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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 Second Presidency compromise text, part 1, to be discussed at the meetings of the Working Party on Pharmaceuticals and Medical Devices on 10-11 September 2026. This compromise covers the following aspects: scope, definitions, including Well-Established Technologies, UDI and Eudamed, notified bodies, conformity assessment, sandboxes, clinical evaluation, post-market surveillance, vigilance, international cooperation, and the corresponding annexes.

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

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ANNEX

Recitals

(36) To ensure that the legal framework governing the highly innovative sectors of medical devices and in vitro medical devices is future-proof and able to support innovation, Member States and the Commission should be able to establish regulatory sandboxes in the field of medical devices or in vitro diagnostic medical devices to facilitate the development and testing of innovative devices or regulatory approaches under strict oversight. **Those regulatory sandboxes should be available to manufacturers, which, in the context of regulatory sandboxes includes early-stage start-ups and device developers.**

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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) **the first subparagraph of** paragraph 2 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~~ **This Regulation shall also apply to** accessories **for such products, provided that common specifications have been adopted for those accessories pursuant to Article 9. The common specifications for each of the groups of products listed in Annex XVI and, where relevant, for those accessories, shall address, at least, application of risk management as set out in Annex I and, where necessary, clinical evaluation regarding safety**, 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 (a) is replaced by the following:

'(a) in vitro diagnostic medical devices covered by Regulation (EU) 2017/746, without ~~affecting~~ **prejudice to** 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) any of the 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).';

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(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.';[1]

(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.';

[1] The PCY suggests adding a 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, **the risks related to the interaction with the body** and its functional contribution to the overall safety and performance of the integral product.'

(ii) the second subparagraph, first sentence, is replaced by 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)**, with the exception of accessories to Annex XVI products**.';

(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;

(d) point (48) is replaced by the following:
'(48) 'clinical data' means information concerning safety or performance that is generated from the use of a device and is sourced from any of the following:
- clinical investigations of the device concerned or of a device for which equivalence to the device concerned can be demonstrated;
- other studies published in peer-reviewed scientific literature on the device concerned or of a device for which equivalence to the device concerned can be demonstrated;
- other clinical experience published in peer-reviewed scientific literature with the device concerned or a device for which equivalence to the device concerned can be demonstrated;
- clinically relevant information coming from post-market surveillance, in particular the post-market clinical follow-up;';

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

'(72) 'well-established technology device' means a device that fulfils all the following criteria:

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

(**a**~~b~~) it 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.

(b) the design of the device is simple and similar to other devices in the generic device group, with a stable manufacturing process.';

['(73)'combined study' means a clinical trial, as defined in Article 2(2), point (2), of Regulation (EU) No 536/2014, concerning one or more medicinal products, combined with a performance study of one or more in vitro diagnostic medical devices as defined in Article 2, point (42), of Regulation (EU) 2017/746, ~~and/~~or with a clinical investigation of one or more devices as defined in Article 2, point (45) of this Regulation;';**]**

'(74) 'regulatory sandbox' means a controlled environment set up by a competent authority which offers manufacturers the possibility, before placing the product on the market or putting it into service, to develop, test, validate and use, where appropriate in real-world conditions, an innovative product or technology potentially falling within the scope of this Regulation, pursuant to a sandbox plan for a limited time under regulatory supervision;

(75) 'sandbox plan' means a document **agreed between the**~~, proposed by (a)~~ participating manufacturer(s) and ~~approved by~~ the competent authority, describing the objectives, responsibilities, processes, conditions, timeframe, methodology and requirements for the activities carried out within the regulatory sandbox;

(76) 'Union regulatory sandbox' means a controlled environment set up by the Commission for testing alternative or new regulatory requirements or enforcement practices and appraising their validity in comparison with existing requirements and practices under this Regulation for a limited time.';

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

'Article 3

Amendment and implementation of certain definitions

1. The Commission**, in consultation with the MDCG,** 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. **In order to ensure the uniform application of the definition of well-established technology devices set out in Article 2, point (72), the Commission shall, in consultation with the MDCG, adopt implementing acts to the extent necessary to resolve issues of divergent interpretation and of practical application.** ~~The Commission 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~~ **implementing acts** 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~~**do not** fall under that definition. Those ~~guidelines~~ **implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).** ~~shall be published by [one year after publication of this Regulation in OJEU], and shall be assessed and updated regularly, as appropriate.~~

(…)

(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~~**taking** 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 to all higher levels of packaging.

(d) the following paragraphs 3a~~,~~ **and** 3b ~~and 9a~~ 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. **If applicable, the natural or legal person responsible shall assign a UDI to all higher levels of packaging.**

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 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.';

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

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

'(c) determining, following consultation with the MDCG and other stakeholders, the UDI-related obligations included 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, for example contact lenses. In such cases, the Commission shall, by means of implementing acts, define the specific device obligations.

(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 ~~9~~ **12** 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. 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.

(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 **or investigational devices**, 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 **the device** 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.

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2. ~~Without undue delay, t~~**T**he 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).';

(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.';

(24) Article 32 is amended as follows:

(a) paragraph 1 is replaced by the following:

'1. For class IIb implantable devices and for class III devices, other than custom-made or investigational devices and well-established technology devices, the manufacturer shall draw up a summary of safety and clinical performance.

The summary of safety and clinical performance shall be written in a way that is clear to the intended user and shall be made available to the public via Eudamed.

The draft of the summary of safety and clinical performance shall be part of the documentation to be submitted to the notified body involved in the conformity assessment pursuant to Article 52. The manufacturer shall ensure that the summary of safety and clinical performance is available in Eudamed as part of the information on the device to be provided pursuant to Article 29(1) and mention on the label or instructions for use where that summary is available.';

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(b) in paragraph 2, point (h) is replaced by the following:

'(h) information on any residual risks**,** ~~, or~~ undesirable effects, ~~and~~ any warnings and precautions.';

(25) Article 33 is amended as follows:

(-a) in paragraph 1 the following subparagraph is added:

Eudamed shall be the principal electronic system that supports this Regulation.

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

'By way of derogation from the first subparagraph, the Commission, in consultation with the MDCG, may decide that that one or more of the electronic systems referred to in that subparagraph are not to be included in Eudamed or may identify additional system functionality required to support the implementation of the Regulations. In these cases, the Commission shall ensure 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.';

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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.'

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(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.';

(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.';

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(27) Article 35 is amended as follows:

(a) the following paragraph 6a is inserted:

'6a. Without prejudice to other administrative or judicial remedies, **including those set out in Article 44(6),** a manufacturer or **a** notified body may raise with the authority responsible for notified bodies, in a duly substantiated manner, any regulatory**, procedural, scientific** or technical unresolved dispute arising **between the manufacturer and the notified body in relation to the notified body's activities in applying** ~~from the application of the procedural~~ requirements set out in Annex VII and the involvement of ~~a~~ **the** notified body in the conformity assessment in accordance with procedural requirements set out in Article 52 and Annexes IX, X and XI. The authority shall hear and decide within 150 days, without prejudice to extension of that period, where duly justified. Where the manufacturer is established in another Member State than the notified body, the authority responsible for the notified body shall consult the competent authority of the Member State where the manufacturer is established.

In duly justified cases, the authority responsible for notified bodies may seek guidance from the MDCG, which it shall take duly into account.

Each authority responsible for notified bodies shall inform the Commission and the MDCG at least annually about the disputes raised with it pursuant to the first subparagraph, their outcome and the parties involved. That information shall be taken into consideration in the framework of the monitoring of notified bodies in accordance with Article 44.

By way of derogation from the first subparagraph and without prejudice to other administrative or judicial remedies, a Member State may choose to assign the tasks set out in this paragraph to another authority or to an out of court dispute resolution body.';

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(b) paragraph 8 is replaced by the following:

‘8. The authorities responsible for notified bodies shall coordinate, within the framework of the sub-group established under Article 105a, their activities to be carried out in accordance with this Chapter, cooperate with each other and with the Commission and resolve issues of diverging opinions between themselves to ensure a harmonised application of the requirements relating to notified bodies.’;

(28) Article 36 is amended as follows:

(a) paragraph 1 is replaced by the following:

‘1. Notified bodies shall fulfil the tasks for which they are designated in accordance with this Regulation in the public interest. They shall satisfy the organisational and general requirements and the quality management, resource and process requirements, as set out in further detail in Annex VII, that are necessary to fulfil those tasks in a competent, effective, independent, impartial, diligent and expeditious manner.

Notified bodies designated for conformity assessment activities relating to devices that are high-risk AI systems as referred to in Article 6(1) of Regulation (EU) 2024/1689, or that use high-risk AI systems as safety components, shall also meet the requirements set out in Article 31(4), (5), (10) and (11) of that Regulation.’;

(b) the following paragraph 4 is added:

‘4. The Commission is empowered to adopt delegated acts in accordance with Article 115 in order to amend Annex VII in order to adapt to technical or scientific progress regarding conformity assessment in the field of medical devices, including developments at international level.’;

(29) in Article 37, paragraph 4 is deleted;

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(30) Article 39 is replaced by the following:

'Article 39

Assessment of the application

1. The authority responsible for notified bodies shall within 30 days check that the application referred to in Article 38 is complete and shall request the applicant to provide any missing information. Once the application is complete, that authority shall send it to the Commission.

2. Within 14 days of the receipt of the application referred to in paragraph 1 of this Article, the Commission, in consultation with the MCDG, shall appoint three experts, chosen from the list referred to in Article 40(2) upon their agreement and inform the authority responsible for notified bodies. In view of the specific circumstances of the application, a different number of experts may be appointed.

   At least one of the experts shall be an expert representing the Commission. The other experts shall be experts nominated by Member States other than the one in which the applicant conformity assessment body is established.

   In order to be chosen in accordance with the first subparagraph, the experts shall be competent to assess the conformity assessment activities or the **applied for** scope of designation ~~applied for~~ which ~~are~~ **is** the subject of the application.

3. The experts appointed in accordance with paragraph 2 and the authority responsible for notified bodies shall form a joint assessment team that shall be led by the authority responsible for notified bodies and ~~coordinated~~ **assisted** by the expert**(s)** representing the Commission. The authority responsible for notified bodies shall ensure that the joint assessment team is fully integrated into the joint assessment process and shall work in close collaboration with the **expert(s) representing the** Commission ~~coordinating expert~~.

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4. Within 90 days of the appointment of the experts in accordance with paragraph 2, the joint assessment team shall review the application and supporting documentation and shall draw up a preliminary assessment report. During that period, the joint assessment team may request any clarifications **or corrections** from the applicant conformity assessment body. The authority responsible for notified bodies shall **lead**~~facilitate~~ the **drafting and finalisation** ~~development~~ of the preliminary assessment report. The **authority responsible for notified bodies shall, on behalf of the** joint assessment team**,** ~~shall~~ submit the preliminary assessment report to the applicant conformity assessment body. ~~The on-site assessment of the applicant body shall be led by the authority responsible for notified bodies.~~

5. Where, based on the review of the application and supporting documentation referred to in this paragraph, the joint assessment team considers that the applicant body does not and, within a reasonable period of time, will not be able to meet the requirements of this Regulation and that any further assessment in accordance with paragraphs 6 to 9 is not appropriate, it shall draw up a final assessment report and the authority responsible for the notified bodies shall reject the application.

   Where diverging opinions amongst joint assessment team experts arise regarding the continuation of the application, **such diverging opinions shall be submitted to the MDCG for further opinion. The**~~the~~ authority responsible for notified bodies shall consider such opinions and justify its reasons **for accepting or rejecting** ~~not to reject~~ the application. ~~Such diverging opinions may be submitted to the MDCG for further opinion.~~

6. Unless the application is rejected, the joint assessment team, led by the authority responsible for notified bodies, shall plan and conduct an on-site assessment of the applicant conformity assessment body and, where relevant, of any subsidiary or subcontractor, located inside or outside the Union, that is to be involved in the conformity assessment process. **The on-site assessment of the applicant body shall be led by the authority responsible for notified bodies.**

Where an on-site assessment of the applicant body, a subsidiary or a subcontractor is temporarily impossible or impracticable due to exceptional circumstances, the joint assessment team may decide to carry out the assessment by other appropriate means.

At the end of the on-site assessment, the joint assessment team shall list for the applicant conformity assessment body any non-compliances resulting from the assessment and summarise the assessment.

7. Within 30 days after the finalisation of the on-site assessment, the **authority responsible for notified bodies, on behalf of the** joint assessment team**,** shall submit the assessment report to the applicant conformity assessment body and, where applicable, inform that body about any non-compliances resulting from the assessment.

Where the joint assessment team has not identified any non-compliances, its assessment report shall be considered the final assessment report and paragraph 11 shall apply.

8. Where the joint assessment team has identified non-compliances, the applicant conformity assessment body shall, within 30 days of receipt of the assessment report or within a timeline agreed with the joint assessment team, submit to the joint assessment team a proposed corrective and preventive action plan to address the non-compliances effectively and in a timely manner.

That plan shall indicate the root cause of the identified non-compliances and shall include a timeframe for implementation of the actions therein.

9. On receipt of the proposed corrective and preventive action plan referred to in paragraph 8, the joint assessment team shall assess whether the non-compliances identified during the assessment have been appropriately addressed**.** ~~, and, where~~ **Where** necessary, **the authority responsible for notified bodies shall** provide any comments on it to the applicant conformity assessment body, including requests for further clarification and modifications.

PUBLIC

The applicant conformity assessment body and the joint assessment team shall endeavour to agree on a final corrective and preventive action plan in due course.

10. Within 45 days of receipt of evidence of the final corrective and preventive action plan, or of the moment the joint assessment team concludes that no agreement on a final plan and its implementation has been reached, **the authority responsible for notified bodies shall lead the drafting and finalisation of the** ~~the joint assessment team shall draw up its~~ final assessment report. That report shall include the result of the assessment, conclusions regarding the corrective and preventive action plans and whether the non-compliances have been appropriately addressed ~~and~~, any issue or view in accordance with paragraph 15, **and,** where applicable, the recommended scope of designation.

11. The **authority responsible for notified bodies shall, on behalf of the** joint assessment team**,** ~~shall~~ submit its final assessment report to the MCDG without undue delay.

    Based on the findings of the final assessment report, the authority responsible for notified bodies shall submit to the MDCG a draft decision on the designation of the notified body or reject the application.

12. Within 21 days of receipt of the draft decision on the designation referred to in paragraph 11, the MDCG shall issue a recommendation with regard to the envisaged designation, which the authority responsible for notified bodies shall duly take into consideration for its final decision on the designation of the notified body. That 21-day period may be extended once on justified grounds.

13. Where the authority responsible for notified bodies does not agree with the recommendation of the MDCG, within 30 days, it shall submit to the MDCG a duly justified request to reconsider its recommendation. Within 30 days of receipt of that request, the MDCG shall either confirm its recommendation or issue a new recommendation.

PUBLIC

14. Where no agreement can be reached between the MDCG and the authority responsible for notified bodies, either party may refer the matter to the Commission.

Within 180 days of receipt of the referral, the Commission shall, after consulting the MDCG, the authority responsible for notified bodies and, where necessary, the applicant conformity assessment body concerned, evaluate the draft decision on the designation and decide, by means of implementing act, whether or not the draft designation is justified.

15. If, at any stage of the process, consensus cannot be reached within the joint assessment team on any issue, the authority responsible for notified bodies or the **expert(s) representing the** Commission ~~coordinating expert~~ may refer the issue to the MDCG, which shall provide its views without undue delay and at the latest within 60 days from the referral. In such cases, timelines for the joint assessment shall be adjusted to account for the referral to the MDCG.

16. The Commission may, by means of implementing acts, adopt measures setting out detailed arrangements specifying the procedures and any relevant documentation for the following:
    (a) the application for designation referred to in Article 38;
    (b) the assessment of the application set out in this Article;
    (c) the nomination and selection of experts referred to in Article 40;
    (d) the monitoring of notified bodies pursuant to Article 44.

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

(31) Article 40 is amended as follows:
    (a) the title is replaced by the following:
    'Nomination of experts for joint assessment';

PUBLIC

(b) paragraph 1 is replaced by the following:

'1. All Member States that have appointed an authority responsible for notified bodies and the Commission shall nominate experts who are qualified in the assessment, designation or monitoring of conformity assessment bodies in the field of medical devices or in the assessment of manufacturers' technical documentation and who will be available to participate in the activities referred to in Articles 39, 44 and 48. Member States that have not appointed an authority responsible for notified bodies may nominate experts who have those qualifications.';

(32) the following Article 40a is inserted:

'Article 40a

Funding of activities related to designation and monitoring of notified bodies

1. Conformity assessment bodies and notified bodies shall pay to the ~~designating authority~~ **authorities responsible for notified bodies** a fee for the assessment of their application for designation and their monitoring, including the costs for the involvement of experts nominated in accordance with Article 40 in those assessment and monitoring activities. The fee shall be proportionate to the scope of designation applied for.

Article 112 shall continue to apply until the date of application of this article.';

(33) the third paragraph of Article 41 is replaced by the following:

'The Commission shall provide translations of the documentation pursuant to Articles 38 and 39, or parts thereof, into an official Union language, such as is necessary for that documentation to be readily understood by the joint assessment team referred to in Article 39(4).';

PUBLIC

(34) Article 42 is amended as follows:

(a) paragraph 1 is replaced by the following:

'1. Member States may designate conformity assessment bodies for which an assessment pursuant to Article 39 was completed and there is a recommendation of the MDCG issued in accordance with Article 39(11) or (12), or in accordance with an implementing act adopted by the Commission in accordance with Article 39(14), and which comply with this Regulation.';

(b) paragraph 4 is replaced by the following:

'4. The notification shall be accompanied by the recommendation of the MDCG.';

(c) paragraphs 6 to 9 are deleted;

(d) paragraph 10 is replaced by the following:

'10. When publishing the notification in NANDO, the Commission shall add to the electronic system referred to in Article 57 the information relating to the notification of the notified body along with the documents referred to in paragraph 4 of this Article.';

(35) Article 44 is amended as follows:

(a) the title is replaced by the following:

'Monitoring of notified bodies';

(b) in paragraph 2, the second sentence is replaced by the following:

'Notified bodies shall, upon request by their authority responsible for notified bodies, supply all relevant information and documents required to enable the authority, the joint assessment team~~,~~ **and** the Commission ~~and other Member States~~ to verify compliance.';

PUBLIC

(c) the following paragraph 3a is inserted:

'3a. The authority responsible for notified bodies shall conduct its monitoring and assessment activities in accordance with an assessment programme considering the full scope of the notified body's activities. That programme shall ensure that the authority can effectively monitor the continued compliance of the notified body with the requirements of this Regulation and shall provide a reasoned schedule for the frequency of assessment of the notified body and, where applicable, its subsidiaries or subcontractors for a period of at least two years. The authority responsible for notified bodies shall submit the programme for monitoring or assessment for each notified body for which it is responsible to the sub-group with members representing authorities responsible for notified bodies laid down in Article 105a, MDCG and to the Commission. The authority shall address any request for clarification or modification made by the **sub-group, the** Commission or the MDCG.';

(d) paragraph 4 is replaced by the following:

'4. At least once a year, the authorities responsible for notified bodies shall assess whether each notified body established on their respective territory and, where appropriate, the subsidiaries and subcontractors under the responsibility of those notified bodies still satisfy the requirements and fulfil their obligations set out in this Regulation, in particular Annex VII.

Where necessary, the assessment shall include an on-site audit of the notified body, its subsidiaries or subcontractors.

The authority, the MDCG or the Commission may request the participation of experts from the Commission and other Member States in the annual assessment of a notified body.';

PUBLIC

(e) the following paragraphs 4a, 4b and 4c are inserted:

'4a. At least every three years, and proportionate to risk and compliance history, the annual assessment of a notified body, referred to in paragraph 4 above, shall be carried out by a joint assessment team including the authority responsible for notified bodies and two experts from the list referred to in Article 40(2) appointed by the Commission in consultation with the MDCG. At least one of those experts shall be an expert representing the Commission. In ~~light~~ **view** of the specific circumstances of the monitoring, the Commission may appoint a different number of experts. The joint assessment team shall be led by the authority responsible for notified bodies and ~~coordinated~~ **assisted** by the expert**(s)** representing the Commission.

If, at any stage of the process, consensus cannot be reached within the joint assessment team on any issue, the authority responsible for notified bodies or the **expert(s) representing the** Commission ~~coordinating expert~~ may refer the issue to the MDCG, which shall provide its views without undue delay and at the latest within 60 days from the referral. **In such cases, timelines for the joint assessment shall be adjusted to account for the referral to the MDCG.**

4b. At the end of any assessment carried out pursuant to paragraph 4 or 4a, the authority responsible for notified bodies or the joint assessment team, as applicable, shall **list for** ~~inform~~ the notified body ~~about~~ any non-compliances resulting from the assessment and summarise their assessment and if immediate action ~~by the notified body~~ is required.

Within 30 days after the finalisation of the ~~on-site~~ assessment, the **authority responsible for notified bodies, on behalf of the** joint assessment team**, as applicable,** shall submit the assessment report to the ~~conformity assessment~~**notified** body and, where applicable, inform that body about any non-compliances resulting from the assessment.

Where non-compliances have been identified, the notified body shall submit a proposed corrective and preventive action plan to address the non-compliances **effectively** in a timeframe agreed with the authority responsible for notified bodies or the joint assessment team. That plan shall indicate the root cause of the identified non-compliances and shall include a timeframe for implementation of the actions set out therein.

The authority responsible for notified bodies or the joint assessment team, as applicable, shall assess whether the non-compliances identified during the assessment have been appropriately addressed in the plan referred to in the second subparagraph**.** ~~and, where~~**Where** necessary, **the authority responsible for notified bodies shall** provide any comments on the plan to the notified body, including requests for further clarification and modifications. The notified body and the authority or the joint assessment team, as applicable, shall endeavour to agree on a final corrective and preventive action plan in due course.

4c. After receipt of the final corrective and preventive action plan, or where the authority responsible for notified bodies or the joint assessment team, as applicable, have not identified non-compliances or conclude that no agreement on a final plan has been reached, the authority **responsible for notified bodies, in conjunction with** ~~or~~ the joint assessment team, as applicable, shall draw up their final monitoring report which shall include the result of the assessment and, where applicable, conclusions regarding the corrective and preventive action plan and, where applicable, any recommendations regarding the notified body's designation.

The authority responsible for notified bodies**, on behalf of** ~~or~~ the joint assessment team, as applicable, shall submit their final monitoring report to the MDCG and to the Commission without undue delay.

The authority responsible for notified bodies shall monitor the implementation of the corrective and preventive action plan by the notified body, as appropriate.

PUBLIC

Where the final monitoring report concludes that the notified body no longer meets the requirements set out in this Regulation, or where the notified body fails to implement the corrective and preventive action plan, the authority responsible for notified bodies shall follow the procedure set out in Article 46(4).';

(f) paragraph 5 is replaced by the following:

'5. The monitoring of notified bodies by the authority responsible for notified bodies shall include observed audits of notified body personnel, including where necessary any personnel from subsidiaries and subcontractors, whilst such personnel are in the process of conducting quality management system assessments at a manufacturer's facility.';

(g) in paragraph 6, the first subparagraph is replaced by the following:

'The monitoring of notified bodies shall consider data arising from market surveillance, vigilance and post-market surveillance.';

(h) paragraph 8 is replaced by the following:

'8. During the monitoring of a notified body, an appropriate number of the notified body's assessments of manufacturers' quality management system and technical documentation, in particular the clinical evaluation documentation, shall be reviewed either off-site or on-site. The sampling of files shall be representative of the types and risk classes of devices certified by the notified body, in particular high-risk devices, and shall include reviewing whether the assessment by the notified body was conducted appropriately and shall check the procedures used, associated documentation and the conclusions drawn by the notified body. Such review~~ing~~ shall include the technical documentation and clinical evaluation documentation of the manufacturer upon which the notified body has based its assessment.';

(i) paragraphs 9, 10 and 11 are deleted;

(j) paragraph 12 is replaced by the following:

'12. The authority responsible for notified bodies shall draw up an annual summary of their monitoring activities regarding notified bodies and, where applicable, subsidiaries and subcontractors. That summary shall be made publicly available through the electronic system referred to in Article 57.';

(36) Article 45 is deleted;

(37) Article 46 is amended as follows:

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

‘1. The authority responsible for notified bodies shall notify the Commission and the MDCG of any application for relevant changes to the designation of a notified body.

Unless otherwise agreed by the MDCG, the ~~The~~ procedures set out in Articles 39 and 42 shall apply to extensions of the scope of the designation. ~~Such procedures shall not apply to other changes to the scope of designation, as agreed by the MDCG.~~ By way of derogation from Article 39, an on-site assessment shall not be conducted where the Joint Assessment Team considers such assessment not to be necessary for the assessment of the requested scope extension.

For changes to the designation other than extensions of its scope, the procedures laid down in paragraphs 2 to 9 shall apply.

2. After having assessed the application for changes, the authority responsible for notified bodies shall notify the Commission of the relevant changes to the designation. The Commission shall without undue delay publish the amended notification in NANDO. The Commission shall also, without undue delay, enter information on the changes to the designation of the notified body in the electronic system referred to in Article 57.’;

(b) in paragraph 4, the first subparagraph is replaced by the following:

‘Where an authority responsible for notified bodies has ascertained that a notified body no longer meets the requirements set out in this Regulation or that it is failing to fulfil its obligations or has not implemented the necessary corrective measures, the authority shall suspend, restrict, or fully or partially withdraw the designation or impose conditions on the notified body, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. A suspension shall not exceed a period of one year, renewable once for the same period.’;

PUBLIC

(38) Article 47 is amended as follows:

(a) paragraph 1 is replaced by the following:

‘1. The Commission, in consultation with the MDCG, shall investigate all cases where concerns have been brought to its attention regarding the continued fulfilment by a notified body, or of one or more of its subsidiaries or subcontractors, of the requirements set out in this Regulation. It shall ensure that the relevant authority responsible for notified bodies is informed and is given an opportunity to investigate those concerns.’;

(b) paragraph 3 is replaced by the following:

‘3. The Commission, in consultation with the MDCG, may initiate the assessment by a joint assessment team as referred to in Article 44(4a) to (4c), where there is reasonable concern about the ongoing compliance of a notified body, or a subsidiary or subcontractor of the notified body, with the requirements set out in the Regulation and where the investigation by the authority responsible for notified bodies is not deemed to have fully addressed the concerns or upon request of the authority responsible for notified bodies. The reporting and outcome of that assessment shall follow the principles set out in Article 39.’;

(39) Article 48 is amended as follows:

(a) the title is replaced by the following:

‘Exchange of experience between authorities responsible for notified bodies’;

(b) paragraphs 2 to 5 are deleted;

(40) Articles 49 and 50 are replaced by the following:

‘Article 49

Coordination of notified bodies

1. The Commission shall ensure that appropriate coordination and cooperation between notified bodies is put in place and operated in the form of a coordination group of notified bodies in the field of medical devices, including in vitro diagnostic medical devices. The coordination group shall meet on a regular basis, at least annually, and will operate under the auspices of the MDCG.

PUBLIC

The Commission may establish the specific arrangements for the functioning of the coordination group.

2. Notified bodies shall ensure that their technical, scientific and clinical personnel with adequate experience participate in the relevant activities of the coordination group.

3. All bodies notified under this Regulation and under Regulation (EU) 2017/746 shall actively participate in the work of the coordination group to support the implementation of this Regulation and of Regulation (EU) 2017/746 by sharing experience and developing draft common templates and draft technical guidance, to be submitted to the MDCG for approval, in order to facilitate harmonisation and common approaches regarding conformity assessment activities. They shall cooperate with each other, with the Commission, with the relevant authorities of the Member States, with expert panels and, where applicable, expert laboratories or European Union reference laboratories to ensure a harmonised application of the requirements set out in this Regulation and in Regulation (EU) 2017/746.

4. All bodies notified under this Regulation and under Regulation (EU) 2017/746 shall adhere to a code of conduct developed by the coordination group and approved by the MDCG. The code of conduct shall set out the principles of public interest, highest professional competence and integrity, impartiality, independence, transparency, proportionality, predictability and accountability to which notified bodies commit when exercising the rights and obligations conferred on them by this Regulation or Regulation (EU) 2017/746.

Article 50

Access to notified bodies and fees

1. Notified bodies shall establish lists of their fees for the conformity assessment activities that they carry out and shall make those lists publicly available. They shall notify the lists to the Commission, which shall make references to them available to the public on a dedicated website.

PUBLIC

2. Notified bodies ~~shall apply at least a [50]% fee reduction for manufacturers that are micro enterprises within the meaning of Recommendation 2003/361/EC and at least a [25]% fee reduction for small enterprises within the meaning of that Recommendation. They~~ shall apply at least a 50 % fee reduction for manufacturers that apply for conformity assessment of an orphan device referred to in Article 52a(3). Notified bodies shall provide manufacturers that are micro or small enterprises within the meaning of Recommendation 2003/361/EC the possibility to defer the payment of fees until the relevant conformity assessment activity is finalised.

4. Notified bodies shall ensure that manufacturers, which are micro, small or medium-sized enterprises within the meaning of Recommendation 2003/361/EC, have access to their conformity assessment activities in a manner that is not less favourable than the manner in which access is provided to other manufacturers.

5. Notified bodies shall deal with any request for conformity assessment activities from a manufacturer and, within 30 days of receipt of the request, inform the manufacturer accordingly.

6. When duly justified in the interest of public health or patient health or safety, and other measures cannot be applied effectively, the authority responsible for notified bodies, upon request by the MDCG, may instruct a notified body to accept a manufacturer's request for conformity assessment activities falling within that notified body's scope of designation.';[2]

(…)

[2] The Presidency suggests adding the following recital in support of Article 50(6): **"The mechanism provided for in Article 50(6) should remain an exceptional measure. It should therefore be applied only where other measures available under this Regulation cannot be applied effectively. Such measures including derogations under Article 59 and, where applicable, measures available to competent authorities pursuant to Articles 94 to 97. It should be used only where those measures are not suitable or sufficient to safeguard public health or patient health or safety."**

(43) Article 52 is amended as follows:

(a) in paragraph 3, the following subparagraph is added:

'By way of derogation from the first subparagraph, class III non-implantable devices that are well-established technology devices shall be subject to a conformity assessment as specified in Chapters I and III of Annex IX, including an assessment of the technical documentation, as specified in Section 4 of that Annex, of ~~at least~~ one representative device per generic device group. ~~The selection of samples of technical documentation for assessment shall be proportionate to the risk and compliance history of the generic device group.~~

The representative device shall be chosen in accordance with the approach outlined in the third paragraph of Section 2.3 of Annex IX.

Where, having applied the approach in the third paragraph of Section 2.3 of Annex IX, a notified body considers it necessary, on justified grounds, to assess the technical documentation of additional representative devices due to their specific characteristics or properties, it shall document its rationale as part of the sampling plan to be drawn up in accordance with Annex VII Section 4.5.2(a).

The sampling plan shall be made available to the authority responsible for notified bodies upon request.';

(b) paragraph 4 is replaced by the following:

'4. Manufacturers of class IIb devices, other than custom-made or investigational devices, shall be subject to a conformity assessment as specified in Chapters I and III of Annex IX, including an assessment of the technical documentation**,** as specified in Section 4 of that Annex, of ~~at least~~ one representative device per generic device group or, in the case of non-implantable class IIb devices that are well-established technology devices, ~~at least~~ one representative device per each category of devices.

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~~The selection of technical documentation for assessment should be proportionate to the risk and compliance history of the generic device group or category of devices as applicable.~~

The representative device shall be chosen in accordance with the approach outlined in the third paragraph of Section 2.3 of Annex IX.

Where, having applied the approach in the third paragraph of Section 2.3 of Annex IX, a notified body considers it necessary, on justified grounds, to assess the technical documentation of additional representative devices due to their specific characteristics or properties, it shall document its rationale as part of the sampling plan to be drawn up in accordance with Annex VII Section 4.5.2(a).

The sampling plan shall be made available to the authority responsible for notified bodies upon request.

By way of derogation from the first subparagraph, for class IIb implantable devices, except well-established technology devices, the assessment of the technical documentation as specified in Section 4 of Annex IX shall apply for every device. Alternatively, the manufacturer may choose to apply a conformity assessment based on type examination as specified in Annex X coupled with a conformity assessment based on product conformity verification as specified in Annex XI.';

(c) paragraph 5 is deleted;

(d) paragraph 6 is replaced by the following:

'6. Manufacturers of class IIa devices, other than custom-made or investigational devices, shall be subject to a conformity assessment as specified in Chapters I and III of Annex IX, including an assessment of the technical documentation**,** as specified in Section 4 of that Annex, of ~~at least~~ one representative device for each category of devices.

Alternatively, the manufacturer may choose to draw up the technical documentation set out in Annexes II and III coupled with a conformity assessment as specified in Section 10 or Section 18 of Annex XI. The assessment of the technical documentation shall apply for at least one representative device for each category of devices.

The representative device shall be chosen in accordance with the approach outlined in the third paragraph of Section 2.3 of Annex IX.

Where, having applied the approach in the third paragraph of Section 2.3 of Annex IX, a notified body considers it necessary, on justified grounds, to assess the technical documentation of additional representative devices due to their specific characteristics or properties, it shall document its rationale as part of the sampling plan to be drawn up in accordance with Annex VII Section 4.5.2(a).

The sampling plan shall be made available to the authority responsible for notified bodies upon request.';

~~The quantity of samples of technical documentation selected for assessment should be proportionate to the risk and compliance history of the category of devices.';~~

(e) paragraph 7 is amended as follows:

(i) the second sentence is replaced by the following:

'If those devices are placed on the market in sterile condition, have a measuring function or are reusable surgical instruments, the manufacturer shall apply the procedures set out in Chapters I and III of Annex IX, or in Section 10a of Annex XI.';

~~(ii) the following subparagraph is added:~~

~~'Where the manufacturer of class I reusable surgical instruments has applied harmonised standards or CS covering all relevant aspects referred to in the first subparagraph, point (c), the involvement of a notified body is not required.';~~

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(f) paragraph 12 is replaced by the following:

‘12. The documents relating to the procedures referred to in paragraphs 1 to 7 shall be available in any official Union language acceptable to the notified body and the authority responsible for notified bodies.’;

(g) in paragraph 14, the first subparagraph is replaced by the following:

‘The Commission may, by means of implementing acts, specify detailed arrangements and procedural aspects for any of the following aspects:

(a) the basis for the selection of representative device(s) for the assessment of the technical documentation as referred to in paragraphs 3, 4 and 6;

(b) the modalities of unannounced on-site audits and sample tests to be conducted by notified bodies in accordance with Section 3.4 of Annex IX, taking into account the risk-class and the type of device;

(c) the physical, laboratory or other tests to be carried out by notified bodies in the context of sample tests, assessment of the technical documentation and type examination;

(d) the modalities of the conformity assessment procedures regarding breakthrough devices and orphan devices set out in Article 52a;’;

(h) the following paragraph 15 is added:

‘15. The Commission is empowered to adopt delegated acts in accordance with Article 115 to amend Annexes IX, X, XI and XIII in order to adapt to technical or scientific progress or to developments regarding conformity assessment of devices at international level, in particular with regard to:

(a) the application and documentation to be submitted by the manufacturer to the notified body;

(b) the audits and assessments to be conducted by the notified body for initial certification and for surveillance assessments, including the assessment of the technical documentation of representative devices;

(c) the specific additional procedures laid down in Annex IX, Section 5;

(d) the statement to be drawn up by the manufacturer for custom-made devices laid down in Annex XIII, Section 1;

(e) the administrative provisions regarding the keeping of documentation.

PUBLIC

When adopting delegated acts pursuant to this paragraph, the Commission shall, where relevant, take into account the needs of particular devices in view of their special characteristics.';

(44) the following Articles 52a and 52b are inserted:

'Article 52a

Conformity assessment of breakthrough devices, orphan devices, and essential paediatric devices

1. For the conformity assessment of breakthrough devices, orphan devices, and essential paediatric devices, where the conformity assessment procedure requires the involvement of a notified body, ~~is involved in the conformity assessment,~~ the procedures laid down in Article 52 shall apply**, and may, upon request by the manufacturer, be** subject to the specific arrangements set out in this Article.

2. A device shall be considered a breakthrough device if it meets ~~all~~ the following criteria:
   (a) it is expected to introduce in the Union a high degree of novelty with respect to the device technology, related clinical procedure or the application of the device in clinical practice; **and**
   (b) it is expected to provide a significant positive clinical impact on patients or public health, for a life-threatening or irreversibly debilitating disease or condition, by either of the following:
      (i) offering a significant positive clinical or health impact compared to available alternatives and the state of the art;
      (ii) fulfilling an unmet medical need where there is an absence or insufficiency of available alternative options for that purpose.

3. A device shall be considered an orphan device if it meets ~~all~~ the following criteria:
   (a) it is intended for the treatment, diagnosis, or prevention of a disease or condition that presents in not more than 12 000 individuals in the Union per year; **and**

PUBLIC

(b) at least one of the following criteria is met:

(i) there are insufficient available alternatives;

(ii) the device is expected to provide a clinical benefit compared to available alternatives or the state of the art, taking into account both device-specific factors and patient population-specific factors.

3a. A device**, other than an orphan or breakthrough device,** shall be considered an essential paediatric device if it meets ~~all~~ the following criteria:

(a) It is intended to be used exclusively for patients in the paediatric population, and

(b) it is expected to provide a significant positive clinical impact on patients or public health, for a life-threatening or irreversibly debilitating disease or condition, by either of the following:

(i) offering a significant positive clinical or health impact compared to available alternatives and the state of the art;

(ii) fulfilling an unmet medical need where there is an absence or insufficiency of available alternative options for that purpose.

4. Upon a duly substantiated request by a manufacturer or a notified body, an expert panel referred to in Article 106 shall provide an opinion with respect to confirming whether the criteria set out in paragraph 2, 3 or 3a of this Article, as applicable, are fulfilled. In addition, with the exception of devices covered by Article 54, upon a duly substantiated request by a notified body, an expert panel shall provide an opinion ~~with respect to confirming~~**on the notified body's assessment of** whether the criteria set out in paragraph 7 of this Article are fulfilled. Those opinions shall be published on a dedicated website without disclosing any confidential information as referred to in Article 109 and shall be duly taken into consideration by the manufacturer and the notified body.

PUBLIC

5. Where the opinion of the expert panel has confirmed the fulfilment of the criteria set out in paragraph 2, 3 or 3a of this Article, the manufacturer of a breakthrough device, orphan device, or essential paediatric device, as applicable, may request advice from the expert panels referred to in Article 106 regarding its clinical development strategy and appropriate preclinical or clinical data for the clinical evaluation of the device.

6. For a breakthrough device, orphan device, or essential paediatric device, confirmed by the relevant expert panel, as applicable, the notified body involved in the conformity assessment procedure set out in Article 52 shall **prioritise the conformity assessment of that device,** offer priority access to supports to the manufacturer throughout the conformity assessment procedure **and apply, where appropriate, a rolling review with a view to reduce assessment timelines**.

~~These supports may include, where appropriate:~~

~~(a) Reduced assessment timelines;~~

~~(b) Rolling reviews of technical documentation;~~

~~(c) Priority access, free of charge, to the dialogues outlined in Annex VII section 1.2.9;~~

~~(d) Proportionate reductions in related fees; and~~

~~(e) Deferral of payments of fees until the relevant conformity assessment activity is finalised.~~

The notified body shall give due consideration to an opinion or advice provided by the expert panels in accordance with paragraph 4 or 5 and, where it does not follow such opinion or advice, it shall provide duly justified reasons. The notified body may ask the expert panel to clarify the opinion it has provided.

7. The notified body ~~shall~~ **may** issue a certificate pursuant to Article 56 where **all applicable requirements of this Regulation are fulfilled and**, based on their assessment of the clinical evaluation report, the pre-market clinical evidence is deemed sufficient, even if based on limited clinical data, provided that each of the following criteria is fulfilled:

   (a) the benefit of the immediate availability on the market of the device outweighs the risk associated with the fact that additional clinical data are still required;

   (b) the benefit-risk-ratio of the device is favourable and the manufacturer commits to providing additional data from post-market clinical follow-up activities**, pursuant to an appropriate PMCF plan**.

   Where appropriate, the notified body shall limit the validity of the certificate and specify any conditions for or limitations to the certificate's validity in accordance with Article 56, such as a requirement for the manufacturer to conduct specific post-market clinical follow-up activities within a specified period of time.

8. The Commission is empowered to adopt delegated acts in accordance with Article 115 in order to amend this Article to adapt to technical or scientific progress or to take into account developments regarding conformity assessment of breakthrough devices, orphan devices, or essential paediatric devices at international level.

9. The Commission may, by means of implementing acts, lay down further details of the procedure for the conformity assessment of breakthrough devices, orphan devices, or essential paediatric devices set out in this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

PUBLIC

Article 52b

Digitalisation of technical documentation, conformity assessment and reports

1. The manufacturer may draw up and make available in a digital format the technical documentation and any reports or other documents required pursuant to this Regulation. That digital format may be a structured machine-readable format, provided that it is possible to transform it into human-readable format, and that there is version-control to enable the conduct of retrospective conformity checks. Where the technical documentation, reports or other documents are to be submitted to and assessed by a notified body or made available to competent authorities for the purposes of market surveillance, the manufacturer shall ensure that the digital format is suitable for and agreed with the notified body or competent authority or national authorities responsible for notified bodies as applicable.

2. Where necessary to ensure that the digital format referred to in paragraph 1 is reliable, interoperable and standardised, the Commission may establish minimum requirements or functional specifications for the digital format by means of common specifications as referred to in Article 9.';

(45) in Article 53, paragraph 5 is replaced by the following:

'5. Notified bodies and the personnel of notified bodies shall carry out their conformity assessment activities in the public interest and with the highest degree of professional integrity and the requisite technical and scientific competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups with an interest in the results of those activities.';

PUBLIC

(46) Articles 54 and 55 are replaced by the following:

'Article 54

Clinical evaluation consultation procedure for certain high-risk devices

1. In addition to the procedures applicable pursuant to Article 52, a notified body shall follow the procedure regarding clinical evaluation consultation as specified in Section 5.1 of Annex IX or as referred to in Section 6 of Annex X, as applicable, when performing a conformity assessment of class III implantable devices, other than custom-made devices.

   Where justified in order to protect the health and safety of patients, users or other persons or other aspects of public health, the Commission is empowered to adopt delegated acts in accordance with Article 115 to amend paragraph 1 in order to add other types of devices to those devices that are subject to the clinical evaluation consultation procedure referred to in the first subparagraph.

2. By way of derogation from paragraph 1, the procedure referred to in that paragraph is not required in the following cases:
   (a) for a renewal of a certificate issued under this Regulation;
   (b) where the device has been designed by modifying a device already marketed by the same manufacturer for the same intended purpose, provided that the manufacturer has demonstrated to the satisfaction of the notified body that the modifications do not adversely affect the benefit-risk ratio of the device;
   (c) where the principles of the clinical evaluation of the device type or category have been addressed in a harmonised standard referred to in Article 8 or in CS referred to in Article 9 and the notified body confirms that the clinical evaluation of the manufacturer for this device is in compliance with the relevant harmonised standard or CS for clinical evaluation of that kind of device.

PUBLIC

3. The notified body shall notify the competent authorities, the authority responsible for notified bodies and the Commission through the electronic system referred to in Article 57 of whether or not the procedure referred to in paragraph 1 of this Article is to be applied. That notification shall be accompanied by the clinical evaluation assessment report.

4. The notified body shall give utmost consideration to the opinion issued by the expert panel in the framework of the clinical evaluation consultation procedure. Where the notified body has not followed the views and recommendations expressed in that opinion, it shall provide a substantiated justification of the reasons therefore and its final clinical evaluation assessment report to the authority responsible for notified bodies of the Member State in which it is established, to the expert panel that issued the opinion and to the Commission.

Article 55

Mechanism for scrutiny of conformity assessments

1. The MDCG~~, a competent authority~~ or the Commission may, based on reasonable concerns, **and having consulted the authority responsible for notified bodies,** request advice from an expert panel in relation to the safety and performance of any device. For that purpose, the MDCG~~, a competent authority~~ or the Commission may request the notified body that issued the certificate for the device in question to submit to the expert panel its clinical evaluation assessment report and any subsequent surveillance assessment reports regarding that device. The expert panel may request the notified body or the manufacturer to submit additional information ~~needed for its assessment~~**necessary to provide its advice**. ~~The expert panel may request an assessment from the relevant authority responsible for notified bodies.~~

PUBLIC

2. The MDCG~~, a competent authority~~ or the Commission may, based on reasonable concerns, **and having consulted the authority responsible for notified bodies** request advice from one or more expert laboratories, based on their expertise related to laboratory testing, in relation to the safety and performance of any device, provided that the device or the field of laboratory testing falls within the scope of designation of those expert laboratories. For that purpose, the MDCG~~, a competent authority~~ or the Commission may request the notified body that issued the certificate for the device in question to submit to the expert laboratories its clinical evaluation assessment report, other relevant parts of the technical documentation and any subsequent surveillance assessment reports regarding that device. The expert laboratories may request the notified body or the manufacturer to submit samples of the device or any additional information ~~needed for their assessment~~**necessary to provide its advice**.

3. The notified body shall give utmost consideration to the advice provided by the expert panel or the expert laboratory and, where needed, take any appropriate measures, including those referred to in Article 56(3) and (4).';

(47) Article 56 is amended as follows:

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

'1. The notified bodies shall issue certificates in accordance with Annexes IX, X and XI in an official Union language and upload them **within 30 days of issuance** ~~in a timely manner~~ in Eudamed. The minimum content of the certificates shall be as set out in Annex XII.

2. The EU technical documentation assessment certificates **or EC type examination certificates** related to Class III devices and implantable Class IIb devices, other than well-established technology devices, shall be valid for the period they indicate, which shall not exceed five years. On application by the manufacturer, the initial validity of the certificates for Class III devices and implantable Class IIb devices, other than well-established technology devices, may be extended for a further period not limited in time, based on a re-assessment after the initial five years and periodic reviews thereafter, in accordance with the applicable conformity assessment procedures and with Annex VII, Section 4.11.

All other ~~The~~ certificates ~~related to all other devices~~ shall not be limited in time.

Notwithstanding subparagraphs 1 and 2, the notified body may limit the period of validity of certificates it issues based on duly justified grounds. In those cases, the notified body shall indicate the period of validity on the certificate.

If the period of validity of the certificate is limited, on application by the manufacturer, the notified body may, following an assessment performed in accordance with Annex VII, Section 4.11, extend the validity of the certificate. Any supplement to a certificate shall remain valid as long as the certificate which it supplements is valid.';

(b) the following paragraph 2a is inserted:

'2a. During the validity of the certificate, ~~where applicable~~ the notified body shall carry out appropriate surveillance activities, including periodic reviews taking into consideration developments of the state of the art, in accordance with Section 4.11 of Annex VII. Those reviews shall be proportionate to the risk class of the device.';

(c) paragraph 3 is replaced by the following:

'3. Notified bodies may impose conditions on the validity of the certificate, in accordance with Section 4.8 of Annex VII.';

(d) in paragraph 4, the first sentence is replaced by the following:

'Where a notified body finds that the requirements of this Regulation are no longer met by the manufacturer, it shall, taking account of the principle of proportionality, suspend or withdraw the certificate issued or impose any conditions on it unless compliance with such requirements is ensured by appropriate corrective action taken by the manufacturer within an appropriate deadline set by the notified body.';

(e) in paragraph 5, the first sentence is replaced by the following:

'The notified body shall enter in the electronic system referred to in Article 57 any information regarding certificates issued, including amendments and supplements thereto, and regarding suspended, reinstated, withdrawn or refused certificates and conditions imposed on certificates.';

(48) Article 57 is amended as follows:

(a) paragraph 1 is amended as follows:

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

'(f) the notifications for conformity assessments and information or documents referred to in Article 54(3)

(49) Article 59 is amended as follows:

(a) paragraph 1 is replaced by the following:

'1. By way of derogation from Article 52, on a duly justified request, any competent authority may authorise, for a limited period of time or for a ~~defined~~ **limited** number of devices **for a limited period of time**, the placing on the market or putting into service within the territory of the Member State concerned of a specific device for which the applicable conformity assessment procedures have not been carried out, provided that the use of that device is in the interest of public health, patient safety or patient health.';

(b) the following paragraphs 1a, 1b and 1c are inserted:

'1a. By way of derogation from Article 6(2)**,** on a duly justified request, any competent authority may authorise for a limited period of time or for a ~~defined~~ **limited** number of devices **for a limited period of time**, the use of a **specific** device that is not placed on the Union market for the provision of a diagnostic or therapeutic service referred to in that Article to (a) natural or legal person(s) established within the territory of the Member State concerned using a **specific** device for which the applicable conformity assessment procedures set out in this Regulation have not been carried out, provided that the provision of that service is in the interest of public health, patient safety or patient health.;

1b. Where appropriate, the competent authority shall specify and impose **additional** conditions or limitations to the derogation, such as conditions on labelling, serious incident reporting, and traceability~~, and limitations on time and number of devices~~.

1c. Where **necessary to support the decision-making processes referred to in paragraphs 1 and 1a, for a request for use other than for a single patient**~~appropriate, and in order to support the decision-making process referred to in the first paragraph~~, the competent authority may request an opinion from the relevant expert panel **or expert laboratory** established under this Regulation.'

(c) paragraph 2 is replaced by the following:

'2. The Member State shall inform the Commission**, the Agency,** and the other Member States of any decision to authorise or refuse the placing on the market or putting into service of a device in accordance with paragraph 1, or the use of a device for the provision of a service in accordance with paragraph 1a, where such authorisation is granted for use other than for a single patient. The ~~Commission~~ **Agency** shall share this information with the relevant expert panels referred to in Article 106.

The Member State shall also make information about such authorisations publicly available.';

PUBLIC

(d) in paragraph 3, the first subparagraph is replaced by the following:

‘3. Where a request pursuant to paragraph 1 or paragraph 1a has been submitted to competent authorities in more than one Member State and based on an opinion, **where applicable,** requested by the Commission or a Member State, of an expert panel referred to in Article 106, the Commission, in exceptional cases relating to public health, patient safety or patient health, may, by means of implementing acts, extend for a limited period of time or number of devices the validity of an authorisation granted by a Member State in accordance with paragraph 1 or paragraph 1a to the territory of the Union, or provide an authorisation referred to in paragraph 1 or paragraph 1a for the territory of the Union. The Commission may set out the conditions under which the device may be placed on the market or put into service, or under which the diagnostic or therapeutic service may be provided. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3). The Commission shall make information about ~~extensions and~~**such Union-wide** authorisations publicly available.’;

(e) the following paragraphs 4 and 5 are added:

‘4. In the event of a public health emergency at Union level recognised in accordance with Article 23 of Regulation (EU) 2022/2371 of the European Parliament and of the Council*****, the Commission may, by means of implementing acts, on its own initiative after consulting the MDCG, and if appropriate, the relevant expert panel, authorise the placing on the market or putting into service of a device in accordance with paragraph 3. The authorisation shall cease to apply at the latest when the recognition of the public health emergency is terminated pursuant to Article 23(2) of Regulation (EU) 2022/2371. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

On duly justified imperative grounds of urgency relating to the health and safety of humans, the Commission may adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 114(4).

PUBLIC

5. The Commission may, by means of implementing acts, lay down rules further specifying the procedure set out in this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).';

***** Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU (OJ L 314, 6.12.2022, p. 26, ELI: http://data.europa.eu/eli/reg/2022/2371/oj).';

(50) the following Articles 59a, 59b and 59c are inserted:

'Article 59a

Derogations from certain requirements in the event of a serious cross-border threat to health, disaster or crisis

1. Upon a duly justified request, a competent authority may authorise for a limited period of time or a limited number of devices **for a limited period of time**, by way of derogation from the relevant provisions in Annexes II, III, IX, X and XI, an exemption from the requirements related to changes to the manufacturing**,** ~~or~~ design **or intended purpose** of a **specific** CE marked device, where it is in the interest of public health, patient safety or patient health, in either of the following circumstances:
   (a) a serious cross-border threat to health as defined in Article 3, point (1), of Regulation (EU) 2022/2371;
   (b) a disaster or a crisis within the meaning of Regulation (EU) …/… of the European Parliament and of the Council******+.

2. The manufacturer shall ensure that the manufactured devices remain in conformity with the relevant general safety and performance requirements set out in Annex I. The manufacturer shall ensure that any changes ~~to the manufacturing or design of the device exempted in accordance with~~**referred to in** paragraph 1 do not adversely affect the benefit-risk ratio of the device.

3. The competent authority may request the notified body that issued a certificate for the device in question, to assist it in the assessment of a request referred to in paragraph 1.

3a. Where appropriate, the competent authority shall impose and specify conditions or limitations, as applicable, to the authorisation of exemption in accordance with paragraph 1. These may include, but are not limited to, conditions on labelling, incident reporting, and traceability, and limitations on time and number of devices.

4. Where applicable, the manufacturer shall keep the notified body that issued a certificate for the device in question~~,~~ informed about the authorisation and any changes made regarding the manufacturing, design or intended purpose of a CE marked device in accordance with the authorisation referred to in paragraph 1.

5. Where a request pursuant to paragraph 1 has been submitted to competent authorities in more than one Member State, the Commission, in exceptional cases relating to public health, patient safety or patient health, may, by means of implementing acts, extend for a limited period of time or a limited number of devices **for a limited period of time**, the validity of an exemption granted by a Member State in accordance with paragraph 1 to the territory of the Union, or provide an exemption referred to in paragraph 1 for the territory of the Union. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

On duly justified imperative grounds of urgency relating to the health and safety of humans, the Commission may adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 114(4).

****** Regulation (EU) .../... of the European Parliament and of the Council of ... on ... (OJ ..., ELI) [+] OJ: Please insert in the text the number of the Regulation contained in 2025/0223(COD) (Proposal for a Regulation on the Union Civil Protection Mechanism and Union support for health emergency preparedness and response, and repealing Decision No 1313/2013/EU) and insert the number, date, title and OJ reference of that Regulation in the footnote.'

PUBLIC

Article 59b

Regulatory sandboxes at national level

1. Member States, on their own initiative or upon a substantiated request by a manufacturer, may establish one or more regulatory sandboxes to which the application of certain requirements of Chapters V or VI or of **Chapters II and III of Annex I or** Annexes ~~I,~~ VIII**,** IX, X, XI, XIV or XV would not be appropriate from a technical**, clinical,** ~~or~~ scientific **or regulatory** viewpoint, and that, with regard to those requirements, every precaution has been taken to protect the health and safety of patients, users, and other persons. The Member States shall designate the competent authority that is responsible for the supervision of the regulatory sandbox.

   Member States may also establish regulatory sandboxes jointly with other Member States.

1a. Regulatory sandboxes shall not involve ~~investigational devices or~~ the placing on the market, or putting into service of, devices which do not comply with the requirements of this Regulation other than those that are not applicable pursuant to paragraph 1.

2. The activities within a regulatory sandbox shall take place pursuant to a specific sandbox plan that shall set out **technical,** clinical, scientific ~~and~~ **or** regulatory justification for the necessity to establish a regulatory sandbox, including at least:
   (a) identification of the requirements of this Regulation referred to in paragraph 1, which, by way of derogation from this Regulation, are temporarily adapted in the regulatory sandbox;
   (b) justification that the application of those requirements is considered not appropriate and an explanation as to how potential risks related to the adaptation are controlled and mitigated;
   (c) recommendations for alternative or mitigation measures, where appropriate; and
   (d) identification of the reasonable duration of the regulatory sandbox necessary to achieve its objectives and the participants in the regulatory sandbox and their respective roles.

(e) identification of the responsibilities and obligations of each participant in the regulatory sandbox, including the person or persons responsible for the conduct and oversight of the regulatory sandbox

(f) procedures for the reporting, assessment and management of incidents, serious incidents, or serious adverse events, including the implementation of appropriate corrective and preventive measures, taking into consideration paragraph 5 of this Article.

3. A regulatory sandbox shall be set up only if the following conditions are met:
   (a) the device is expected to address unmet medical needs or to provide a significant clinical benefit to patients or to the health system compared with similar existing alternatives, if any, or the state of the art;
   (b) the application of the requirements of this Regulation referred to in paragraph 1 would not be appropriate due to **technical, clinical,** scientific or regulatory challenges arising from characteristics or methods related to the device.

4. The Member State may request an expert panel referred to in Article 106 to provide scientific, technical or regulatory advice on the draft sandbox plan.

5. Any participant in the regulatory sandbox shall **report**, without undue delay, ~~inform~~ **to** the competent authority that is responsible for the supervision of the regulatory sandbox and the competent authority according to Article 89(2)**,** ~~about~~ any serious incidents **or serious adverse events that have** occurred in relation to the implementation of the regulatory sandbox. Any risks identified during the implementation of the regulatory sandbox shall be appropriately managed in accordance with the risk management system as described in Section 3 of Annex I. The competent authority shall have the power to take immediate and adequate corrective measures, including temporarily or permanently suspend participation in the sandbox, or suspend, revoke or restrict the scope of the regulatory sandbox, including amending the sandbox plan.

PUBLIC

6. Manufacturers participating in a regulatory sandbox shall remain liable under applicable Union and national law for any damage inflicted on third parties as a result of their activities taking place in the regulatory sandbox.

7. The Member State shall inform the Commission and the MDCG about the establishment of a regulatory sandbox and keep them informed about its implementation and outcome.

8. Where a Member State has taken a measure referred to in paragraph 5 of this Article, that Member State shall communicate the corresponding decision and the grounds therefor to the Commission and the MDCG.

Article 59c

Union regulatory sandboxes

1. The Commission, on its own initiative**, and in consultation with the MDCG,** or upon a substantiated request by a Member State, may establish, by means of implementing acts for a limited time and pursuant to a specific plan, Union regulatory sandboxes, which shall inform whether the existing requirements appropriately regulate a specific type of device with particular characteristics or emerging technologies, and there is a risk that the existing requirements:
   (a) would not be appropriate due to scientific or regulatory challenges arising from characteristics or methods related to the device;
   (b) would not adequately protect the health and safety of patients, users or other persons or other aspects of public health.

   Union regulatory sandboxes shall not involve ~~investigations devices or~~ the placing on the market or putting into service of devices which do not comply with this Regulation.

2. The Commission shall, following consultation with the MDCG, request an expert panel as referred to in Article 106 to provide scientific, technical or regulatory advice on the design of a Union regulatory sandbox.

PUBLIC

3. The Commission shall consult with the MDCG about the establishment of a regulatory sandbox and keep it informed about its outcome.

4. The Commission shall, by means of implementing acts, specify common principles or the detailed arrangements for the establishment, operation and supervision of regulatory sandboxes pursuant to Article 59b or of Union regulatory sandboxes pursuant to this Article.

The implementing acts shall include common principles on at least the following:

(a) eligibility and selection criteria for participation in a regulatory sandbox;

(b) procedures for the application, participation, monitoring, exiting from and termination of a regulatory sandbox, including the sandbox plan and outcome;

(c) the terms and conditions, and rights and obligations applicable to the participants.

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

5. The Commission is empowered to adopt delegated acts in accordance with Article 115 to amend this Article or Article 59b in order to adapt it to scientific, technical or regulatory progress and to take into account developments regarding regulatory sandboxes, including in areas other than medical devices.;

(51) in Article 60, the following paragraphs 1a and 1b are inserted:

‘1a. The person referred to in Article 22(1) or (3) may request the Member State where it is established to issue a certificate of free sale for a system or procedure pack for which it has drawn up a statement in accordance with Article 22.

1b. The manufacturer [or the authorised representative] shall make the certificates of free sale issued in accordance with paragraphs 1 and 1a publicly available in Eudamed within 30 days of issuance.

(52) Article 61 is amended as follows:

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

‘1. Manufacturers shall plan, conduct and document a clinical evaluation in accordance with this Article and with Part A of Annex XIV to~~, at least,~~ confirm the safety and performance of the device under normal conditions of use in accordance with the intended purpose of the device, and evaluate any undesirable side-effects and the acceptability of the benefit-risk ratio referred to in Sections 1 and 8 of Annex I.

The manufacturer shall specify and justify the level of clinical evidence necessary to confirm the safety and performance of the device. That level of clinical evidence shall be appropriate in view of the characteristics of the device and its intended purpose.

The clinical evaluation, its results and the clinical evidence derived from it shall be documented in a clinical evaluation report as referred to in Section 4 of Annex XIV, which, except for custom-made devices, shall be part of the technical documentation referred to in Annex II relating to the device concerned.

2. For class IIb and class III devices, a manufacturer may, prior to its clinical investigation or clinical evaluation, consult an expert panel as referred to in Article 106, with the aim of reviewing the manufacturer's intended clinical development strategy or proposals for clinical investigation. The manufacturer and the notified body involved in any future conformity assessment procedure shall, in the clinical evaluation report and the clinical evaluation assessment report, give due consideration to the advice of the expert panel and where they do not follow the advice, they shall provide duly justified reasons.’;

PUBLIC

(b) in paragraph 4, first subparagraph, the introductory wording is replaced by the following:

'In the case of implantable class IIb devices and class III devices, other than custom-made devices, clinical investigations shall be performed, except if:';

(c) paragraph 5 is replaced by the following:

'5. A manufacturer of a device demonstrated to be equivalent to an already marketed device not manufactured by it, may also rely on paragraph 4 in order not to perform a clinical investigation provided that the original clinical evaluation has been performed in compliance with the requirements of this Regulation, the manufacturer has sufficient **levels of** access to relevant information on the design, materials and the clinical evaluation of the equivalent device, and the manufacturer provides clear evidence thereof to the notified body.';

(d) paragraph 6 is amended as follows:

(i) the introductory wording is replaced by the following:

'The requirement to perform clinical investigations pursuant to paragraph 4 shall not apply to implantable class IIb devices and class III devices:';

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

'(b) that are well-established technology devices for which the clinical evaluation is based on sufficient clinical evidence and is in compliance with the relevant product-specific CS or harmonised standards, where available, provided that the manufacturer sets in place appropriate specific PMCF activities to ensure early systematic monitoring of the clinical safety and performance of the devices under real world conditions;'

(e) paragraph 8 is deleted;

PUBLIC

(f) paragraphs 10 and 11 are replaced by the following:

’10. Without prejudice to paragraph 4, where the confirmation of safety and performance based on clinical data is not deemed appropriate, adequate justification ~~for any such exception~~ shall be given based on the results of the manufacturer's risk management and on consideration of the specifics of the interaction between the device and the human body, the clinical performance intended and the claims of the manufacturer and the data available for the generic device group. In such a case, the manufacturer shall duly substantiate in the technical documentation referred to in Annex II why it considers a demonstration of conformity with general safety and performance requirements that is based on the results of non-clinical testing methods alone, including performance evaluation, bench testing, in vitro, ex vivo, in silico testing, computational modelling or simulation and pre-clinical evaluation, to be adequate.

Where necessary to ensure the uniform application of this paragraph, the Commission may, in consultation with the MDCG, adopt implementing acts to the extent necessary to resolve issues of divergent interpretation and of practical application. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

11. The clinical evaluation, its documentation and, where applicable and needed, the summary of safety and clinical performance referred to in Article 32 shall be updated throughout the life cycle of the device concerned with data and findings obtained from the implementation of the manufacturer's PMCF plan in accordance with Part B of Annex XIV and the post-market surveillance plan referred to in Article 84, whenever those data and findings provide information relevant for the confirmation of safety and performance of the device. For Class IIb implantable and Class III devices, these shall be updated at least every two years.’;

(g) paragraph 12 is deleted;

(h) the following paragraph 14 is added:

'14. The Commission is empowered to adopt delegated acts in accordance with Article 115 to amend **sections 1, 4 or 6 of** Annex XIV in order to adapt it to technical and scientific progress and developments at international level, having due regard to the protection of the health and safety of patients, users or other persons and other aspects of public health.';

(53) Article 62 is amended as follows:[3]

(a) The title is replaced by the following:

'General requirements regarding ~~certain~~ clinical investigations conducted as part of the clinical evaluation of devices that have not been placed on the market or put into service';

(b) In paragraph 1, the introductory wording is replaced by the following:

'Clinical investigations shall be designed, authorised, conducted, recorded and reported in accordance with the provisions of this Article, of Articles 63 to 73 and of Articles 75 to 80, the acts adopted pursuant to Article 81, and Annex XV, where they are carried out **as part of the clinical evaluation of**~~to assess~~ an investigational device that has not been placed on the market or put into service in accordance with this Regulation and where carried out for one or more of the following purposes:';

[3] The Presidency suggests adding the following recital: 'To ensure that clinical investigations accurately represent the target population in all its diversity, and to enhance the medical devices available for vulnerable populations, medical devices which are likely to offer significant clinical benefit should be fully and appropriately studied in these specific groups, including as regards requirements related to their specific characteristics and the protection of the health and well-being of subjects belonging to these groups. The protection of vulnerable populations, in this context, such as incapacitated subjects, minors and pregnant or breastfeeding women, requires a proper consideration of the risks of exclusion against risks of inclusion in clinical investigations. This is in accordance with the 2024 version of the World Medical Association's Declaration of Helsinki.'

~~(c) In paragraph 1, points (a), (b) and (c) are replaced by the following:~~

~~'(a) to assess, establish and verify that, under normal conditions of use, a device is designed, manufactured and packaged in such a way that it is suitable for one or more of the specific purposes listed in point (1) of Article 2, and achieves the performance intended as specified by its manufacturer;~~

~~(b) to assess, establish and verify the clinical benefits of a device as specified by its manufacturer;~~

~~(c) to assess, establish and verify the clinical safety of the device and to determine any undesirable side-effects, under normal conditions of use of the device, and assess whether they constitute acceptable risks when weighed against the benefits to be achieved by the device.';~~

(54) in Article 64(1), point (g) is replaced by the following:

'(g) there are scientific grounds for expecting that participation in the clinical investigation will produce either of the following:

(i) a direct benefit to the incapacitated subject outweighing the risks and burdens involved;

(ii) some benefit for the population represented by the incapacitated subject concerned when the clinical investigation relates directly to the life-threatening or debilitating medical condition from which the subject suffers and such clinical investigation will pose only minimal risk to, and will impose minimal burden on, the incapacitated subject concerned in comparison with the standard treatment of the subject's condition.';

(55) in Article 65, point (g) is replaced by the following:

'(g) there are scientific grounds for expecting that participation in the clinical investigation will produce either of the following:

(i) a direct benefit to the minor subject outweighing the risks and burdens involved;

(ii) some benefit for the population represented by the minor ~~subject~~ concerned and such a clinical investigation will pose only minimal risk to, and will impose minimal burden on, the minor ~~subject~~ in comparison with the standard treatment of the subject's condition.';

(56) in Article 66, point (a) is replaced by the following:

'(a) the clinical investigation has the potential to produce a direct benefit for the pregnant or breastfeeding woman concerned, or her embryo, foetus or child after birth, outweighing the risks and burdens involved, or if the clinical investigation has not the potential to produce such direct **benefit**, the following conditions are met:

(i) a clinical investigation of comparable effectiveness cannot be carried out on women who are not pregnant or breastfeeding;

(ii) the clinical investigation contributes to the attainment of results capable of benefitting pregnant or breastfeeding women or other women in relation to reproduction, or other embryos, foetuses or children;

(iii) the clinical investigation poses a minimal risk to, and imposes a minimal burden on, the pregnant or breastfeeding woman concerned, her embryo, foetus or child after birth.';

(…)

(58) in Article 72, the following paragraph 7 is added:

'7. The processing of personal data in the context of a clinical investigation, including the secondary use of personal data initially collected for other investigations, shall be deemed to be carried out for scientific research purposes as referred to in Article 9(2), point (j), of Regulation (EU) 2016/679, without prejudice to the obligations and requirements set out in that Regulation.';

(58a) In Article 73, paragraph 3, point (a) is replaced by the following:

'(a) protection of personal data in accordance with Regulation (EU) 2018/1725;';

PUBLIC

(59) in Article 74, paragraph 1 is replaced by the following:

'1. Where a clinical investigation is to be conducted to further assess, within the scope of its intended purpose and in accordance with its PMCF plan, a device which already bears the CE marking in accordance with Article 20(1), ('PMCF investigation'), and where the investigation would involve submitting subjects to procedures additional to those performed under the normal conditions of use of the device and those additional procedures are invasive or burdensome, the sponsor shall notify the Member States concerned at least 30 days prior to its commencement by means of the electronic system referred to in Article 73. The sponsor shall include the documentation referred to in Chapter II, Sections 1, 3 and 4, of Annex XV as part of the notification. Article 62(4), points (b) to (k) and (m), Article 75(1), Articles 76 and 77, Article 80(5) and (6), and the relevant provisions of Annex XV shall apply to PMCF investigations involving additional invasive or burdensome procedures.

Unless otherwise stated by national law, where a PMCF investigation does not involve additional invasive or burdensome procedures, the sponsor shall notify the Member States concerned upon its commencement by means of the electronic system referred to in Article 73, and the second and third sentences of the first subparagraph shall apply.';

(60) Article 75 is amended as follows:

(a) in paragraph 1, the first sentence is replaced by the following:
'If a sponsor intends to introduce modifications to a clinical investigation that are likely to have a substantial impact on the safety, health or rights of the subjects or on the robustness or reliability of the clinical data generated by the investigation, it shall notify, by means of the electronic system referred to in Article 73, the Member State(s) in which the clinical investigation is being or is to be conducted of the reasons for and the nature of those modifications.';

PUBLIC

(b) paragraph 2 is replaced by the following:

‘2. Where the clinical investigation has been the subject of an authorisation in accordance with Article 62(4), point (a), the Member State shall assess any substantial modification to the clinical investigation in accordance with the procedure laid down in Article 71.

The Member State shall notify the sponsor of the outcome of its assessment within 38 days of receipt of the sponsor’s notification under paragraph 1.

During its assessment, the Member State may request additional information from the sponsor. The period of 38 days shall be suspended from the date of the first request until such time as the additional information has been received.’;

(c) in paragraph 3, the introductory wording is replaced by the following:

‘The sponsor may implement the modifications referred to in paragraph 1 as soon as the Member State concerned has notified the sponsor of its authorisation or following expiry of the period defined in paragraph 2, whichever is sooner, unless:’;

(61) Article 78 is amended as follows:

(a) in paragraph 4, the second subparagraph is replaced by the following:

‘The final assessment report shall be taken into account by all Member States concerned when deciding on the sponsor's application in accordance with paragraph 11.’;

(b) paragraph 5 is replaced by the following:

‘5. Each Member State concerned may request, on a single occasion, additional information from the sponsor. The sponsor shall submit the requested additional information within 12 days of receipt of the request. The expiry of the last deadline pursuant to paragraph 4, point (d), shall be suspended from the date of the request until such time as the additional information has been received.’;

(c) in paragraph 6, the reference to ‘50 days’ is replaced by ‘30 days’;

PUBLIC

(d) the following paragraph 15 is added:

'15. The Commission is empowered to adopt delegated acts in accordance with Article 115 to amend this Article in light of experience gained from the practical application of the coordinated assessment procedure, in particular as regards timelines and the authorisation of clinical investigations subject to a coordinated assessment.';

(62) Article 79 is deleted;

[(63) the following Article 79a is inserted:

'Article 79a

Clinical investigations in combined studies

Clinical investigations that are part of combined studies, and which are subject to authorisation in accordance with Article 62, shall be carried out in accordance with Article 14c of Regulation (EU) No 536/2014.

Where Article 14c of Regulation (EU) No 536/2014 applies, the requirements laid down therein and in any implementing or delegated acts adopted in accordance with that Article shall apply instead of the corresponding requirements laid down in this Regulation. Member States shall ensure that the assessment of the clinical investigation part of the combined study is done in accordance with the requirements specified in ~~a~~**A**rticle 71.';**]**

(64) Article 82 is replaced by the following;

'1. Clinical investigations, not performed pursuant to any of the purposes listed in Article 62(1) or Article 74, shall comply with the provisions of Article 62 (2) and (3), points (b)**, (c), (d), (f), (h) and** ~~to~~ (l) of Article 62(4)~~, Article 62(5)~~ and Article 62(6).

2. In order to protect the rights, safety, dignity and well-being of subjects and the scientific and ethical integrity of clinical investigations not performed for any of the purposes listed in Article 62(1) or Article 74, each Member State shall define any additional requirements for such investigations, as appropriate for each Member State concerned.

3. ~~Article 80 shall apply for clinical investigations of devices conducted in accordance with this Article. Where the device already bears the CE marking in accordance with Article 20(1), the provisions on vigilance laid down in Articles 87 to 90 and in the acts adopted pursuant to Article 91 shall apply instead of Article 80.~~ **In order to ensure the uniform application of this Article and of Articles 62(1) and 74, the Commission may, in consultation with the MDCG, adopt implementing acts to the extent necessary to resolve issues of divergent interpretation and of practical application. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).**';

(65) ~~in~~ Article 83(4)~~, the first sentence~~ is replaced by the following:

'If in the course of the post-market surveillance, a need for preventive or corrective action, or both, is identified, the manufacturer shall implement the appropriate measures. **Where preventive or corrective action is taken to reduce a risk that may compromise the safety of the device, the manufacturer shall inform the competent authorities concerned.**~~These preventive or corrective actions shall be appropriately documented and, where relevant, included in the reports referred to in Articles 85, 86, 87 and 88. A Member State may request that a manufacturer informs the competent authorities and, where appropriate, the notified body of such preventive or corrective action, including those not already included in the reports mentioned in Articles 85, 86, 87 and 88, to reduce a risk that may compromise the safety or performance of the device.~~ *Where ~~a serious incident is identified or a field safety corrective action is implemented~~**such corrective actions are associated with an identified serious incident or an implemented field safety corrective action**, it shall be reported in accordance with Article 87*.';

(66) in Article 84, the following sentence is added after the second sentence:

'The post-market surveillance plan shall specify the criteria, and timelines where relevant, for updating the Post-Market Surveillance Report as referred to in Article 85 or the Periodic Safety Update Report as referred to in Article 86.';

(66a) Article 85 is replaced by the following:

*Manufacturers of **custom-made and of** class I devices shall prepare a post-market surveillance report summarising the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan referred to in Article 84 together with a rationale and description of any preventive and corrective actions taken. The report shall be updated when necessary and made available to the competent authority upon request.*

(67) Article 86 is amended as follows:

(a) paragraph 1 is amended as follows:

(i) in the first subparagraph, the first sentence is replaced by the following: 'Manufacturers of class IIa, class IIb and class III devices, other than custom-made devices, shall prepare a periodic safety update report ('PSUR') for each device, or where relevant for each category or group of devices, summarising the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan referred to in Article 84, together with a description of any preventive and corrective actions taken, including their rationale.';

(ii) the second and third subparagraphs are replaced by the following: 'Manufacturers of class IIb and class III devices shall update the PSUR in the first year after the certificate is issued and every two years thereafter or when there is a significant change in the benefit-risk determination or in the acceptability of undesirable side-effects. The PSUR shall be part of the technical documentation as specified in Annex III.

Manufacturers of class IIa devices shall update the PSUR ~~and~~ in accordance with the criteria set out in the manufacturer's post-market surveillance plan referred to in Article 83, and in any event when there is a significant change in the benefit-risk determination or in the acceptability of undesirable side-effects. The PSURs shall be part of the technical documentation specified in Annex III.';

(iii) the fourth subparagraph is deleted.

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(b) paragraph 2 is replaced by the following:

'2. For class III devices or class IIb implantable devices, other than well-established technology devices, the notified body shall review the PSUR ~~during the~~ **as part of its** surveillance ~~assessment~~**activities**, where applicable~~, or as part of the technical documentation review~~. The manufacturer ~~and the notified body~~ shall make such PSURs available ~~to competent authorities~~ through the electronic system referred to in Article 92. The notified body shall make its evaluation of such PSURs available ~~to competent authorities~~ through the electronic system referred to in Article 92.

For all other devices where the PSUR is applicable, the notified body shall **have documented procedures for reviewing** ~~review~~ PSURs on a representative basis as part of the surveillance activities in accordance with Section 4.10 of Annex VII ~~or periodic reviews in accordance with Section 4.11 of Annex VII~~.';

(68) Article 87 is amended as follows:

(a) paragraph 1 is amended as follows:

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

'(a) any serious incident involving devices made available on the Union market, except expected undesirable side-effects which are clearly documented in the device information and quantified in the technical documentation and are subject to trend reporting pursuant to Article 88;';

(ii) the second subparagraph is replaced by the following:

'The reports referred to in the first subparagraph shall be submitted in accordance with the timelines specified in this Article through the electronic system referred to in Article 92.';

(b) paragraph 3 is replaced by the following:

'3. Manufacturers shall report any serious incident as referred to in paragraph 1, first subparagraph, point (a), immediately after they have established that there is a causal relationship between that incident and their device or that such causal relationship is reasonably possible and not later than 30 days after they become aware of the incident.';

(69) the following Article 87a is inserted:

'Article 87a

Reporting of actively exploited vulnerabilities and severe incidents related to devices

1. Without prejudice to the reporting obligations regarding serious incidents and field safety corrective actions set out in Article 87, the manufacturer of a device shall report to the computer security incident response teams ('CSIRTs'), designated as coordinators of the Member States where a device has been made available, and to the European Union Agency for Cybersecurity (ENISA), either of the following:
   (a) any actively exploited vulnerability as defined in Article 3, point (42), of Regulation (EU) 2024/2847 of the European Parliament and of the Council******* contained in the device;
   (b) any severe incident as referred in Article 14(5) of Regulation (EU) 2024/2847 having an impact on the security of the device.

2. The manufacturer shall submit the report referred to in paragraph 1 through the electronic system referred to in Article 92 immediately after and not later than 30 days after it becomes aware of the actively exploited vulnerability or the severe incident.

3. The report referred to in paragraph 1, as well as any report submitted by a manufacturer in accordance with Article 87 that also qualifies as actively exploited vulnerability or severe incident, shall be made available simultaneously to the CSIRTs designated as coordinators of the Member States in which the device has been made available and to ENISA.

4. For the purposes of this Article, the CSIRTs designated as coordinators and ENISA shall have access to Eudamed.

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5. In respect of the report referred to in paragraph 1, the competent authorities shall cooperate with the CSIRTs designated as coordinators of the Member States in which the device has been made available, and with ENISA.';

_____

******* Regulation (EU) 2024/2847 of the European Parliament and of the Council of 23 October 2024 on horizontal cybersecurity requirements for products with digital elements and amending Regulations (EU) No 168/2013 and (EU) 2019/1020 and Directive (EU) 2020/1828 (Cyber Resilience Act) (OJ L, 2024/2847, 20.11.2024, ELI: http://data.europa.eu/eli/reg/2024/2847/oj).';

(70) in Article 88(1), the first sentence is replaced by the following:

'Manufacturers shall report, by means of the electronic system referred to in Article 92, any statistically significant increase in the frequency or severity of incidents that are not serious incidents or that are expected undesirable side-effects that could have a significant impact on the benefit-risk analysis referred to in Sections 1 and 8 of Annex I.';

(71) Article 89 is amended as follows:

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

'*Following ~~the~~ reporting ~~of a serious incident~~ pursuant to Article 87(1), the manufacturer shall, without delay, perform the necessary investigations in relation to the serious incident and the devices concerned. This shall include a risk assessment of the incident ~~and~~ **or** field safety corrective action taking into account criteria as referred to in paragraph 3 of this Article as appropriate.*

The manufacturer shall cooperate with the competent authorities during the investigations referred to in the first subparagraph and shall not perform any investigation which involves altering the device or a sample of the batch concerned in a way which may affect any subsequent evaluation of the causes of the incident **or the field safety corrective action**, prior to informing the competent authorities of such action.';

(b) paragraph 2 is replaced by the following:

‘2. Member States shall take the necessary steps to ensure that any information regarding a serious incident that has occurred within their territory, or a field safety corrective action that has been or is to be undertaken within their territory, and that is brought to their knowledge in accordance with Article 87 is evaluated centrally at national level by their competent authority, if possible together with the manufacturer.’;

(c) the following paragraph 3a is inserted:

‘3a. The competent authorities may exchange information in relation to their assessments in paragraph 3 and, where relevant, engage with the authorities responsible for notified bodies and the authorities responsible for market surveillance.

The competent authority may request the notified body that issued a certificate for the device in question in accordance with Article 56 to provide assistance in evaluating a corrective action related to a serious incident or a field safety corrective action, taking into account the risk management and conformity assessment performed for the device.’;

(d) paragraph 6 is replaced by the following:

‘6. In the case of devices referred to in Article 1(8), first subparagraph, and where the serious incident or field safety corrective action is confirmed by the manufacturer to be related to a substance which, if used separately, would be considered to be a medicinal product, the evaluating competent authority or the coordinating competent authority referred to in paragraph 9 shall inform the national competent authority or the EMA, which issued the scientific opinion on that substance in accordance with Article 52(9), of that serious incident or field safety corrective action.

PUBLIC

In the case of devices falling within the scope of this Regulation in accordance with Article 1(6), point (g), or in accordance with Article 1(10), the competent authority or the coordinating competent authority referred to in paragraph 9 of this Article shall inform the competent authority for substances of human origin that was consulted by the notified body in accordance with Article 52(10), provided that the serious incident or field safety corrective action is confirmed by the manufacturer to be related to the derivatives of substances of human origin utilised for the manufacture of the device or to the non-viable substances of human origin or their derivatives that have an action ancillary to that of the device.';

(e) paragraph 7 is replaced by the following:

'7. If, after carrying out the evaluation in accordance with paragraph 3 of this Article, the evaluating competent authority identifies the need for additional corrective actions from the manufacturer to minimise the risk of recurrence of the serious incident, it shall, through the electronic system referred to in Article 92, inform, without delay, the other competent authorities of the corrective action taken or envisaged by the manufacturer or required of it to minimise the risk of recurrence of the serious incident, including information on the underlying events and the outcome of its assessment.';

(f) in paragraph 9, the introductory wording is replaced by the following:
'The competent authorities shall actively participate in a procedure in order to coordinate their assessments referred to in paragraph 3 whenever such coordination is needed to ensure a high level of protection of the health and safety of patients, users and other persons or the protection of public health throughout the Union, and in particular in the following cases:';

(72) in Article 91, the first subparagraph is amended as follows:

(a) the introductory wording is replaced by the following:
'The Commission may, by means of implementing acts, and after consulting the MDCG, adopt the detailed arrangements and procedural aspects necessary for the implementation of Articles 84 to 90 and Article 92 as regards the following:';

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

'(b) the reporting of serious incidents and field safety corrective actions and field safety notices, and the provision and content of the post-market surveillance plan, periodic summary reports, post-market surveillance reports, PSURs and trend reports by manufacturers as referred to in Articles 84, 85, 86, 87, 88 and 89 respectively;';

(73) in Article 92(2), the reference to 'Article 53' is replaced by 'Article 56';

(…)

(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**, in consultation with Member States via the MDCG,** shall explore avenues to contribute to the development and adoption of global principles, standards and guidance which 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 **systems**, conformity assessment and post-market surveillance.

2. The Commission shall make full use of and build on, within the limits of the tasks conferred upon it, existing international 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.

3. In its activities in accordance with paragraphs 1 and 2, the Commission shall ~~seek the views of~~**consult** the MDCG **and take into account its position**. **The Commission shall invite Member States to nominate experts, in view of their competence in medical devices or in vitro diagnostic medical devices, to participate in those activities.**

4. The Commission, in consultation ~~and agreement~~ with Member States **via the MDCG**, may sign administrative arrangements with authorities of third countries and with international organisations 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 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.

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Article 108b

Reliance mechanisms

1. In the framework of the implementation of this Regulation or of Regulation (EU) 2017/746, as applicable, notified bodies and competent authorities ~~shall~~ **may** take into consideration the outcome of assessments, **audits,** inspections, and other regulatory decisions carried out or taken by regulatory authorities of third countries or international organisations or **within the framework of** international ~~bodies~~ **cooperation mechanisms in the field of**~~related to a~~ medical device**s** and ~~an~~ in vitro diagnostic medical device**s**, provided that the following conditions are fulfilled:
   (a) the assessments, **audits,** inspections, or other regulatory decisions of the regulatory authority of the third country, the international organisation or **those decisions taken within the framework of an**~~the~~ international **cooperation mechanism** ~~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 ~~with~~ **between** the relevant regulatory authority of the third country, the international organisation or the ~~international~~ body **participating in the international cooperation mechanism and the Union** 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.

4. The Commission shall adopt implementing acts identifying the regulatory authorities of third countries, the international organisations or the international ~~bodies~~ **cooperation mechanisms,** referred to in paragraph 1 and, where relevant, establishing the detailed rules for the ~~recognition~~ **taking into consideration** of assessments, **audits,** inspections **carried out** or other relevant regulatory decisions taken **for the purpose of**~~in~~ 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 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 the activities referred to in paragraph 1, a financial allocation may also be made available from the general budget of the Union.';

(…)

(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~~**avoiding** duplication of ~~core~~ Union data**, where possible** ~~is avoided~~.;'

(…)

(2) Annex II is amended as follows:
(a) Section 6.1. is amended as follows:
(i) the heading of Section 6.1. is replaced by the following:
'6.1. Non-clinical, pre-clinical and clinical data';

(ii) point (a) is replaced by the following:

'(a) results of tests, such as engineering, laboratory, in vitro, ex vivo, in silico testing, computational modelling, simulated use and animal tests, and evaluation of published literature applicable to the device, taking into account its intended purpose, or to similar devices, regarding the pre-clinical safety of the device and its conformity with the specifications;';

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

'(c) the clinical evaluation plan, the clinical evaluation report and its updates referred to in Article 61(1) and Part A of Annex XIV.';

(iv) point (d) is deleted;

(v) point (e) is added:

'(e) The draft summary of safety and clinical performance referred to in Article 32, where applicable.';

(b) Section 6.2. is amended as follows:

(i) in point (b), the first sentence is replaced by the following:

'(b) Where a device is manufactured utilising substances of human origin or tissues or cells of animal origin, or their derivatives, and is covered by this Regulation in accordance with Article 1(6), points (f) and (g), and where a device incorporates, as an integral part, substances of human origin or their derivatives that have an action ancillary to that of the device and is covered by this Regulation in accordance with Article 1(10), first subparagraph, a statement indicating this fact.';

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(ii) the following point (h) is added:

‘(h) Where the device incorporates as an integral part an in vitro diagnostic medical device that has an action ancillary to that of the device, as referred to in Article 1(7) of this Regulation, the documentation shall include the results of the assessment of the conformity of the in vitro diagnostic medical device part with the relevant general safety and performance requirements set out in Annex I to Regulation (EU) 2017/746 contained in the manufacturer's EU declaration of conformity or the relevant certificate issued by a notified body allowing the manufacturer to affix a CE marking to the in vitro diagnostic medical device. Where those results of the conformity assessment are not available and where for the conformity assessment of the in vitro diagnostic medical device, if used separately, the involvement of a notified body is required in accordance with Regulation (EU) 2017/746, an opinion on the conformity of the in vitro diagnostic medical device part with the relevant general safety and performance requirements set out in Annex I to Regulation 2017/746 issued by a notified body designated in accordance with that Regulation for the type of device in question shall be included in the documentation.’;

(3) in Annex III, Section 2 is replaced by the following:

‘2. The PSUR referred to in Article 86 or the post-market surveillance report referred to in Article 85.’;

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(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:

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.

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,

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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~~**substances** 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),

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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),
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.';

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(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.';

(5) Annex VII is amended as follows:

(a) in Section 1.1.1., the following sentence is added:

'It shall also include information about the larger organisation to which the notified body belongs.';

(b) Section 1.1.2. is replaced by the following:

'1.1.2. If the notified body is a legal entity that is part of a larger organisation, the activities of that organisation as well as its organisational structure and governance, and the relationship with the notified body shall be clearly documented. In such cases, the requirements of Section 1.2 are applicable to both the notified body and the larger organisation to which it belongs. The larger organisation and any of the legal entities belonging to it shall not be involved in the design, manufacture, marketing, installation or maintenance of the devices for which the notified body is designated or offer consultancy services for such activities, neither shall they represent the parties engaged in such activities.';

(c) in Section 1.2.9., the following sentences are added:

'The notified body shall have documented procedures in place to offer and carry out dialogues with the manufacturer before and after an application for conformity assessment is lodged. These procedures should clearly prohibit services that fall within the scope of consultancy services.';

(d) Section 1.3.1. is replaced by the following:

'1.3.1. The notified body shall have documented procedures in place ensuring that its personnel, committees, branch offices, subsidiaries, subcontractors, and any associated body or personnel of external bodies respect the confidentiality of the information which comes into its possession during the performance of conformity assessment activities, except when disclosure is required by law.';

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(f) the following Section 1.4.3. is inserted:

'1.4.3. By way of derogation from Sections 1.4.1 and 1.4.2, the notified body may demonstrate coverage for liability through adherence to a guarantee fund that provides effective protection and is recognised by the Member State(s) concerned.';

(g) Section 1.6.1. is replaced by the following:

'1.6.1. The notified body shall participate in the activities of the notified body coordination group referred to in Article 49 and ensure that its assessment and decision-making personnel are ~~sufficiently~~ **adequately** informed of all relevant legislation, standards, guidance and best practice documents adopted in the framework of this Regulation.';

(h) Section 2.1. is replaced by the following:

'2.1. The notified body shall establish, document, implement, maintain and operate a quality management system that is appropriate to the nature, area and scale of its conformity assessment activities taking into account state of the art, and is capable of supporting and demonstrating in an efficient manner the consistent fulfilment of the requirements of this Regulation.';

(i) Section 2.3. is replaced by the following:

'2.3. The top-level management of the notified body shall ensure that the quality management system is fully understood, implemented and maintained throughout the notified body organisation, including branch offices, subsidiaries and subcontractors involved in conformity assessment activities pursuant to this Regulation.';

(j) Section 3.2.3. is amended as follows:

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

'3.2.3. The personnel responsible for establishing qualification criteria and for authorising other personnel to perform specific conformity assessment activities shall not be external experts or be subcontracted.';

(ii) the sixth indent is replaced by the following:

'- adequate experience in conformity assessments under this Regulation, Regulation (EU) 2017/746 or previously applicable law within a notified body.';

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(k) in Section 3.2.4., the first sentence is replaced by the following:
'The notified body shall have permanent availability of personnel with relevant clinical expertise.';

(l) in Section 3.2.7., the first sentence is replaced by the following:
'The personnel with overall responsibility for final reviews and decision-making on certification shall not be external experts or be subcontracted.';

(m) in Section 3.4.1., first paragraph, the following sentence is added:
'They shall inform the manufacturer accordingly.';

(n) in Section 4.1., the second paragraph is replaced by the following:
'The requirements laid down in Sections 4.3, 4.4, 4.7 and 4.8 shall not be subcontracted or fulfilled by external experts.';

(o) in Section 4.2.(a), the second sentence is replaced by the following:
'That description shall include which languages are acceptable for submission of documentation and for any related correspondence and the modalities for carrying out the dialogue referred to in Section 1.2.9 before an application is lodged.';

(p) in Section 4.5.1., the second subparagraph is amended as follows:

(i) the ninth indent is replaced by the following:

'- in the case of all class IIa devices and class IIb non-implantable devices, and in the case of well-established technology devices that are class IIb implantable devices or class III non-implantable devices, ~~as referred to in Article 52,~~ assess the technical documentation of the representative device(s),';

(ii) the eleventh indent is deleted;

(iii) the following indents are added:

'- where appropriate, perform a rolling review of the manufacturer's data or documentation as they become available,

- in case of class I devices that are placed on the market in sterile condition, have measuring function or are reusable surgical instrument, assess the quality management system only in relation to the relevant special aspects of these devices,

- leverage evidence from previous assessments performed.';

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(q) Section 4.5.2.(a) is amended as follows:

(i) the introductory wording is replaced by the following:

'(a) As part of the assessment of the quality management system, a notified body shall prior to or in relation with an audit and in accordance with its documented procedures:';

(ii) the fourth indent is replaced by the following:

'- clearly identify, for the devices referred to in Section 4.5.1, ninth indent, the representative devices selected for the assessment of technical documentation as referred to in Annexes II and III,';

(iia) the following indent is inserted after the fourth indent:

'- draw up and keep up to date, for in the case of the devices referred to in Section 4.5.1, ninth indent, a sampling plan justifying the device(s) selected for the assessment of technical documentation as referred to in Annexes II and III~~, taking into account the risk-based approach as referred to in Article 52 and considering the range of devices covered by the manufacturer's application~~.';

(r) in Section 4.5.2.(b), the second paragraph is replaced by the following:

'The documentation shall be sampled in such a manner as to reflect the risks associated with the intended use of the device, the complexity of the manufacturing technologies, the range and classes of devices produced or under certification**,** ~~and~~ any available post-market surveillance information**, and giving due consideration to the size and diversity of the manufacturer's portfolio**.';

(s) in Section 4.5.4(a), the second indent is replaced by the following:

'- the pre-clinical testing, for example laboratory, in vitro, ex vivo, in silico testing, simulated use testing, computer modelling, the use of animal models;';

(t) in Section 4.5.5., third paragraph, the following indent is added:

'- where applicable, the justification for the confirmation of the safety and performance that is based on the results of non-clinical testing methods alone,';

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(u) in Section 4.5.6., the second paragraph is replaced by the following:

'In the case of devices manufactured utilising tissues or cells of animal origin or their derivatives, such as from transmissible spongiform encephalopathy (TSE) susceptible species, as referred to in Regulation (EU) No 722/2012, or in any subsequent implementing rules adopted pursuant to this Regulation, the notified body shall have documented procedures in place that fulfil the requirements laid down in Regulation (EU) No 722/2012 or those subsequent implementing rules.';

(v) in Section 4.6., second paragraph, the introductory wording is replaced by the following:

'The report(s) of the notified body shall:';

(w) Section 4.8. is amended as follows:

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

'The notified body shall have documented procedures for decision-making including as regards the allocation of responsibilities for the issuance, suspension, limitation and withdrawal of certificates.';

(ii) the third sentence is amended as follows:

(1) the fourth indent is replaced by the following:

'- decide whether conditions or limitations need to be defined for the certification,';

(2) the fifth indent is replaced by the following:

'- where appropriate, decide, based on the novelty, risk classification, clinical evaluation and conclusions from the risk analysis of the device, on a period of certification, not exceeding five years for initial certification of class III devices and class IIb implantable devices, other than well-established technology devices, in accordance with Article 56(2),';

(3) the eighth indent is replaced by the following:

'- issue a certificate or certificates in accordance with the minimum requirements laid down in Annex XII and indicate whether there are conditions or limitations associated with the certification,';

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(x) Section 4.9. is amended as follows:

(i) the third indent is replaced by the following:

‘- the intended purpose of or claims made for the device,’;

(ii) the second paragraph is replaced by the following:

‘The procedures and contractual arrangements referred to in the first paragraph shall clearly distinguish between changes that do not need to be reported, that need to be reported without requiring prior approval and that require prior approval.’;

(iii) in the third paragraph, the introductory sentence is replaced by the following:

‘In accordance with its documented procedures, the notified body in question shall, where changes require prior approval:’;

(iv) the following paragraph is added:

‘Where appropriate, the notified body and the manufacturer shall agree on a predetermined change control plan enabling the manufacturer to implement changes in accordance with such a plan without prior information.’;

(y) Section 4.10. is amended as follows:

(i) in the first paragraph, the second and third indents are replaced by the following:

‘- for screening relevant sources of scientific and clinical data and post-market information relating to the scope of their designation. That screening shall be conducted in the framework of the coordination group established in Article 49 to avoid unnecessary duplication and to enhance efficiency and work-sharing. The findings from the screening shall be taken into account in the planning and conduct of surveillance activities,

- to assess whether any reported serious incident related to a serious public health threat or any field safety corrective action taken or envisaged by the manufacturer or required of it by a competent authority has an impact on the validity of existing certificates. The results of the evaluation and any decisions taken shall be thoroughly documented.’;

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(ii) the second paragraph is amended as follows:

(1) the introductory wording is replaced by the following:

'The notified body in question shall, with regard to signals arising from vigilance data to which they have access under Article 92(2), decide which of the following options to apply, where appropriate:';

(2) the first indent is deleted;

(iii) the third paragraph is amended as follows:

(1) the first indent is replaced by the following:

'- conduct surveillance audits of the manufacturer which shall be planned and conducted in line with the relevant requirements in Section 4.5,';

(2) the eighth indent is replaced by the following:

'- where necessary, impose conditions or limitations on the relevant certificate, or suspend or withdraw it.';

(iv) in the fourth paragraph, the third indent is replaced by the following:

'- ensure that the clinical evaluation, as most recently updated, is appropriately reflected in the instructions for use and, where applicable, the summary of safety and clinical performance.';

(z) Section 4.11. is replaced by the following:

'4.11. Periodic reviews and extension of a certificate's period of validity'

The notified body shall have documented procedures in place relating to the re-assessment of EU technical documentation assessment certificates and relating to the periodic reviews of approved quality management systems or EU technical documentation assessment certificates or EU type-examination certificates.

Those procedures shall require the manufacturer in question to submit at predefined intervals a summary of changes and scientific findings for the device, including:

(a) all changes to the originally approved device **or QMS**, including changes not yet notified,

(b) relevant data gathered by the manufacturer's post-market surveillance system,

PUBLIC

(c) changes to the regulatory requirements, such as changes to the legal requirements, revised or new harmonised standards, CS or equivalent documents, and

(d) changes in medical, scientific and technical state of the art.

The notified body shall assess such information and shall pay particular attention to clinical data from post-market surveillance and PMCF activities undertaken since the previous certification or periodic review, including appropriate updates to manufacturers' clinical evaluation reports, without repeating assessments already conducted.

In the case of EU technical documentation assessment certificates where a maximum period of validity is indicated in accordance with Article 56(2), the notified body shall conduct a reassessment of the relevant technical documentation prior to extending the period of validity.

The notified body shall have documented procedures in place relating to the extension of the period of validity of a certificate in cases where it has exceptionally limited the period of validity or for EU technical documentation assessment certificates where a maximum period of validity is indicated in accordance with Article 56(2). Those procedures shall require the manufacturer to submit prior to the expiry of the certificate the data or documentation specified by the notified body to enable it to decide about the extension of the period of validity of the certificate.';

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(6) Annex VIII is amended as follows:

(-a) The following Section 2a is added:

'2a. SOFTWARE

2a.1. A 'non-serious situation' is characterised as a situation where an erroneous software recommendation can be easily detected prior to causing harm and where the output provided by the software could influence subsequent healthcare tasks/interventions over the long term.

2a.2. A 'serious situation' is characterised as a situation where an erroneous software recommendation could result in serious deterioration of a person's state of health and where the output provided by the software influences subsequent healthcare tasks/interventions in the short to medium term.

2a.3. A 'critical situation' is characterised as a situation where an erroneous software recommendation could result in death or irreversible deterioration of a person's state of health and where the output provided by the software influences subsequent healthcare tasks/ interventions of an immediate nature.';

(a) Section 3.2 is replaced by the following:

'3.2. If the device in question is intended to be used in combination with another device, the classification rules shall apply separately to each of the devices. Accessories for a medical device and accessories for a product listed in Annex XVI~~, where relevant,~~ shall be classified in their own right separately from the device with which they are used.';

~~(b) in Section 4.2, first paragraph, the second indent is replaced by the following:~~

~~'– if they are intended for use for channelling or storing blood or other body liquids or for storing organs, parts of organs or body cells and tissues, except for blood bags;';~~

~~(c) in Section 5.2, the second indent is replaced by the following:~~

~~'– are reusable surgical instruments regardless of the anatomophysiological system with which they come into contact, in which case they are classified as class I;;'~~

(d) in Section 5.3, the following indent is added:

‘- are reusable surgical instruments ~~regardless of the anatomophysiological system with which they come into contact~~, in which case they are classified as class I;’;

(e) Section 5.4 is amended as follows:

(i) the sixth indent is replaced by the following:

‘- are active implantable devices, in which cases they are classified as class III;’;

~~(ii) the eighth and ninth indents are replaced by the following:~~

~~‘- are total or partial joint replacements, in which case they are classified as class III, with the exception of components that are well-established technology devices; or~~

~~- are spinal disc replacement implants or are implantable devices that come into contact with the spinal column, in which case they are classified as class III with the exception of components that are well-established technology devices.’;~~

(f) in Section 6.1, the first and second paragraphs are replaced by the following:

‘All active therapeutic devices and all active products listed in Annex XVI intended to administer or exchange energy are classified as class IIa unless their characteristics are such that they may administer energy to or exchange energy with the human body in a potentially hazardous way, taking account of the nature, the density and site of application of the energy, in which case they are classified as class IIb.

All active devices intended to control or monitor the performance of active therapeutic class IIb devices, and of any active product listed in Annex XVI falling in class IIb, or intended directly to influence the performance of such devices are classified as class IIb.’;

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(g) Section 6.3 is replaced by the following:

‘6.3. Rule 11

Software which is intended to generate an output used to achieve a medical purpose, as specified in Article 2(1) is:

i. class I if the output is intended to be used for a disease or condition in a non-serious situation, except if the software is directly providing **diagnoses or** treatment **to a lay person,** in a non-serious situation, in which case it is class IIa.

ii. class IIa if the output is intended to be used for a disease or condition in serious situation with professional clinical oversight or class IIb if it is intended for a lay ~~user~~**person**.

iii. class ~~IIb~~ **III** if the output is intended to be used for a disease or condition in critical situation ~~with professional clinical oversight or class III if it is intended for a lay user~~.

AI enabled medical devices are classified, at a minimum, as class IIa.

~~With respect to this rule:~~

~~A 'non-serious situation' is characterised as a situation where an erroneous software recommendation can be easily detected prior to causing harm and where the output provided by the software could influence subsequent healthcare tasks/interventions over the long term.~~

~~A 'serious situation' is characterised as a situation where an erroneous software recommendation could result in serious deterioration of a person's state of health and where the output provided by the software influences subsequent healthcare tasks/interventions in the short to medium term.~~

~~A 'critical situation' is characterised as a situation where an erroneous software recommendation could result in death or irreversible deterioration of a person's state of health and where the output provided by the software influences subsequent healthcare tasks/ interventions of an immediate nature.~~

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For software placed on the market as solutions/ platforms with customisable modules, the risk class of the software solution will be the risk class of the module with highest risk.'

(ga) Section 7.5 is replaced by the following:

'7.5. Rule 18

All devices manufactured utilising ***substances of human origin, or their derivatives, or*** *tissues or cells of ~~human or~~ animal origin, or their derivatives, which are non-viable or rendered non-viable, are classified as class III, unless such devices are manufactured utilising tissues or cells of animal origin, or their derivatives, which are non-viable or rendered non-viable and are devices intended to come into contact with intact skin only.';*

(h) in Section 7.6, the introductory wording is replaced by the following:

'Rule 19

All devices incorporating or consisting of nanomaterial as defined in Commission Recommendation C/2022/3689 are classified as:';

(i) in Section 7.8, the introductory wording is replaced by the following:

'Devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body via a body orifice or applied to the skin and that are absorbed by or locally dispersed in the human body are classified as:';

~~(ia) Section 7.10 is added as follows:~~

~~'7.10 Rule 23~~

~~By way of derogation from rules defined in Chapter III, blood bags are classified as class IIb.'~~

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(7) Annex IX is amended as follows:

(a) in Section 2.3, the third and fourth paragraphs are replaced by the following:

'Moreover, in the case of class IIa devices and class IIb non-implantable devices, and in the case of well-established technology devices that are class IIb implantable devices or class III non-implantable devices, the quality management system assessment shall be accompanied by the assessment of the technical documentation, as referred to in Annex II and III, as specified in Sections 4.3 to 4.8 ~~and Articles 52(4) and 52(6)~~ for a representative device **in accordance with Article 52**. In choosing the representative device(s), the notified body shall apply a risk-based approach, taking into account the principle of proportionality and in particular the physical, chemical, biological characteristics of the device, the novelty of the technology, similarities in design, technology, manufacturing and sterilisation methods, the intended purpose, the application by the manufacturer of harmonised standards or CS for the device and the results of any previous relevant assessments such as with regard to physical, chemical, biological or clinical properties, that have been carried out in accordance with this Regulation. The notified body in question shall document its rationale for the representative devices taken.

For class IIa devices and class IIb non-implantable devices, and in the case of well-established technology devices that are class IIb implantable devices or class III non-implantable devices, the notified body may include an assessment of the technical documentation of additional representative devices on duly justified grounds identified during the quality management system assessment.

If the quality management system and the technical documentation of the assessed representative device(s) conform~~s~~ to the relevant provisions of this Regulation, the notified body shall issue an EU quality management system certificate. The notified body shall notify the manufacturer of its decision to issue the certificate. The decision shall contain the conclusions of the audit and be included in the report of the notified body in accordance with Section 4.6 of Annex VII.';

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(b) in Section 3.2, the second indent is replaced by the following:

'- documentation on any findings and conclusions resulting from the application of the post-market surveillance plan, including the PMCF plan, for the representative device(s), and of the provisions on vigilance set out in Articles 87 to 92,';

(c) Section 3.3 is replaced by the following:

'3.3. Notified bodies shall periodically carry out appropriate audits and assessments to make sure that the manufacturer in question applies the approved quality management system and the post-market surveillance plan, taking into account the state of the art. Those audits and assessments shall include audits on the premises of the manufacturer and, if appropriate, of the manufacturer's suppliers or subcontractors. On justified grounds, a surveillance audit may be conducted remotely instead of on-site. The notified body shall inform the authority responsible for notified bodies ~~on~~ **of** the justified grounds ~~and~~ **for** the ~~conducted~~ remote audits **conducted**. The notified body shall, where necessary, carry out or ask for tests in order to check that the quality management system is working properly. It shall provide the manufacturer with a surveillance audit report and, if a test has been carried out, with a test report.

The notified body shall carry out the surveillance audits and assessments once every 12 months. However, where justified in light of the results of previous surveillance audits and assessments, and in the absence of any concerns resulting from data from post-market surveillance or vigilance, the notified body may carry out the surveillance audits and assessments only once every 24 months.';

(d) Section 3.4 is amended as follows:

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

'The notified body shall perform short-notice or unannounced audits on the site of the manufacturer and, where appropriate, of the manufacturer's suppliers or subcontractors when justified based on concerns related to post-market surveillance or vigilance data or at the request of a competent authority or, in the absence thereof, randomly but at least once per five years. The short-notice or unannounced audit may be combined with the periodic surveillance assessment referred to in Section 3.3. or be performed in addition to that surveillance assessment.';

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(ii) in the second paragraph, the first sentence is replaced by the following: 'Within the context of such unannounced on-site audits, the notified body may test an adequate sample of the devices produced or an adequate sample from the manufacturing process to verify that the manufactured device is in conformity with the technical documentation, with the exception of the devices referred to in the second subparagraph of Article 52(8).';

(iii) in the third paragraph, the first sentence is replaced by the following: 'Instead of, or in addition to, the sampling referred to in the second paragraph, the notified body may take samples of devices from the market to verify that the manufactured device is in conformity with the technical documentation, with the exception of the devices referred to in the second subparagraph of Article 52(8).';

(e) Section 3.5 is replaced by the following:

'3.5. In the case of class IIa devices and class IIb non-implantable devices, and in the case of well-established technology devices that are class IIb implantable devices or class III non-implantable devices, during the surveillance assessment the notified body ~~may~~ **shall** include an assessment of the technical documentation as specified in Section 4 for the device or devices concerned on the basis of further ~~representative~~ samples chosen in accordance with ~~the~~ **a** rationale documented by the notified body in accordance with the third paragraph of Section 2.3 **or based on the compliance history of the generic device group or category of devices as applicable, and giving due consideration to the size and diversity of the manufacturer's portfolio**.

In the case of class III devices, with the exception of well-established technology devices, the surveillance assessment shall also include a test of the approved parts and/or materials that are essential for the integrity of the device, including, where appropriate, a check that the quantities of produced or purchased parts and/or materials correspond to the quantities of finished devices.';

(f) Section 3.7. is replaced by the following;

'3.7. If the notified body finds a divergence between the sample taken from the devices produced or from the market and the specifications laid down in the technical documentation or the approved design, it shall suspend or withdraw the relevant certificate or impose conditions or limitations on it.';

(g) the title of Section 4 is replaced by the following:

'4. Assessment of the technical documentation';

(h) in Section 4.2, the second sentence is replaced by the following:

'It shall include the technical documentation as referred to in Annexes II and III or a plan and related timelines for submission of such technical documentation to be agreed with the notified body.';

(i) in Section 4.4, the second sentence is replaced by the following:

'The notified body shall use product reviewers with sufficient clinical expertise and, if necessary, use external clinical experts with direct and current experience relating to the device in question or the clinical condition in which it is utilised, for the purposes of that review.';

(j) Section 4.8 is replaced by the following:

'The notified body shall provide the manufacturer with a report on the technical documentation assessment, including a clinical evaluation assessment report.';

(k) in Section 4.9, the first **and the third** sentence**s** ~~is~~ **are** deleted;

~~(ka) in Section 4.9 the third sentence is replaced by the following:~~

~~'The certificate shall contain a description of the intended purpose of the device.'~~

(l) Section 5.1 is amended as follows:

(i) the title is replaced by the following:

'5.1. Assessment procedure for devices covered by Article 54;'

(ii) in point (a), the first and second paragraphs are replaced by the following:

'(a) For devices covered by Article 54, the notified body shall, having verified the quality of clinical data supporting the clinical evaluation report of the manufacturer referred to in Article 61(1), prepare a clinical evaluation assessment report which sets out its conclusions concerning the clinical evidence provided by the manufacturer, in particular concerning the benefit-risk determination, the consistency of that evidence with the intended purpose, including the medical indication or indications and the PMCF plan referred to in Article 10(3) and Part B of Annex XIV.

The notified body shall transmit its clinical evaluation assessment report, along with the manufacturer's clinical evaluation report and, where applicable, the PMCF plan, to the Commission.';

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(iii) in point (b), the following sentence is added:

'Where appropriate, the expert panel may also invite the manufacturer to present the conclusions of its clinical evaluation.';

(iv) point (g) is replaced by the following:

'(g) The notified body shall give utmost consideration to the views expressed in the scientific opinion of the expert panel and, where appropriate, update its clinical evaluation assessment report. Where the expert panel finds that the level of clinical evidence is not sufficient or otherwise gives rise to serious concerns about the benefit-risk determination, the consistency of that evidence with the intended purpose, including the medical indication(s), and with the PMCF plan, the notified body shall, if necessary, ~~,~~ **:**

- require the manufacturer to gather additional clinical data and update its clinical evaluation,
- ~~to~~ limit the intended purpose of the device to certain groups of patients or certain medical indications or to impose a limit on the duration of validity of the certificate,
- **require the manufacturer** to undertake specific PMCF studies,
- **require the manufacturer** to adapt the instructions for use or the summary of safety and clinical performance, or to impose other conditions in its conformity assessment report, as appropriate. The notified body shall provide an explanation of how it has addressed the views and recommendations expressed in the expert panel opinion and, where it has not followed the views and recommendations of the expert panel, provide a substantiated justification for it. The scientific opinion of the expert panel and the explanation of how is has been addressed or, if applicable, the substantiated justification provided by the notified body shall be publicly available via Eudamed without any confidential information as referred to in Article 109.';

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(m) Section 5.2 is amended as follows:

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

'The medicinal products authority consulted shall provide its opinion to the notified body within 180 days of receipt of all the necessary documentation. This 180-day period may be extended once for a further 30 days on justified grounds. Where the medicinal substance is not previously authorised in the Union, the medicinal products authority consulted shall provide its opinion within 180 days. When preparing its opinion, the medicinal products authority consulted may request the notified body, or the manufacturer, to provide within a specific time period additional information necessary for its assessment referred to in point (b). In case of such a request, the time-limit set out in this paragraph shall be suspended until the additional information requested is provided.';

(ii) point (g) is replaced by the following:

'(g) Where the medicinal products authority consulted obtains information on the ancillary substance, which could have an impact on the risk or benefit previously established concerning the incorporation of the substance into the device, it shall advise the notified body as to whether this information has an impact on the risk or benefit previously established concerning the incorporation of the substance into the device. In the case of information relating to serious incidents obtained via the notification outlined in the first subparagraph of Article 89(6) of this Regulation, the medicinal products authority consulted shall review the data, which may be presented in aggregated form and may engage with the notified body to obtain further information where necessary. The notified body shall take that advice into account in reconsidering its assessment of the conformity assessment procedure.';

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(n) Section 5.3.1. is replaced by the following:

‘5.3.1. Substances of human origin or their derivatives

(a) For devices manufactured utilising derivatives of substances of human origin that are covered by this Regulation in accordance with point (g) of Article 1(6) and for devices that incorporate, as an integral part, substances of human origin, or their derivatives, covered by Regulation (EU) 2024/1938, that have an action ancillary to that of the device, the notified body shall, prior to issuing an EU technical documentation assessment certificate, seek a scientific opinion from one of the competent authorities designated by the Member States in accordance with Regulation (EU) 2024/1938 (‘SoHO competent authority’) on the aspects relating to donor registration, donor review, collection and testing of the substances of human origin or their derivatives. The notified body shall submit a summary of the preliminary conformity assessment which provides, among other things, information about the non-viability of the substance of human origin in question, donor registration, donor review, collection and testing and the risk or benefit of the incorporation of the substance of human origin or their derivatives into the device.

(b) Within 120 days of receipt of all the necessary documentation, the SoHO competent authority shall provide to the notified body its opinion. This 120-day period may be extended once for a further 30 days on justified grounds.

(c) The scientific opinion of the SoHO competent authority, and any possible update, shall be included in the documentation of the notified body concerning the device. The notified body shall give due consideration to the views expressed in the scientific opinion of the SoHO competent authority when making its decision. The notified body shall not deliver the certificate if that scientific opinion is unfavourable. It shall convey its final decision to the SoHO competent authority concerned.

PUBLIC

(d) Before any change is made with respect to non-viable substances of human origin or their derivatives incorporated in a device, in particular relating to donor registration, donor review, collection and testing, the manufacturer shall inform the notified body of the intended changes. The notified body shall consult the authority that was involved in the initial consultation, in order to confirm that the quality and safety of the substances of human origin or their derivatives incorporated in the device are maintained. The SoHO competent authority concerned shall take into account the data relating to the usefulness of incorporation of the substances of human origin or their derivatives into the device as determined by the notified body, in order to ensure that the changes have no negative impact on the established benefit-risk ratio of the addition of the substances of human origin or their derivatives in the device. It shall provide its opinion within 60 days of receipt of all the necessary documentation regarding the intended changes. The notified body shall not deliver a supplement to the EU technical documentation assessment certificate if the scientific opinion is unfavourable and shall convey its final decision to the SoHO competent authority concerned.

(e) In the case of information relating to serious incidents obtained via the notification outlined in the second subparagraph of Article 89(6), the SoHO competent authority consulted shall review the data and may engage with the notified body to obtain further information where necessary.';

(8) Annex X is amended as follows:

(a) in Section 3, point (c) is replaced by the following:

'(c) review the clinical evidence presented by the manufacturer in the clinical evaluation report in accordance with Section 4 of Annex XIV. The notified body shall use device reviewers with sufficient clinical expertise and, if necessary, use external clinical experts with direct and current experience relating to the device in question or to the clinical condition in which it is utilised, for the purposes of that review;';

(b) Section 4 is replaced by the following:

'If the type conforms to this Regulation, the notified body shall issue an EU type-examination certificate. The relevant parts of the documentation shall be annexed to the certificate and a copy kept by the notified body.';

(9) Annex XI is amended as follows:

(a) Section 3 is replaced by the following:

'3. By way of derogation from Sections 1 and 2, Section 10 or Section 18 of this Annex coupled with the drawing up of technical documentation as set out in Annexes II and III may also be applied by manufacturers of class IIa devices.';

(b) the following Section 3a is inserted before Part A:

'3a. By way of derogation from Sections 1 and 2 above, Section 10a may also be applied by manufacturers of class I devices that are placed on the market in sterile condition, have a measuring function or are reusable surgical instruments.';

(c) in Section 7, the second paragraph is replaced by the following:

'In the case of class III devices, surveillance shall also include a check that the quantities of produced or purchased raw material or crucial components approved for the type correspond to the quantities of finished devices.';

(d) Section 10 is replaced by the following:

'10. Application to class IIa devices

10.1. The manufacturer shall ensure that the quality management system approved for the manufacture of the devices concerned is implemented.

10.2 By virtue of the EU declaration of conformity the manufacturer shall be deemed to ensure and to declare that the class IIa devices in question are manufactured in conformity with the technical documentation referred to in Annexes II and III and meet the requirements of this Regulation which apply to them.

10.3. The manufacturer shall lodge an application for assessment of its quality management system with a notified body. The application shall include all elements listed in Section 2.1 of Annex IX. The manufacturer shall ensure that an adequate description of all elements listed in Section 2.2, points (a), (b), (d) and (e) of Annex IX is available for the assessment of the quality management system.

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10.4 The first four paragraphs of Section 2.3 of Annex IX shall apply.

10.5. Where the assessment under Section 10.4. of this Annex confirms that the devices in question conform to the technical documentation referred to in Annexes II and III and meet the requirements of this Regulation which apply to them, the notified body shall issue an EU production quality assurance certificate pursuant to Part A of this Annex.

10.6. Section 2.4 of Annex IX shall apply.

10.7. Section 3.1, Section 3.2, first, second and fourth indents, and Sections 3.3 to 3.7 of Annex IX shall apply.

10.8. The manufacturer or its authorised representative shall, for a period ending no sooner than 10 years after the last device has been placed on the market, keep at the disposal of the competent authorities:

- the EU declaration of conformity,
- the technical documentation referred to in Annexes II and III, and
- the certificate referred to in Section 10.5 of this Annex.

10.9. Section 8 of Annex IX shall apply.';

(e) the following Section 10a is inserted before Part B:

'10a. Application to class I devices that are placed on the market in sterile condition, have a measuring function or are reusable surgical instruments

10a.1. The manufacturer shall ensure that the quality management system approved for the manufacture of the devices concerned is implemented.

10a.2. By virtue of the EU declaration of conformity the manufacturer shall be deemed to ensure and to declare that the devices in question are manufactured in conformity with the technical documentation referred to in Annexes II and III and meet the requirements of this Regulation which apply to them.

10a.3. The manufacturer shall lodge an application for assessment of its quality management system with a notified body. The application shall include the elements listed in Section 2.1, first to sixth indents, of Annex IX. The manufacturer shall ensure that an adequate description of all elements listed in Section 2.2, points (d) and (e), of Annex IX is available for the assessment of the quality management system.

10a.4. Section 2.3, first and second paragraphs, of Annex IX shall apply. The assessment of the notified body shall be limited:

- in the case of devices placed on the market in sterile condition, to the aspects relating to establishing, securing and maintaining sterile conditions;
- in the case of devices with a measuring function, to the aspects relating to the conformity of the devices with the metrological requirements;
- in the case of reusable surgical instruments, to the aspects relating to the reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

10a.5. Where the assessment under Section 10a.4. confirms that elements of the quality management system comply with the relevant provisions of this Regulation, the notified body shall issue an EU production quality assurance certificate pursuant to this Part of this Annex.

10a.6. Section 2.4 of Annex IX shall apply.

10a.7. Section 3.1, Section 3.2, first, second and fourth indents, Sections 3.3, 3.4 and 3.6 of Annex IX shall apply.

10a.8. The manufacturer or its authorised representative shall, for a period ending no sooner than 10 years after the last device has been placed on the market, keep at the disposal of the competent authorities:

- the EU declaration of conformity,
- the documentation referred to in the fifth indent of Section 2.1 of Annex IX,
- the certificate referred to in Section 10a.5.

10a.9. Section 8 of Annex IX shall apply.';

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(f) in Section 12, the second paragraph is replaced by the following:

'In addition, for devices placed on the market in a sterile condition, and only for those aspects of the manufacturing process designed to secure and maintain sterility, the manufacturer shall apply the provisions of Sections 6.1, 6.2, 6.3, first paragraph, 6.4 and 7.';

(g) Section 18 is replaced by the following:

'18. Application to class IIa devices

18.1. Product verification shall be understood to be the procedure whereby after examination of every manufactured device, the manufacturer, by issuing an EU declaration of conformity in accordance with Article 19 and Annex IV, shall be deemed to ensure and to declare that the devices which have been subject to the procedure set out in Sections 14 and 15 conform to the technical documentation referred to in Annexes II and III and meet the requirements of this Regulation which apply to them.

18.2. The manufacturer shall take all the measures necessary to ensure that the manufacturing process produces devices which conform to the devices described in the EU declaration of conformity and to the requirements of the Regulation which apply to them. Prior to the start of manufacture, the manufacturer shall prepare documents defining the manufacturing process, in particular as regards sterilisation where necessary, together with all routine, pre-established procedures to be implemented to ensure homogeneous production.

In addition, for devices placed on the market in a sterile condition, and only for those aspects of the manufacturing process designed to secure and maintain sterility, the manufacturer shall apply the provisions of Sections 10.3, 10.4, 10.6 and 10.7.

18.3. Sections 13 and 14 shall apply. Section 15 shall apply with the aim of verifying the conformity of the devices with those described in the EU declaration of conformity.

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18.4. By way of derogation from Section 17, the manufacturer or its authorised representative shall, for a period ending no sooner than 10 years after the last device has been placed on the market, keep at the disposal of the competent authorities:

- the EU declaration of conformity,
- the documentation referred to in Section 18.2,
- the technical documentation referred to in Annexes II and III,
- the certificate referred to in Section 15.2.

18.5. Section 8 of Annex IX shall apply.';

(10) Annex XII is amended as follows:

(a) in Chapter I, Section 4, point (b) is replaced by the following:

'(b) EU quality management system certificates and EU quality assurance certificates shall include the identification of the devices or groups of devices, the risk classification, for class IIb devices, the intended purpose and the manufacturing site(s) covered.';

(b) Chapter II is amended as follows:

(i) Section 6 is replaced by the following:

'6. where applicable, date of expiry;'

(ii) Section 7 is replaced by the following:

'7. data needed for the unambiguous identification of the device or devices where applicable as specified in Section 4 of Chapter I;;'

(iii) Section 10 is replaced by the following:

'10. reference to relevant CS and harmonised standards;;'

(11) Annex XIII is amended as follows:

(a) in Section 1, the eighth indent is replaced by the following:

'where applicable, an indication that the device contains or incorporates a medicinal substance, including a human blood or plasma derivative, or tissues or cells of human origin, or of animal origin as referred to in Regulation (EU) No 722/2012, or in any subsequent implementing rules adopted pursuant to this Regulation.';

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(b) in Section 5, the first sentence is replaced by the following:

'The manufacturer shall review and document experience gained in the post-production phase, including where applicable from PMCF as referred to in Part B of Annex XIV, and implement appropriate means to apply any necessary corrective action.';

(12) Annex XIV is amended as follows:

(a) Section 1 is amended as follows:

(i) point (a) is amended as follows:

(1) the first indent is replaced by the following:

'- an identification of the general safety and performance requirements that require support from relevant clinical data, or adequate justification that confirmation of safety and performance based on clinical data is not deemed appropriate in accordance with Article 61(10);';

(2) the seventh and eighth indents are replaced by the following:

'- an indication how benefit-risk issues relating to specific components such as use of pharmaceutical, non-viable substances of human origin or non-viable animal tissues, are to be addressed;

- where applicable, a clinical development strategy indicating progression from exploratory investigations, such as first-in-man studies, feasibility and pilot studies, to confirmatory investigations, such as pivotal clinical investigations, and a PMCF as referred to in Part B with an indication of milestones and a description of potential acceptance criteria. Where a clinical development strategy is deemed not applicable, the manufacturer shall provide a justification in the clinical evaluation plan;';

(2a) Points (b) to (e) are amended as follows:

'(b) identify available clinical data relevant to the device and its intended purpose;

(c) appraise all relevant clinical data by evaluating their suitability for establishing the safety and performance of the device;

PUBLIC

(d) analyse all relevant clinical data in order to reach conclusions about the safety and clinical performance of the device including its clinical benefits and identify any gaps in clinical evidence; and

(e) generate, through properly designed clinical investigations in accordance with the clinical development plan, any new or additional clinical data necessary to address outstanding issues.';

(ii) the following paragraph is added:

'Points (b) to (e) shall not apply to devices for which confirmation of safety and performance based on clinical data is not deemed appropriate in accordance with Article 61(10).';

(b) in Section 3, the second and third indents are replaced by the following:

'- Biological: the device uses the same **or similar** materials or substances in contact with the same human tissues or body fluids for a similar kind and duration of contact and similar release characteristics of substances, including degradation products and leachables;

– Clinical: the device is used for the same clinical condition or purpose, including similar severity and stage of disease, at the same site in the body, in a similar population, including as regards age, anatomy and physiology; has the same kind of user; has similar relevant critical performance in view of the expected clinical effect for a specific intended purpose.';

(c) in Section 5, the following sentence is inserted after the first sentence:

'Where PMCF is deemed not applicable, the manufacturer shall provide a justification in the post-market surveillance plan as referred to in Section 1 of Annex III.';

(d) Section 7 is replaced by the following:

'7. The manufacturer shall analyse the findings of the PMCF and document the results in the clinical evaluation report and the technical documentation.';

(e) Section 8 is replaced by the following:

'8. The conclusions of the PMCF shall be taken into account for the clinical evaluation referred to in Article 61 and Part A of this Annex and in the risk management referred to in Section 3 of Annex I. If, through the PMCF, the need for preventive and/or corrective measures has been identified, the manufacturer shall implement them.';

PUBLIC

(13) Annex XV is amended as follows:

[(a) in Chapter I, Section 2.6., the following sentence is added:

'For combined studies, endpoints reporting on the device and medicinal product together may be used.';]

(b) Chapter II is amended as follows:

(i) Section 1.4. is replaced by the following:

'1.4. status of the clinical investigation application (i.e. first submission, resubmission, substantial modification);';

(ii) Section 1.6. is replaced by the following:

'1.6. If the application is a resubmission with regard to a device for which an application has been already submitted, the date or dates and reference number or numbers of the earlier application or, in the case of substantial modification, reference to the original application. The sponsor shall identify all of the changes from the previous application together with a rationale for those changes, in particular, whether any changes have been made to address conclusions of previous competent authority or ethics committee reviews.';

PUBLIC

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.’;

(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;’;

PUBLIC

(d) the following points (75), (76), (77) and (78) are added:

[‘(75)‘combined study’ means a clinical trial as defined in Article 2(2), point (2), of Regulation (EU) No 536/2014, concerning one or more medicinal products, combined with a performance study of one or more in vitro diagnostic medical devices as defined in Article 2, point (42) of this Regulation, or with a clinical investigation of one or more devices as defined in Article 2, point (45), of Regulation (EU) 2017/745;’;**]**

‘(76) ‘regulatory sandbox’ means a controlled environment set up by a competent authority which offers manufacturers the possibility, before placing the product on the market or putting into service, to develop, test, validate and use, where appropriate in real-world conditions, an innovative product or technology potentially falling within the scope of this Regulation, pursuant to a sandbox plan for a limited time under regulatory supervision;

(77) ‘sandbox plan’ means a document **agreed between the**~~, proposed by (a)~~ participating manufacturer(s) and ~~approved by~~ the competent authority, describing the objectives, responsibilities, conditions, timeframe, methodology and requirements for the activities carried out within the regulatory sandbox;

(78) ‘Union regulatory sandbox’ means a controlled environment set up by the Commission for testing alternative or new regulatory requirements or enforcement practices and appraising their validity in comparison with existing requirements and practices under this Regulation for a limited time.’;

(…)

(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’;

PUBLIC

(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~~**taking** 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 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 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 **or device for performance study** 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 **the device** 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, t~~**T**he 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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(24) Article 31 is replaced by the following:

'Article 31

Application of Chapter IV of Regulation (EU) 2017/745

Article 35 and Articles 37 to 50 of Regulation (EU) 2017/745 shall apply, mutatis mutandis, to the following:

(a) the authorities responsible for notified bodies to be appointed by Member States for the purpose of this Regulation and their exchange of experience;

(b) the conformity assessment bodies applying for designation under this Regulation and the assessment of their applications;

(c) the nomination of experts for joint assessment and the funding of activities related to the designation and monitoring of notified bodies;

(d) the designation and notification procedure regarding notified bodies under this Regulation, their subsidiaries and subcontracting, and their identification number;

(e) the language requirements;

(f) the monitoring of notified bodies;

(g) changes to the designation and notification of notified bodies and challenges to their competence;

(h) the coordination of notified bodies;

(i) the access to notified bodies and fees.';

(25) Article 32 is amended as follows:

(a) paragraph 1 is replaced by the following:

'1. Notified bodies shall fulfil the tasks for which they are designated in accordance with this Regulation in the public interest. They shall satisfy the organisational and general requirements and the quality management, resource and process requirements, as set out in Annex VII, that are necessary to fulfil those tasks in a competent, effective, independent, impartial, diligent and expeditious manner.

PUBLIC

Notified bodies designated for conformity assessment activities relating to devices that are high-risk AI systems as referred to in Article 6(1) of Regulation (EU) 2024/1689, or that use high-risk AI systems as safety components, shall also meet the requirements set out in Article 31(4), (5), (10) and (11) of that Regulation.';

(b) the following paragraph 4 is added:

'4. The Commission is empowered to adopt delegated acts in accordance with Article 108 to amend Annex VII in order to adapt to technical and scientific progress regarding conformity assessment in the field of in vitro diagnostic medical devices, including developments at international level.';

(26) Articles 33 to 46 are deleted;

(…)

(51) ~~in~~ Article 78(4)~~, the first sentence~~ is replaced by the following:

'If, in the course of the post-market surveillance, a need for preventive or corrective action, or both, is identified, the manufacturer shall implement the appropriate measures. **Where preventive or corrective action is taken to reduce a risk that may compromise the safety of the device, the manufacturer shall inform the competent authorities concerned.**~~These preventive or corrective actions shall be appropriately documented and, where relevant, included in the reports referred to in Articles 80, 81, 82 and 83. A Member State may request that a manufacturer informs the competent authorities and, where appropriate, the notified body of such preventive or corrective action, including those not already included in the reports referred to in Articles 80, 81, 82 and 83, to reduce a risk that may compromise the safety or performance of the device.~~ *Where ~~a serious incident is identified or a field safety corrective action is implemented~~* ***such corrective actions are associated with an identified serious incident or an implemented field safety corrective action****, it shall be reported in accordance with Article 82*.';

(52) in Article 79, the following sentence is added after the second sentence:

'The post-market surveillance plan shall specify the criteria, and timelines where relevant, for updating the Post-Market Surveillance Report as referred to in Article 80 or the Periodic Safety Update Report as referred to in Article 81.';

(53) Article 81 is amended as follows:

(a) paragraph 1 is amended as follows:

(i) in the first subparagraph, the first sentence is replaced by the following: ‘Manufacturers of class C and class D devices shall prepare a periodic safety update report (‘PSUR’) for each device, or where relevant, for each category or group of devices, summarising the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan referred to in Article 79, together with a description of any preventive and corrective actions taken, including their rationale.’;

(ii) the second subparagraph is replaced by the following: ‘Manufacturers of class C and class D devices shall update the PSUR in the first year after the certificate is issued and every two years thereafter or when there is a significant change in the benefit-risk determination or in the acceptability of erroneous results. The PSUR shall be part of the technical documentation specified in Annex III.’;

(b) paragraph 2 is replaced by the following:

‘2. For class D devices, the notified body shall review the PSUR ~~during the~~**as part of its** surveillance ~~assessment~~**activities**, where applicable, or as part of the technical documentation review. The manufacturer ~~and notified body~~ shall make such PSURs available ~~to competent authorities~~ through the electronic system referred to in Article 87. The notified body shall make its evaluation of such PSURs available ~~to the competent authorities~~ through the electronic system referred to in Article 87.

For all other devices where the PSUR is applicable, the notified body shall **have documented procedures for reviewing** ~~review~~ PSURs on a representative basis as part of the surveillance activities in accordance with Section 4.10 of Annex VII ~~or periodic reviews in accordance with Section 4.11 of Annex VII~~.’;

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(54) Article 82 is amended as follows:

(-a) In paragraph 1, first subparagraph, point (a) is replaced by the following:

‘(a) any serious incident involving devices made available on the Union market, except expected erroneous results which are clearly documented in the device information and quantified in the technical documentation and are subject to trend reporting pursuant to Article 83;’;

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

‘The reports referred to in the first subparagraph shall be submitted in accordance with the timelines specified in this Article through the electronic system referred to in Article 87.’;

(b) paragraph 3 is replaced by the following:

‘3. Manufacturers shall report any serious incident as referred to in paragraph 1, first subparagraph, point (a), immediately after they have established that there is a causal relationship between that incident and their device or that such causal relationship is reasonably possible, and not later than 30 days after they become aware of the incident.’;

(55) The following Article 82a is inserted:

‘Article 82a

Reporting of actively exploited vulnerabilities and severe incidents related to devices

1. Without prejudice to the reporting obligations regarding serious incidents and field safety corrective actions set out in Article 82, the manufacturer of a device shall report to the computer security incident response teams (‘CSIRTs’), designated as coordinators of the Member States where a device has been made available, and to the European Union Agency for Cybersecurity (ENISA), either of the following:

(a) any actively exploited vulnerability as defined in Article 3, point (42), of Regulation (EU) 2024/2847 of the European Parliament and of the Council******** contained in the device;

(b) any severe incident as referred in Article 14(5) of Regulation (EU) 2024/2847 having an impact on the security of the device.

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2. The manufacturer shall submit the report referred to in paragraph 1 through the electronic system referred to in Article 87 immediately after and not later than 30 days after it becomes aware of the actively exploited vulnerability or the severe incident.

3. The report referred to in paragraph 1, as well as any report submitted by a manufacturer in accordance with Article 82 that also qualifies as actively exploited vulnerability or severe incident, shall be made available simultaneously to the CSIRTs designated as coordinators of the Member States in which the device has been made available and to ENISA.

4. For the purposes of this Article, the CSIRTs designated as coordinators and ENISA shall have access to Eudamed.

5. In respect of the report referred to in paragraph 1, the competent authorities shall cooperate with the CSIRTs designated as coordinators of the Member States in which the device has been made available, and with ENISA.';

******** Regulation (EU) 2024/2847 of the European Parliament and of the Council of 23 October 2024 on horizontal cybersecurity requirements for products with digital elements and amending Regulations (EU) No 168/2013 and (EU) 2019/1020 and Directive (EU) 2020/1828 (Cyber Resilience Act) (OJ L, 2024/2847, 20.11.2024, ELI: http://data.europa.eu/eli/reg/2024/2847/oj).';

(56) in Article 83(1), the first subparagraph is replaced by the following:
'Manufacturers shall report by means of the electronic system referred to in Article 87 any statistically significant increase in the frequency or severity of incidents that are not serious incidents, which could have a significant impact on the benefit-risk analysis referred to in Sections 1 and 8 of Annex I or of any significant increase in expected erroneous results established in comparison with the stated performance of the device as referred to in Section 9.1, points (a) and (b), of Annex I and specified in the technical documentation and product information.';

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(57) Article 84 is amended as follows:

(-a) in paragraph 1, the first subparagraph is replaced by the following:
‘Following reporting pursuant to Article 82(1), the manufacturer shall, without delay, perform the necessary investigations in relation to the serious incident and the devices concerned. This shall include risk assessment of the incident or field safety corrective action taking into account the criteria as referred to in paragraph 3 of this Article as appropriate.’;

(a) in paragraph 1, the second subparagraph is replaced by the following:
‘The manufacturer shall cooperate with the competent authorities during the investigations referred to in the first subparagraph and shall not perform any investigation which involves altering the device or a sample of the batch concerned in a way which may affect any subsequent evaluation of the causes of the incident **or the field safety corrective action**, prior to informing the competent authorities of such action.’;

(b) paragraph 2 is replaced by the following:
‘2. Member States shall take the necessary steps to ensure that any information regarding a serious incident that has occurred within their territory, or a field safety corrective action that has been or is to be undertaken within their territory, and that is brought to their knowledge in accordance with Article 82 is evaluated centrally at national level by their competent authority, if possible together with the manufacturer.’;

(c) the following paragraph 3a is inserted:
‘3a. The competent authorities may exchange information in relation to their assessments in paragraph 3 and, where relevant, engage with the authorities responsible for notified bodies and the authorities responsible for market surveillance.

The competent authority may request the notified body that issued a certificate in accordance with Article 51 for the device in question for assistance in evaluating a corrective action related to a serious incident or a field safety corrective action, taking into account the risk management and conformity assessment performed for the device.’;

(d) paragraphs 6 and 7 are replaced by the following:

‘6. In the case of a companion diagnostic and where the manufacturer confirms that the serious incident or field safety corrective action may affect the safe and efficient use of the corresponding medicinal product, the evaluating competent authority or the coordinating competent authority referred to in paragraph 9 shall inform the national competent authority or the EMA, which was consulted by the notified body in accordance with the procedures set out in Section 5.2 of Annex IX and Section 3, point (k), of Annex X.

7. If, after carrying out the evaluation in accordance with paragraph 3, the evaluating competent authority identifies the need for additional corrective actions from the manufacturer to minimise the risk of recurrence of the serious incident, it shall, through the electronic system referred to in Article 87, inform without delay the other competent authorities of the corrective action taken or envisaged by the manufacturer or required of it to minimise the risk of recurrence of the serious incident, including information on the underlying serious incidents and the outcome of its assessment.’;

(e) in paragraph 9, the introductory sentence is replaced by the following:
‘The competent authorities shall actively participate in a procedure in order to coordinate their assessments referred to in paragraph 3 whenever such coordination is needed to ensure a high level of protection of the health and safety of patients, users and other persons or the protection of public health throughout the Union, and in particular in the following cases:’;

(58) Article 86 is amended as follows:

(a) in the first subparagraph, the reference to ‘Articles 80 to 85 and 87’ is replaced by ‘Articles 79 to 85 and 87’;

PUBLIC

(b) in the first subparagraph, point (b) is replaced by the following:

'(b) the reporting of serious incidents and field safety corrective actions and field safety notices, and the provision and content of the post-market surveillance plan, periodic summary reports, post-market surveillance reports, PSURs and trend reports by manufacturers as referred to in Articles 79, 80, 81, 82, 83 and 84 respectively;';

(59) in Article 87(2), second sentence, the reference to 'Article 49' is replaced by 'Article 51';

(…)

(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~~**avoiding** duplication of ~~core~~ Union data**, where possible** ~~is avoided~~.;'

(…)

(3) Annex III is amended as follows:

(a) in Section 1, point (a), the sixth indent is replaced by the following:

'- publicly-available information about similar devices.';

(b) Section 2 is replaced by the following:

'2. The PSUR referred to in Article 81 or the post-market surveillance report referred to in Article 80.';

(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),

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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,
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),

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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.';

(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 **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. 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.';

(5) Annex VII is amended as follows:

(a) in Section 1.1.1., the following sentence is added:

'It shall also include information about the larger organisation to which the notified body belongs.';

(b) Section 1.1.2. is replaced by the following:

‘1.1.2. If the notified body is a legal entity that is part of a larger organisation, the activities of that organisation as well as its organisational structure and governance, and the relationship with the notified body shall be clearly documented. In such cases, the requirements set out in Section 1.2 are applicable to both the notified body and the larger organisation to which it belongs. The larger organisation and any of the legal entities belonging to it shall not be involved in the design, manufacture, marketing, installation or maintenance of the devices for which the notified body is designated or offer consultancy services for such activities. They shall not represent the parties engaged in those activities.’;

(c) Section 1.1.5. is replaced by the following:

‘1.1.5. The notified body shall clearly document its organisational structure and the functions, responsibilities and authority of its top-level management and of other personnel who may have an influence upon the performance by the notified body and upon the results of its conformity assessment activities.’;

(d) in Section 1.2.9., the following sentences are added:

‘The notified body shall have documented procedures in place to offer and carry out dialogues with the manufacturer before and after an application for conformity assessment is lodged. These procedures should clearly prohibit services that fall within the scope of consultancy services.’;

(e) Section 1.3.1. is replaced by the following:

‘1.3.1. The notified body shall have documented procedures in place ensuring that its personnel, committees, branch offices, subsidiaries, subcontractors, and any associated body or personnel of external bodies respect the confidentiality of the information which comes into its possession during the performance of the conformity assessment activities, except when disclosure is required by law.’;

(g) the following Section 1.4.3. is added:

‘1.4.3. By way of derogation from Sections 1.4.1. and 1.4.2, the notified body may demonstrate coverage for liability through adherence to a guarantee fund that provides effective protection and is recognised by the Member State(s) concerned.’;

PUBLIC

(h) Section 1.6.1. is replaced by the following:

‘1.6.1. The notified body shall participate in the activities of the notified body coordination group referred to in Article 49 of Regulation (EU) 2017/745 and ensure that its assessment and decision-making personnel are ~~sufficiently~~ **adequately** informed of all relevant legislation, standards, guidance and best practice documents adopted in the framework of this Regulation.’;

(i) Section 2.1. is replaced by the following:

‘2.1. The notified body shall establish, document, implement, maintain and operate a quality management system that is appropriate to the nature, area and scale of its conformity assessment activities, taking into account the state of the art, and is capable of supporting and demonstrating in an effective manner the consistent fulfilment of the requirements of this Regulation.’;

(j) Section 2.3. is replaced by the following:

‘2.3. The top-level management of the notified body shall ensure that the quality management system is fully understood, implemented and maintained throughout the notified body organisation including branch offices, subsidiaries and subcontractors involved in conformity assessment activities pursuant to this Regulation.’;

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