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WORKING DOCUMENT

From:	Presidency
To:	Delegations
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 *- Examination of the proposal - cluster 3*

Delegations will find in Annex the text of cluster 3 – notified bodies and classification and conformity assessment – to be discussed at the meeting of the Working Party on Pharmaceuticals and Medical Devices on 7 May 2026.

Comments and drafting suggestions, if any, should be submitted to LIFE.Health@consilium.europa.eu using the appropriate template by 19 May 2026.

ANNEX

Notified bodies

Amendments to Regulation (EU) 2017/745

PUBLIC

Chapter IV

(27) Article 35 is amended as follows:

(a) the following paragraph 6a is inserted:

'6a. Without prejudice to other administrative or judicial remedies, a manufacturer or notified body may raise with the authority responsible for notified bodies, in a duly substantiated manner, any unresolved dispute arising from the application of the requirements set out in Annex VII and the involvement of a notified body in the conformity assessment in accordance with Article 52 and Annexes IX, X and XI. The authority shall hear and decide within 90 days. 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.';

(b) paragraph 8 is replaced by the following:

‘8. The authorities responsible for notified bodies shall coordinate 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 an effective, independent, 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;

PUBLIC

(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). 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 and the types of devices which are 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 coordinated by the expert representing the Commission.

4. Within 90 days of the appointment of the experts in accordance with paragraph 3, 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 from the applicant conformity assessment body. The joint assessment team shall submit the preliminary assessment report to the applicant conformity assessment body.

PUBLIC

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.

6. Unless the application is rejected, the joint assessment team 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.

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 by the joint assessment team.

7. Within 30 days after the finalisation of the on-site assessment, 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 submit to the joint assessment team a proposed corrective and preventive action plan to address the non-compliances effectively and in a timely manner.

PUBLIC

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

9. Within 30 days of 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 necessary, provide any comments on it to the applicant conformity assessment body, including requests for further clarification and modifications.

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 30 days of receipt of the final corrective and preventive action plan, or of the moment the joint assessment team concludes that no agreement on a final plan has been reached, 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, where applicable, the recommended scope of designation.

11. 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 for a further 21 days on justified grounds.

PUBLIC

13. Where the authority responsible for notified bodies does not agree with the recommendation of the MDCG, 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.

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, any member of the joint assessment team 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.

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).';

PUBLIC

(31) Article 40 is amended as follows:

(a) the title is replaced by the following:

'***Nomination of experts for joint assessment'***;

(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.

The nominated experts shall commit to participate in joint assessments.';

(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 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.

2. The structure and level of the fees and the scale and type of recoverable costs shall be established by the Commission by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).';

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

'The applicant 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 only designate conformity assessment bodies in accordance with the 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).’;

(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 and the joint assessment team 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 and/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 MDCG and to the Commission. The authority shall address any request for clarification or modification made by 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 two years, the annual assessment of a notified body 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 of the specific circumstances of the monitoring, the Commission may appoint a different number of experts. The joint assessment team shall be coordinated by the expert representing the Commission.

If, at any stage of the process, consensus cannot be reached within the joint assessment team on any issue, any member of the joint assessment team 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.

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 inform the notified body about any non-compliances resulting from the assessment and summarise their assessment.

Where non-compliances have been identified, the notified body shall submit a proposed corrective and preventive action plan to address the non-compliances. 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 necessary, 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.

PUBLIC

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 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 or the joint assessment team, as applicable, shall submit their final monitoring report to the MDCG 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. 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 shall include observed audits of notified body personnel, including where necessary any personnel from subsidiaries and subcontractors, as that personnel is 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.';

PUBLIC

(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 of devices certified by the notified body, in particular high-risk devices. ’;

(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.

The procedures set out in Articles 39 and 42 shall apply to significant extensions of the scope of the designation. 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 significant extensions of its scope, the procedures laid down in paragraphs 2 to 9 shall apply.

PUBLIC

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.';

(38) Article 47 is amended as follows:

(a) paragraph 1 is replaced by the following:

'1. The Commission, in conjunction 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 39(2) to (10), 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.';

PUBLIC

(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 report to the MDCG.

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

2. Notified bodies shall ensure that their specialised personnel 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 common templates and technical guidance 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.

PUBLIC

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.

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.

3. The Commission, in consultation with the MDCG, may adopt implementing acts to specify the structure and level of the fees referred to in paragraph 1, taking into account the need to:
   (a) establish and maintain high standards of quality and safety of devices;
   (b) ensure the availability of devices;
   (c) protect the interests of micro, small or medium-sized enterprises within the meaning of Recommendation 2003/361/EC;
   (d) support innovation and competitiveness.

PUBLIC

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 15 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, the authority responsible for notified bodies may instruct a notified body to accept a manufacturer's request for conformity assessment activities falling within that notified body's scope of designation.';

(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 sentence is 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.';

PUBLIC

(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.’;

(e) in Section 1.4.2., the second sentence is deleted;

(f) the following Section 1.4.3. is inserted:

’1.4.3. By way of derogation from Section 1.4.1, 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 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 and is capable of supporting and demonstrating in the most 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.’;

PUBLIC

(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 an effective, independent, 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;

(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 on the performance by the notified body and on the results of its conformity assessment activities.';

PUBLIC

(d) in Section 1.2.9., the following sentence is 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.';

(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.';

(f) in Section 1.4.2., the second sentence is deleted;

(g) the following Section 1.4.3. is added:

'1.4.3. By way of derogation from Section 1.4.1., 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.';

(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 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 and is capable of supporting and demonstrating in the most effective manner the consistent fulfilment of the requirements of this Regulation.';

PUBLIC

(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.';

PUBLIC

Classification and conformity assessment

Amendments to Regulation (EU) 2017/745

Classification of devices

(6) Annex VIII is amended as follows:

(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 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 channeling or storing blood or other body liquids or for storing organs, parts of organs or body cells and tissues, except for blood bags; by derogation from any other classification rule, blood bags are classified as class IIb.';

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

– 'are reusable surgical instruments regardless of the body part 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 body part 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 such as screws, wedges, plates and instruments and other devices 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 such as screws, wedges, plates and instruments and other devices 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.’;

PUBLIC

(g) Section 6.3 is replaced by the following:

‘6.3 Rule 11

Software which is intended to generate an output that confers a clinical benefit and is used for diagnosis, treatment, prevention, monitoring, prediction, prognosis, compensation or alleviation of a disease or condition is classified as class I, unless the output is intended for a disease or condition:

– in a critical situation with a risk of causing death or an irreversible deterioration of a person's state of health, in which case it is classified as class III;

– in a serious situation with a risk of causing a serious deterioration of a person's state of health or a surgical intervention, or to drive clinical management in a critical situation in which cases it is classified as class IIb;

– in a non-serious situation, or to drive clinical management in a serious situation or to inform clinical management in a critical or serious situation in which cases it is classified as class IIa.’;

(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 on or in the human body are classified as:’;

PUBLIC

(2) Article 2 is amended as follows:

(e) the following points (…) (74), (75) and (76) are added:[1]

(74) 'regulatory sandbox' means a controlled environment set up by a competent authority which offers manufacturers or prospective manufacturers the possibility 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 participating manufacturer(s) or prospective manufacturer(s) and the competent authority describing the objectives, 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.';

Chapter V, Section2

(…)

(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 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 of one representative device per generic device group.';

[1] Article 2 points (72) and (73) are respectively examined under cluster 1 and 4.

(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 of one representative device per generic device group or, in the case of non-implantable class IIb devices that are well-established technology devices, one representative device per each category of devices.

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 of 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 one representative device for each 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.';

(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.';

(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 the representative device 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 and to take into account the needs of particular devices in view of their special characteristics.';

PUBLIC

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

'Article 52a

Conformity assessment of breakthrough devices and of orphan devices

1. For the conformity assessment of breakthrough devices and orphan devices, for which a notified body is involved in the conformity assessment, the procedures laid down in Article 52 shall apply subject to the specific arrangements set out in this Article.

2. A device shall be considered a breakthrough device if it meets 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;
   (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.

PUBLIC

3. A device shall be considered an orphan device if it meets 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;
   (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.

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 as to whether the criteria set out in paragraph 2 or 3 of this Article, as applicable, are fulfilled. That opinion 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.

5. Where the opinion of the expert panel confirms the fulfilment of the criteria set out in paragraph 2 or 3 of this Article, the manufacturer of a breakthrough device or of an orphan 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 confirmed breakthrough device or an orphan device, as applicable, the notified body involved in the conformity assessment procedure set out in Article 52 shall prioritise the conformity assessment of that device and apply, where appropriate, a rolling review with a view to reduce assessment timelines.

   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.

PUBLIC

7. The notified body shall issue a certificate pursuant to Article 56 where the pre-market clinical evidence, even if based on limited clinical data, is deemed adequate, provided that either of the following conditions 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.

   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 or orphan 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 or orphan devices set out in this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

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, the manufacturer shall agree with the notified body on the digital format.

PUBLIC

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.';

(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 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.

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.

PUBLIC

Article 55

Mechanism for scrutiny of conformity assessments

1. The MDCG or the Commission may, based on reasonable concerns, request advice from an expert panel in relation to the safety and performance of any device. For that purpose, the MDCG 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.

2. The MDCG or the Commission may, based on reasonable concerns, request advice from one or more expert laboratories, based on laboratory testing, in relation to the safety and performance of any device, provided that the device falls within the scope of designation of those expert laboratories. For that purpose, the MDCG 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 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.

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 immediately upload them in Eudamed. The minimum content of the certificates shall be as set out in Annex XII.

2. The validity of certificates shall not be limited in time, unless in exceptional cases where the notified body considers it necessary to limit the period of validity 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, the notified body shall carry out appropriate surveillance activities, including periodic reviews taking into consideration developments of the state of the art. 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, such as limiting the intended purpose of a device to certain groups of patients or requiring the manufacturer to undertake specific PMCF studies pursuant to Part B of Annex XIV.';

(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.';

PUBLIC

(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) and (3a);’;

(ii) point (i) is deleted;

(49) Article 59 is amended as follows:

(a) paragraph 1 is replaced by the following:

‘1. By way of derogation from Article 52 and on a duly justified request, any competent authority may authorise 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 paragraph 1a is inserted:

‘1a. By way of derogation from Article 6(2) and on a duly justified request, any competent authority may authorise for a limited period of time the provision of a diagnostic or therapeutic service referred to in that Article to a natural or legal person established within the territory of the Member State concerned using a 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.’;

(c) paragraph 2 is replaced by the following:

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

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 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 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).’;

(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, 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 by the manufacturer, a competent authority may authorise 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, design or intended purpose of a 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.

+ 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.

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.

4. Where applicable, the manufacturer shall keep the notified body that issued a certificate for the device in question, informed about 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 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).

Article 59b

Regulatory sandboxes at national level

1. Member States, on their own initiative or upon a substantiated request by a manufacturer or a prospective manufacturer, may establish one or more regulatory sandboxes to which the application of certain requirements of Chapters V or VI or of Annexes I, VIII IX, X, XI, XIV or XV would not be appropriate. 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.

PUBLIC

2. The activities within a regulatory sandbox shall take place pursuant to a specific sandbox plan that shall clearly identify the requirements of this Regulation referred to in paragraph 1, which, by way of derogation from this Regulation, are temporarily adapted or waived in the regulatory sandbox, a justification that the application of those requirements is considered not appropriate and an explanation as to how potential risks related to the adaptation or waiver are controlled and mitigated. The plan shall also identify the reasonable duration of the regulatory sandbox necessary to achieve its objectives and the participants in the regulatory sandbox and their respective roles.

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 or the state of the art;
   (b) the application of the requirements of this Regulation referred to in paragraph 1 would impede or significantly delay the development of the device and access by healthcare professionals or lay users to such 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, without undue delay, inform the competent authority that is responsible for the supervision of the regulatory sandbox about any harm occurred in relation to the implementation of the regulatory sandbox. The competent authority shall take immediate and adequate corrective measures, including to suspend, revoke or restrict the scope of the regulatory sandbox.

6. Manufacturers and prospective 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.

PUBLIC

Article 59c

Union regulatory sandboxes

1. The Commission, on its own initiative 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 impede or significantly delay the development of such devices and access by healthcare professionals or lay users to those devices; or
   (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 the placing on the market or putting into service of devices which do not comply with this Regulation.

2. The Commission shall 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.

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

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

PUBLIC

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 competent authority of 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 competent authority shall make the certificates of free sale issued in accordance with paragraphs 1 and 1a publicly available in Eudamed.';

(5) Annex VII is amended as follows:

(…)

(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.'

(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.';

PUBLIC

(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 class IIa or class IIb devices, 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.';

PUBLIC

(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 class IIa and class IIb devices, the representative devices selected for the assessment of technical documentation as referred to in Annexes II and III,';

(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.';

(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,';

(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:';

PUBLIC

(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,';

(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,';

(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:';

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(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.';

(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 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 of relevant data gathered by the manufacturer’s post-market surveillance system. 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.

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. 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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(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 and class IIb 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 for a representative device. However, in case of class IIa devices, Section 3(a) of Annex II shall be excluded from the assessment. In choosing the representative device, 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 and class IIb devices, the notified body may include a ‘for-cause’ 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 conforms 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 a reasoned report.’;

(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 devices, and of the provisions on vigilance set out in Articles 87 to 92,’;

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(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. Those audits and assessments shall include audits on the premises of the manufacturer and, if appropriate, of the manufacturer's suppliers and/or subcontractors. On justified grounds, the audit may be conducted remotely instead of on-site. 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 shall 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 and/or subcontractors when justified based on concerns related to post-market surveillance or vigilance data or at the request of a competent authority. 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.’;

(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).’;

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(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 and class IIb devices, and of class III devices that are well-established technology devices, during the surveillance assessment the notified body may include a 'for-cause' assessment of the technical documentation of representative devices where the notified body has identified potential concerns on the basis of post-market surveillance data or other duly justified grounds.

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.';

(i) in Section 4.4, the second sentence is replaced by the following:
'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 the clinical condition in which it is utilised, for the purposes of that review.';

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(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 sentences are deleted;

(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.';

(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.';

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(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, advise 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 and/or to impose a limit on the duration of validity of the certificate, to undertake specific PMCF studies, 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 90 days of receipt of all the necessary documentation. This 90-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 90 days of receipt of all the necessary documentation, the SoHO competent authority shall provide to the notified body its opinion. This 90-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.';

(o) Section 5.3.2. is deleted;

(p) in Section 5.4, points (b), (c) and (d) are deleted;

(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, other than well-established technology 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.

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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.

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.';

PUBLIC

(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.

PUBLIC

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 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.';

Amendments to Regulation (EU) 2017/746

(…)

(2) Article 2 is amended as follows:

(…)

(d) the following points (…) (76), (77) and (78) are added:[2]

'(75) 'combined study' means a clinical trial as defined in Article 2(2), point (2), of Regulation (EU) No 536/2014, combined with a performance study, and/or a clinical investigation 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 or prospective manufacturers the possibility 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 participating manufacturer(s) or prospective manufacturer(s) and the competent authority describing the objectives, conditions, timeframe, methodology and requirements for the activities carried out within the regulatory sandbox;

(78) 'Union regulatory sandbox' means a controlled envrironment 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.';

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[2] Article 2 point (75) is examined under cluster 4.