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

Delegations will find in Annex the first Presidency compromise text on Clusters 3 and 4 - Block 3 (Notified Bodies and Conformity Assessment - elements relating to sampling / certificate validity) to be discussed at the meetings of Working Party on Pharmaceuticals and Medical Devices on 15-16 July 2026.

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

ANNEX

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Amendments to Regulation (EU) 2017/745

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

(…)

(43) Article 52 is amended as follows:

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

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

(b) paragraph 4 is replaced by the following:

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

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

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

(c) paragraph 5 is deleted;

(d) paragraph 6 is replaced by the following:

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

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

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(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 **and the authority responsible for notified bodies**.';

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

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

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

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

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

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

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(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~~**, in** particular ~~devices in view of their special characteristics.;~~**with regard to:**

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

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

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

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

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

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

(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 a timely manner** in Eudamed. The minimum content of the certificates shall be as set out in Annex XII.

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

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

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

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

(b) the following paragraph 2a is inserted:

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

(c) paragraph 3 is replaced by the following:

‘3. Notified bodies may impose conditions on the validity of the certificate, ~~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~~**in accordance with Section 4.8** of Annex ~~XIV~~**VII**.’;

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

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

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

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

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(5) Annex VII is amended as follows:

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

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

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

(ii) the eleventh indent is deleted;

(iii) the following indents are added:

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

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

— leverage evidence from previous assessments performed.’

(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~~ **the** devices **referred to in Section 4.5.1, ninth indent**, the representative devices selected for the

assessment of technical documentation as referred to in Annexes II and III,'

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

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

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

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

(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,';

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

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

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

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

(y) Section 4.10. is amended as follows:

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

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

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

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(ii) the second paragraph is amended as follows:

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

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

(2) the first indent is deleted;

(iii) the third paragraph is amended as follows:

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

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

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

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

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

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

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

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

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

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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~~ **scientific findings for the device, including:**

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

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

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

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

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

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

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

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(7) Annex IX is amended as follows:

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

'Moreover, in the case of class IIa **devices** and class IIb **non-implantable devices, and in the case of well-established technology devices that are class IIb implantable** devices **or class III non-implantable devices**, the quality management system assessment shall be accompanied by the assessment of the technical documentation, as referred to in Annex II and III, as specified in Sections 4.3 to 4.8 **and Articles 52(4) and 52(6)** for a representative device~~. However, in case of class IIa~~ **or** devices~~, Section 3(a) of Annex II shall be excluded from the assessment~~. In choosing the representative device**(s)**, the notified body shall apply a risk-based approach, taking into account the principle of proportionality and in particular the physical, chemical, biological characteristics of the device, the novelty of the technology, similarities in design, technology, manufacturing and sterilisation methods, the intended purpose, the application by the manufacturer of harmonised standards or CS for the device and the results of any previous relevant assessments such as with regard to physical, chemical, biological or clinical properties, that have been carried out in accordance with this Regulation. The notified body in question shall document its rationale for the representative devices taken.

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

If the quality management system and the technical documentation of the assessed representative device**(s)** 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~~ **be included in the** report **of the notified body in accordance with Section 4.6 of Annex VII**.';

(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~~**device(s)**, and of the provisions on vigilance set out in Articles 87 to 92,;'

(e) Section 3.5 is replaced by the following:

'3.5. In the case of class IIa **devices** and class IIb **non-implantable** devices, and in the case of ~~class III devices that are~~ well-established technology **devices that are class IIb implantable devices or class III non-implantable** devices, during the surveillance assessment the notified body may include ~~a 'for-cause'~~**an** assessment of the technical documentation **as specified in Section 4 for the device or devices concerned on the basis of further**~~of~~ representative ~~devices where~~**samples chosen in accordance with the rationale documented by** the notified body ~~has identified potential concerns on the basis of post-market surveillance data or other duly justified grounds~~**in accordance with the third paragraph of Section 2.3**.

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.';

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