b) amending Annex VI in the light of experience obtained from the implementation of the UDI system, or international developments and technical progress in the field of Unique Device Identification.;'

(19) Article 26 is replaced by the following:

'Article 26

Registration of devices

1. Before placing a device, other than a device for performance study, on the market, the manufacturer shall provide the Basic UDI-DI to the UDI database together with the other core data elements referred to in Part B of Annex VI related to that device, as applicable. The manufacturer shall keep ~~up to date~~ the information provided to the UDI database **updated and shall update any changes without undue delay, and in any event no later than 30 days after the change occurs**.

2. For devices that are the subject of a conformity assessment as referred to in Article 48(3) and (4), Article 48(7), second subparagraph, Article 48(8), and Article 48(9), second subparagraph, the notified body shall confirm in Eudamed that the information referred to in **Point 2 of** Part B of Annex VI is correct.;'

(20) in Article 27(2), the following sentence is added:

'Where national distributor databases require information on devices**, where feasible**, such databases shall allow for the retrieval of the device information from the electronic systems referred to in Article 30(2), points (a) and (b).;'

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(21) Article 28 is amended as follows:

(a) the title is replaced by the following:

'Registration of economic operators;'

(b) paragraphs 1 and 2 are replaced by the following:

'1. Before placing a device on the market, manufacturers, authorised representatives and importers shall, in order to register, submit to the electronic system referred to in Article 27 the information referred to in Part A of Annex VI, provided that they have not already registered in accordance with this Article. In cases where the conformity assessment procedure requires the involvement of a notified body pursuant to Article 48, the information referred to in Part A of Annex VI shall be provided to that electronic system before applying to the notified body.

2. Without undue delay, the competent authority shall verify the data entered pursuant to paragraph 1, obtain a single registration number ('SRN') from the electronic system referred to in Article 27 and issue it to the manufacturer, the authorised representative or the importer;'

(c) in paragraph 4, the words 'one week' are replaced by the words 'two weeks';

(d) paragraph 6 is deleted;

(e) paragraph 7 is replaced by the following:

'7. The data entered pursuant to paragraph 1 of this Article in the electronic system referred to in Article 27 shall be accessible to the public, except for details regarding the person responsible for regulatory compliance referred to in Part A, point 1.4 of Annex VI.;'

~~(23) in Article 30(2), the following subparagraph is added:~~

~~'By way of derogation from the first subparagraph, the Commission may decide that one or more of the electronic systems referred to in that subparagraph are not to be included in Eudamed. In that case, the Commission shall ensure that the electronic system is interoperable with Eudamed.;'~~

(…)

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(80) in Article 113(3), point (f), the following subparagraph is added:

'After the date of application of the provisions referred to in the first subparagraph of this point, where Member States maintain national databases, the relevant information available in Eudamed for those national databases shall be retrieved from Eudamed. **This shall be without prejudice to the possibility for Member States to maintain or develop complementary national functionalities and data elements necessary for national market surveillance or other regulatory tasks, provided that duplication of core Union data is avoided.**;'

(…)

(4) Annex VI is amended as follows:

(a) Parts A and B are replaced by the following:

'PART A

INFORMATION TO BE SUBMITTED UPON THE REGISTRATION OF ECONOMIC OPERATORS IN ACCORDANCE WITH ARTICLE 28

Manufacturers and, where applicable, authorised representatives, and, where applicable, importers shall submit the following information relating to the economic operator:

1. type of economic operator (manufacturer, authorised representative, or importer),
2. name, address and contact details, including the digital contact, of the economic operator,
3. where submission of information is carried out by another person on behalf of any of the economic operators mentioned under Section 1.1, the name, address and contact details, including the digital contact, of that person,
4. name, address and contact details, including the digital contact, of the person or persons responsible for regulatory compliance referred to in Article 15.

PART B

CORE DATA ELEMENTS TO BE PROVIDED TO THE UDI DATABASE TOGETHER WITH THE UDI-DI IN ACCORDANCE WITH ARTICLES 25 AND 26

The manufacturer shall provide to the UDI database the following information relating to the manufacturer and the device:

1. Basic UDI-DI as referred to in Article 24 and any additional UDI-DIs,
2. For devices referred to in Article 110(3), type, number and expiry date of the certificate issued by the notified body and the name or identification number of that notified body and the link to the information that appears on the certificate and was entered by the notified body in the electronic system on notified bodies and certificates,
3. Member State in which the device is to be or has been placed on the market in the Union,
4. Member States where the device is or is to be made available,
5. presence of substances of human origin or their derivatives (y/n),
6. presence of cells or substances of microbial origin (y/n),
7. risk class of the device,
8. where applicable, the single identification number of the performance study,
9. in the case of devices designed and manufactured by another legal or natural person as referred in Article 10(14), the name, address and contact details, including the digital contact, of that legal or natural person,
10. where applicable, the summary of safety and performance,
11. status of the device (placed on the market, no longer placed on the market, recalled, field safety corrective action initiated),
12. indication as to whether the device is intended for self-testing or near-patient testing.
13. quantity per package configuration,

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14. the manner in which production of the device is controlled (expiry date or manufacturing date, lot number, serial number),
15. if applicable, the 'unit of use' UDI-DI (where a UDI is not labelled on the device at the level of its 'unit of use', a 'unit of use' UDI-DI shall be assigned so as to associate the use of a device with a patient),
16. name and address of the manufacturer, as indicated on the label,
17. the SRN issued in accordance with Article 28(2),
18. if applicable, name and address of the authorised representative (as indicated on the label),
19. the medical device nomenclature code as provided for in Article 23,
20. if applicable, name or trade name, and if applicable, additional trade names,
21. if applicable, device model, reference, or catalogue number,
22. additional product description (optional),
23. if applicable, storage and/or handling conditions (as indicated on the label or in the instructions for use),
24. labelled as a single use device (y/n),
25. if applicable, the maximum number of reuses,
26. device labelled sterile (y/n),
27. need for sterilisation before use (y/n),
28. if applicable, the instructions for use, or where available, the URL of the website where the instructions for use are made available,
29. if applicable, critical warnings or contra-indications.;'

(b) Part C is amended as follows:

(i) in Section 1, the definition of 'Basic UDI-DI' is replaced by the following:

'Basic UDI-DI

The Basic UDI-DI is the primary identifier of a device model. The Basic UDI-DI is the main key in the database and relevant documentation (e.g. certificates, declaration of conformity, technical documentation and summary of safety and performance) to connect devices with the same intended purpose, risk class and essential design and manufacturing characteristics. It is the main key for records in the UDI database and is referenced in relevant certificates and EU declarations of conformity.;'

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(ii) Section 4.10. is replaced by the following:

‘4.10. Devices that are reusable shall bear a UDI carrier on the device itself. The UDI carrier for reusable devices that require disinfection, sterilisation or refurbishing between patient uses shall be permanent and readable after each process performed to make the device ready for the subsequent use throughout the intended lifetime of the device, unless the device is intended to be reused exclusively by or for the same patient. The requirement of this Section shall not apply to devices in the following circumstances:

(a) any type of direct marking would interfere with the safety or performance of the device;

(b) the device cannot be directly marked because it is not technologically feasible.;’

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International cooperation

Amendments to Regulation (EU) 2017/745

(90) the following Section 2 is inserted after Article 108:

'***SECTION 2 – International cooperation***

Article 108a

International regulatory and administrative cooperation

1. **Without prejudice to the prerogatives of the Council and the relevant procedures laid down in the Treaties,** the Commission shall ~~pursue international regulatory cooperation in the field of medical devices and in vitro diagnostic medical devices with a view to promoting a high level of protection of public health and patient safety, fostering innovation and enhancing efficiency of regulatory compliance through global convergence. For that purpose, the Commission and the Member States shall~~ **explore avenues to** contribute to the development and adoption of global principles, standards~~,~~ and guidance which ~~provide~~ **aim to achieve** a high level of international **regulatory** convergence **and foster innovation** in the field of medical devices and in vitro diagnostic medical devices, including in relation to safety, performance, quality management systems, **risk management,** conformity assessment~~,~~ and post-market surveillance.

2. The Commission shall ~~participate in relevant~~ **make full use of and build on, within the limits of the tasks conferred upon it, existing** international ~~fora in the field of medical devices and in vitro diagnostic medical devices~~ **cooperation mechanisms**, including the International Medical Device Regulators Forum (IMDRF), the Medical Device Single Audit Programme (MDSAP) and International Standardisation Organisations**, to pursue the objectives of paragraph 1**.

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3. In its activities in accordance with paragraphs 1 and 2, the Commission shall ~~be supported by experts nominated by the Member States in view of their competence in medical devices or in vitro diagnostic medical devices~~ **seek the views of the MDCG**.

4. The Commission**, in consultation and agreement with Member States,** may sign administrative arrangements with authorities of third countries and with international organisations ~~for the purpose of regulatory cooperation in the field of medical devices and in vitro diagnostic medical devices~~ **on technical matters falling within the scope of this Article**, including:

   (a) exchange of information and best practices;

   (b) joint or coordinated inspections and assessments;

   (c) coordinated actions relating to safety issues, including recalls or safety communications.

   Those administrative arrangements shall not create legal obligations binding upon the Union and its Member States.

   Where the Commission signs such administrative arrangements which include the exchange of information or data, the administrative arrangement shall provide for protection of such information or data in accordance with Article 109 of this Regulation or in Article 102 of Regulation (EU) 2017/746, as applicable.

5. **For the purposes of carrying out** ~~The Union shall finance~~ the activities of the Commission and the Member States relating to international cooperation as referred to in this Article and the reliance mechanisms referred to in Article 108b**, a financial allocation may also be made available from the general budget of the Union**.

PUBLIC

Article 108b

Reliance mechanisms

1. ~~The Commission, may participate in bilateral or multilateral reliance mechanisms or reliance programmes~~ In the ~~field of medical devices and in vitro diagnostic medical devices, which~~ **framework of the implementation of this Regulation or of Regulation (EU) 2017/746, as applicable, notified bodies and competent authorities** shall ~~enable the use~~ **take into consideration the outcome** of assessments, inspections, and other regulatory decisions carried out or taken by regulatory authorities of third countries or international organisations or international bodies **related to a medical device and an in vitro diagnostic medical device**, provided that the following conditions are fulfilled:
   (a) the ~~reliance mechanism or reliance programme ensures~~ **assessments, inspections, or other regulatory decisions of the regulatory authority of the third country, the international organisation or the international body ensure** a level of health and safety protection equivalent to that required under this Regulation or Regulation (EU) 2017/746, as applicable;
   (b) effective arrangements for mutual exchange of information~~, transparency, and oversight~~ **with the relevant regulatory authority of the third country, the international organisation or the international body** are in place, providing for the confidentiality of information and data referred to in Article 109 of this Regulation or Article 102 of Regulation (EU) 2017/746, as applicable.

~~2. The Commission may invite Member States to nominate experts, in view of their competence in medical devices or in vitro diagnostic medical devices, who participate in reliance mechanisms or reliance programmes referred to in paragraph 1.~~

~~3. Reliance mechanisms or reliance programmes referred to in paragraph 1 shall be taken into consideration by competent authorities, economic operators or notified bodies in the framework of the implementation of this Regulation or of Regulation (EU) 2017/746, as applicable.~~

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4. The Commission ~~may~~ **shall** adopt implementing acts **identifying the regulatory authorities of third countries, the international organisations or the international bodies referred to in paragraph 1 and, where relevant,** establishing **the** detailed rules for the recognition of ~~reliance mechanisms or reliance programmes, which may include conditions for participation of notified bodies to reliance mechanisms or reliance programmes, requirements relating to the scope of~~ assessments, inspections or other **relevant** regulatory decisions ~~carried out or~~ taken in ~~the course of reliance mechanisms or reliance programmes, and procedural safeguards for manufacturers~~ **application of this Article**. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

Article 108c

Capacity building and technical assistance

1. The Commission**, in consultation with MDCG,** may support the strengthening of regulatory capacity in third countries, including through the provision of technical assistance, training, exchange of experts, and dissemination of best practices.

2. The Commission ~~may~~ **shall** invite Member States to nominate experts, in view of their competence in medical devices or in vitro diagnostic medical devices, to participate in its activities referred to in paragraph 1.

3. **For t**~~T~~he activities referred to in paragraph 1**, a financial allocation may also be made available from the general budget of the** ~~may be financed through relevant~~ Union ~~programmes or external action instruments~~.;’

PUBLIC