The European Association of Medical devices Notified Bodies

Team-NB Position Paper

Editor :	Team-NB	Adoption date 30/06/2026	Version 1

Proposal for risk adaptive surveillance system: MDR

Complementary-Proposal to EU Commission Proposal COM(2025) 1023 final

SUMMARY.

- This Proposal provides details for the implementation of risk-adaptive surveillance of medical devices and manufacturers by notified bodies.

- The affected surveillance measures whose frequency and criteria shall be carried out in accordance with the applicable level of risk-adaptive surveillance are in particular:

    - surveillance audits
    - Unannounced audits
    - TD Sampling during surveillance

REASONS FOR AND OBJECTIVES OF THE COMPLEMENTARY-PROPOSAL.

- The Commission intends to remove the maximum validity of certificates. Instead of recertifying devices, notified bodies shall carry out periodic reviews proportionate to the risk of the device. This requires a reliable assessment of risk, based on a systematic process.

- Increased monitoring intensity at the outset provides the basis for assessing the risks associated with a specific device and its manufacturer, and for determining the future level of monitoring based on that assessment.

TEXT OF THE COMPLEMENTARY-PROPOSAL.

The amendments can be summarised as follows, by main topic, Articles concerned and specific provisions of the proposal:

Proposed amendments to Regulation (EU) 2017/745 on medical devices (MDR)	
TOPIC: RISK-ADAPTIVE SURVEILLANCE	
Insertion point	**Function**
Article 52(14)(b)	Empower Commission to specify detailed criteria and modalities by implementing acts
New Article 52c	Establish the core legal framework and principles for risk-adaptive surveillance
Annex VII, Section 4.5.1	General notified body capability/procedure requirement
Annex VII, Section 4.5.2	Taking into account of risk-adaptive surveillance
Annex VII, Section 4.10	Require notified bodies to implement the framework in documented surveillance procedures
Annex VII, Section 4.11	Convert re-certification logic into periodic review if certificate validity changes
Annex IX, Section 3.3	Adapt regular surveillance audit approach
Annex IX, Section 3.4	Adapt unannounced audits and sample testing
Annex IX, Section 3.5	Adapt technical documentation sampling during surveillance
New Article 2(77)	Definition of “for-cause” as used repeatedly

Amendments to Regulation (EU) 2017/745

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

I. RECITAL shall be added as follows:

(30) Surveillance by notified bodies should be proportionate to the risks associated with the device and to the demonstrated compliance and performance history of the manufacturer. A risk-adaptive surveillance system should therefore permit the notified body to adjust the intensity, frequency and modalities of surveillance activities on the basis of objective and documented criteria, including post-market surveillance and vigilance data, audit and sampling results, technical documentation findings, the effectiveness of corrective and preventive actions, and the maturity of the manufacturer's quality management system. Such system should allow surveillance intensity to be reduced only where sustained compliance and stable post-market performance have been demonstrated, while ensuring prompt re-escalation where serious incidents, field safety corrective actions, recurrent or major nonconformities, ineffective remediation, credible third-party information or other evidence indicate potential risks to health, safety, performance or compliance with this Regulation.

II. Art. 2 (72) shall be replaced as follows:

'well-established technology device' means a device that belongs to a generic device group, which fulfils the following criteria:
a) it has simple, common and stable design **supported by common specifications or harmonised standards and does not incorporate novel design features, novel modes of action or recently developed materials or manufacturing processes that may impact safety or performance;**
b) it has not been associated with safety issues in the past **including serious incidents, safety signals, safety corrective actions or systematic adverse trends, at Union or international level, during its period of market availability;**
c) it has well-known **and predictable** clinical performance characteristics and **is widely recognised as part of the standard of care, and presents no significant evolution in intended purpose, indications, clinical use, performance claims or state of the art within the generic device group;**
d) it has a **long, proven, stable and continuous** history on the Union market **demonstrated by safe clinical use and availability within the same generic device group, without material changes affecting safety, performance or clinical benefit;**
e) it does not include human or animal derived tissues or cells, medicinal substances, biologically active substances, pharmacological, immunological or metabolic agents, or software relying on artificial intelligence or machine learning based algorithms;
f) it is supported by harmonised European standards and/or common specifications applicable to the generic device group, which adequately address its design, manufacture, safety and performance characteristics;

g) it does not rely on new or emerging scientific evidence to substantiate its safety, performance or clinical benefit, beyond that which is already well established and generally accepted for the generic device group.

A device shall not be considered a well-established technology device where any of the above criteria are not met.

III. Art. 2 (77) shall be added as follows:

'for-cause' means initiated by a notified body on the basis of specific, identified information indicating that the conformity of a device, the compliance or effectiveness of the manufacturer's quality management system, or the safety or performance of a device may be adversely affected, including information arising from serious incidents, field safety corrective actions, non-conformities, post-market surveillance data, or notifications of substantial changes to the quality management system or to the device range covered by the relevant certificate.

IV. Art. 52 paragraph 14 shall be replaced as follows:

(b) criteria for the adoption of a risk-adaptive surveillance system as specified in Article 52c and the resulting modalities of unannounced on-site audits and sample tests to be conducted by notified bodies in accordance with and Section 3.4 of Annex IX, taking into account the risk-class and the type of device,

V. Art. 52c "Risk-adaptive surveillance during the life cycle of a device" shall be added as follows:

Paragraph 1: Devices which have undergone a conformity assessment involving a notified body in accordance with Article 52 are throughout their life cycle subject to risk-adaptive surveillance. The classification under this Article shall determine the intensity, frequency and modalities of surveillance activities, including surveillance audits, unannounced audits, technical documentation sampling, product sampling, review of post-market surveillance data and any for-cause surveillance measures. The level of risk-adaptive surveillance shall be based on the criteria and thresholds set out in this Article, Annex VII, Annex IX and any delegated act by the Commission in accordance with Article 52 paragraph 14(b).

Paragraph 2. Following completion of the initial conformity assessment procedure, the manufacturer, or where appropriate the relevant device group, shall be assigned to the initial/enhanced surveillance level. A de-escalation of the surveillance level shall be stepwise and time based; while a re-escalation may be immediate if a triggering event occurs. The level of surveillance may be lowered at the earliest [three (3) years] after initial completion of the conformity assessment procedure.

Paragraph 3. For a reduction or increase of the applicable level of surveillance, the notified body shall take into account, in particular, the following events or circumstances:

a. serious incidents with confirmed causal relation to the device, field safety corrective actions or other serious post-market events relating to the device or

device group;

b. major or recurrent non-conformities in the last two surveillance assessments carried out pursuant to Annex IX, Section 3, including controls of critical suppliers and subcontractors; or,

c. failure to implement corrective and preventive actions within the time limits set by the notified body, or failure to provide documented evidence demonstrating the effectiveness of such actions;

d. documented deficiencies in the quality management system that indicate insufficient process control, including ineffective control of critical suppliers and subcontractors as referred to in Annex IX, Section 2.2;

e. serious incident and field safety corrective action data pursuant to Article 87 and 89 and post-market surveillance indicators, including trend reports under Article 88;

f. incomplete or untimely fulfilment of reporting and submission obligations, including to periodic safety update reports referred to in Article 86, post-market surveillance reports referred to in Article 85 and trend reports under Article 88; or

g. delayed, incomplete or inadequate responses by the manufacturer to notified body requests, including responses to nonconformities, where such delay or inadequacy is combined with insufficient documentation quality and results in repeated clarification cycles or multiple rounds of review; or

h. credible information from third parties, including healthcare professionals, users, patients, competent authorities, market surveillance authorities, or persons working for public or private organizations who have obtained relevant information in a work-related context;

i. any other condition indicating that the manufacturer may lack effective control over the design, manufacture, post-market surveillance or corrective action processes relevant to the device.

Paragraph 4. The notified body shall classify the manufacturer, or where appropriate the relevant device group, into one of the following levels of risk-adaptive surveillance:

(a) the initial/enhanced level of surveillance, where one or more of the events or circumstances referred to in paragraph 3 has occurred during the preceding three years;

(b) the medium level of surveillance, where none of the events or circumstances referred to in paragraph 3 has occurred during the preceding three years; and

(c) the reduced surveillance level, where none of the events or circumstances referred to in paragraph 3 has occurred during the preceding six years.

Paragraph 5. Decisions taken pursuant to this Article shall be based on the indicators listed in paragraph 3, reasoned, recorded and kept within the notified body's quality management system in accordance with Annex VII, Chapter 4.10..

Paragraph 6. The applied level of surveillance shall not limit the discretion of the notified body to conduct for-cause surveillance measures at any time where justified by specific concerns or evidence. Irrespective of the applied level of surveillance, competent authorities may at any time require additional measures where necessary to address specific risks to health, safety or compliance with this Regulation. Notified bodies shall ensure the capacity to promptly re-escalate risk-adaptive surveillance.

VI. Article 86 shall be replaced as follows:

Paragraph 1. Manufacturers of class IIa, class IIb and class III devices, other than custom-made devices, shall prepare a periodic safety update report ('PSUR') for each device, or where relevant, for each category or group of devices, summarising the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan referred to in Article 84, together with a description of any preventive and corrective actions taken, including their rationale. Throughout the lifetime of the device concerned, that PSUR shall set out:
(a) the conclusions of the benefit-risk determination;
(b) the main findings of the PMCF; and
(c) the volume of sales of the device and an estimate of the size and other characteristics of the population using the device and, where practicable, the usage frequency of the device.

Manufacturers of class III devices shall update the PSUR at least annually and whenever there is a significant change in the benefit-risk determination or in the acceptability of erroneous results.

Manufacturers of class IIa and class IIb devices shall update the PSUR in the first year after the certificate is issued and every two years thereafter, or when there is a significant change in the benefit-risk determination or in the acceptability of erroneous results.

In cases where a certificate has been issued subject to conditions, the manufacturer shall ensure that the PSUR is reviewed and updated at least annually, irrespective of the device's risk classification.

Each PSUR shall form part of the technical documentation specified in Annex III.

VII. Annex VI shall be amended as follows:

Part A, add 2.16

2.16. method of clinical evidence generation, including whether equivalence has been claimed to an existing device on the Union market.

VIII. Annex VII shall be amended as follows:

a. Chapter 4.5. Conformity assessment activities
Section 4.5.1. General

The notified body and its personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical and scientific competence in the specific fields. The notified body shall have expertise, facilities and documented procedures that are sufficient to effectively conduct the conformity assessment activities for which the notified body in question is designated, taking account of the relevant requirements set out in Annexes IX to XI, and in particular all of the following requirements:

[…] (tenth indent) — plan and periodically carry out appropriate surveillance audits and assessments, carry out or request certain tests to verify the proper functioning of the quality management system and to perform unannounced on site audits, **each taking into account the level of risk-adaptive surveillance as described in Article 52c;**

(eleventh indent) — relating to the sampling of devices, verify that the manufactured device is in conformity with the technical documentation; such requirements shall define the relevant sampling criteria and testing procedure prior to sampling, **taking into account the applicable level of risk-adaptive surveillance as specified in Article 52c.**

— evaluate and verify a manufacturer's compliance with relevant Annexes.

–'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**, also as further specified in Article 52c in order to determine the appropriate level of risk-adaptive surveillance.**

The notified body shall, where relevant, take into consideration available CS, guidance and best practice documents and harmonised standards, even if the manufacturer does not claim to be in compliance.

b. Chapter 4.5. Conformity assessment activities
Section 4.5.2. Quality management system auditing

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

[…]
— draw up and keep up to date **in accordance with the applicable level of surveillance referred to in Article 52c**, for class IIa and class IIb devices, a sampling plan for the assessment of technical documentation as referred to in Annexes II and III covering the range of such devices covered by the manufacturer's application. That plan shall ensure that the entire range of devices covered by the certificate is sampled following certification and thereafter **on an ongoing basis within the periodic review interval as referred to in Annex VII, Section 4.11,** and

c. Chapter 4.10. Surveillance activities and post-certification monitoring Paragraph 1, first indent

Surveillance activities and post-certification monitoring

The notified body shall have documented procedures:

(first indent) – defining how and when surveillance activities of manufacturers are to be conducted, **including how the notified body determines, documents and applies the relevant level of risk-adaptive surveillance in accordance with Article 52c.** Those procedures shall include arrangements for unannounced on-site audits of manufacturers and, where applicable, subcontractors and suppliers carrying out product tests and the monitoring of compliance with any conditions binding manufacturers and associated with certification decisions, such as updates to clinical data at defined intervals,

d. Chapter 4.10. Surveillance activities and post-certification monitoring Paragraph 3, first indent

In relation to surveillance audits of manufacturers, the notified body shall have documented procedures to:
— conduct surveillance audits of the manufacturer which shall be planned and conducted in line with the relevant requirements set out in Section 4.5, **and in accordance with the relevant level of risk-adaptive surveillance pursuant to Article 52c,**

e. Chapter 4.11. Re-certification Paragraph 1

The notified body shall have documented procedures in place relating to the periodic reviews of the approved quality management systems or EU technical documentation assessment certificates or EU type-examination certificates. **The period reviews shall occur at least every three years.**

IX. Annex IX shall be amended as follows:

a. Section 2.3, paragraph 1 is replaced by the following:

The notified body shall audit the quality management system to determine whether it meets the requirements referred to in Section 2.2. Where the manufacturer uses a harmonised standard or CS related to a quality management system, the notified body shall assess conformity with those standards or CS. The notified body shall assume that a quality management system which satisfies the relevant harmonised standards or CS conforms to the requirements covered by those standards or CS, unless it duly substantiates not doing so.

Audit time is dependent on factors such as the audit scope, objectives, and specific regulatory requirements to be audited, as well as the range, class, and complexity of medical devices, and the size and complexity of the organization. The estimated audit time may be reduced where justified by objective and evidence-based considerations, such as low process complexity, demonstrated maturity and effectiveness of the quality management system, high-quality and readily available documentation, and a history of compliant performance.

b. Section 2.3, paragraph 2 is replaced by the following:

The audit team of the notified body shall include at least one member with past experience of assessments of the technology concerned in accordance with Sections 4.3. to 4.5. of Annex VII. In circumstances where such experience is not immediately obvious or applicable, the notified body shall provide a documented rationale for the composition of that team. The assessment procedure shall include an audit on the manufacturer's premises and, if appropriate, on the premises of the manufacturer's suppliers and/or subcontractors to verify the manufacturing and other relevant processes**. The notified body should ensure that the use of technology is implemented in auditing processes wherever feasible to enhance efficiency, accuracy, and overall audit quality.**

c. Section 2.3, paragraph 3 is 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 Annexes 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.

In cases where the certificate contains very few devices and the technical documentations of these have been already reviewed, it is expected that during surveillance audits the notified body will focus on the review of the

technical documentation related to post-market surveillance in accordance with Annex III.

The notified body may include a 'for-cause' assessment, as referred to in Article 2 (77), of the technical documentation of additional representative devices or an in-depth technical documentation assessment on duly justified grounds identified during the quality management system assessment.

d. 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 should ensure that the use of technology is implemented in auditing processes wherever feasible to enhance efficiency, accuracy, and overall audit quality.** 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 **according to the applicable level of risk-adaptive surveillance as specified in Article 52c., the audit approach may be adapted accordingly.**

e. Section 3.4 is replaced by the following:

Paragraph 1. 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 **at a frequency appropriate to the applicable level of risk-adaptive surveillance as specified in Article 52c** 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.

Unannounced audits for-cause may be conducted in addition at any time.

The Notified Body shall establish and maintain a plan for unannounced audits; such plan shall not be disclosed to the manufacturer.

Paragraph 2. Within the context of such unannounced on-site audits, the notified body **may in accordance with the applicable level of risk-adaptive surveillance as specified in Article 52c** 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). Prior to unannounced on-site audits, the notified body shall specify the relevant sampling criteria and testing procedure.

Paragraph 3. Instead of, or in addition to, the sampling referred to in the second paragraph, the notified body shall **may in accordance with the applicable level of risk-adaptive surveillance as specified in Article 52c** 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). Prior to the sampling, the notified body in question shall specify the relevant sampling criteria and testing procedure.

f. Section 3.5 is replaced by the following:

In the case of class IIa and class IIb devices, and of class III devices that are well-established technology devices, the surveillance assessment shall also include an assessment of the technical documentation, **as referred to in Annex II and III,** as specified in Section 4 for the device or devices concerned on the basis of further representative samples chosen in accordance with the rationale documented by the notified body in accordance with the third paragraph of Section 2.3. **The technical documentation subject to assessment shall be determined according to the applicable level of surveillance pursuant to Art. 52c for each category and each generic device group.**

This assessment shall be conducted in addition to the relevant post-market surveillance documentation, including the post-market surveillance report referred to in Article 85 or the periodic safety update report referred to in Article 86, as applicable.

X. Annex XIV shall be amended as follows:

Paragraph 3. A clinical evaluation may be based on clinical data relating to a device for which equivalence to the device in question can be demonstrated. The following technical, biological and clinical characteristics shall be taken into consideration for the demonstration of equivalence:

— Technical: the device is of similar design; is used under similar conditions of use; has similar specifications and properties including physicochemical properties such as intensity of energy, tensile strength, viscosity, surface characteristics, wavelength and software algorithms; uses similar deployment methods, where relevant; has similar principles of operation and critical performance requirements;

— Biological: the device uses the same **or similar** materials or substances in contact with the same human tissues or body fluids for a similar kind and duration of contact

and similar release characteristics of substances, including degradation products and leachables;

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

The characteristics listed in the first paragraph shall be similar to the extent that there would be no clinically significant difference in the safety and clinical performance of the device. Considerations of equivalence shall be based on proper scientific justification. **The device with which they are claiming equivalence must not have claimed equivalence to another device, and must have undergone clinical studies and generated clinical data for it's clinical evaluation.** It shall be clearly demonstrated that manufacturers have sufficient levels of access to the data relating to devices with which they are claiming equivalence in order to justify their claims of equivalence.

ANNEX. SYNOPSIS OF THE LEGISLATIVE VERSIONS AND PROPOSAL

	MDR Regulation (EU) 2017/745	Commission's Proposal for a Regulation of December 16, 2025, COM(2025) 1023 final, 2025/0404 (COD),	COMPLEMENTARY Proposal
1.	**Frequency of regular surveillance Audits**		
	MDR	**MDR COMMISSION Draft Regulation**	**COMPLEMENTARY Proposal**
Article 52(14) **Conformity Assessment Procedures**	The Commission may, by means of implementing acts, specify detailed arrangements and procedural aspects with a view to ensuring the harmonised application of the conformity assessment procedures by the notified bodies for any of the following aspects: (a) the frequency and the sampling basis of the assessment of the technical documentation on a representative basis as set out in the third paragraph of Section 2.3 and in Section 3.5 of Annex IX in the case of class IIa and class IIb devices, and in Section 10.2 of Annex XI in the case of class IIa devices; (b) the minimum frequency 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;	The Commission may, by means of implementing acts, specify detailed arrangements and procedural aspects for any of the following aspects: […] **(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;** […] The implementing acts referred to in the first subparagraph shall be adopted in accordance with the examination procedure referred to in Article 114(3).	The Commission may, by means of implementing acts, specify detailed arrangements and procedural aspects with a view to ensuring the harmonised application of the conformity assessment procedures by the notified bodies for any of the following aspects: […] (b) **criteria for the adoption of a risk-adaptive surveillance system as specified in Article 52c and the resulting** modalities of unannounced on-site audits and sample tests to be conducted by notified bodies in accordance with and Section 3.4 of Annex IX, taking into account the risk-class and the type of device, […]

Article 52c	/	/	**Article 52c [NEW]** **Risk-adaptive surveillance during the life cycle of a device** **Paragraph 1**: Devices which have undergone a conformity assessment involving a notified body in accordance with Article 52 are throughout their life cycle subject to risk-adaptive surveillance. The classification under this Article shall determine the intensity, frequency and modalities of surveillance activities, including surveillance audits, unannounced audits, technical documentation sampling, product sampling, review of post-market surveillance data and any for-cause surveillance measures. The level of risk-adaptive surveillance shall be based on the criteria and thresholds set out in this Article, Annex VII, Annex IX and any delegated act by the Commission in accordance with Article 52 paragraph 14(b). **Paragraph 2**. Following completion of the initial conformity assessment procedure, the manufacturer, or where appropriate the relevant device group, shall be assigned to the initial/enhanced surveillance level. A de-escalation of the surveillance level shall be stepwise and time based; while a re-escalation may be immediate if a triggering event occurs. The level of surveillance may be lowered at the earliest [three (3) years] after initial completion of the conformity assessment procedure. **Paragraph 3**. For a reduction or increase of the applicable level of surveillance, the notified body shall take into account, in particular, the following events or circumstances: a. serious incidents with confirmed causal relation to the device, field safety

			corrective actions or other serious post-market events relating to the device or device group; b. major or recurrent non-conformities in the last two surveillance assessments carried out pursuant to Annex IX, Section 3, including controls of critical suppliers and subcontractors; or, c. failure to implement corrective and preventive actions within the time limits set by the notified body, or failure to provide documented evidence demonstrating the effectiveness of such actions; d. documented deficiencies in the quality management system that indicate insufficient process control, including ineffective control of critical suppliers and subcontractors as referred to in Annex IX, Section 2.2; e. serious incident and field safety corrective action data pursuant to Article 87 and 89 and post-market surveillance indicators, including trend reports under Article 88; f. incomplete or untimely fulfilment of reporting and submission obligations, including to periodic safety update reports referred to in Article 86, post-market surveillance reports referred to in Article 85 and trend reports under Article 88; or g. delayed, incomplete or inadequate responses by the manufacturer to notified body requests, including responses to nonconformities, where such delay or inadequacy is combined with insufficient documentation quality and results in repeated clarification

			cycles or multiple rounds of review; or h. credible information from third parties, including healthcare professionals, users, patients, competent authorities, market surveillance authorities, or persons working for public or private organizations who have obtained relevant information in a work-related context; i. any other condition indicating that the manufacturer may lack effective control over the design, manufacture, post-market surveillance or corrective action processes relevant to the device. **Paragraph 4**. The notified body shall classify the manufacturer, or where appropriate the relevant device group, into one of the following levels of risk-adaptive surveillance: (a) the initial/enhanced level of surveillance, where one or more of the events or circumstances referred to in paragraph 3 has occurred during the preceding three years; (b) the medium level of surveillance, where none of the events or circumstances referred to in paragraph 3 has occurred during the preceding three years; and (c) the reduced surveillance level, where none of the events or circumstances referred to in paragraph 3 has occurred during the preceding six years. **Paragraph 5.** Decisions taken pursuant to this Article shall be based on the indicators listed in paragraph 3, reasoned, recorded and kept within the notified body's quality management system in accordance with Annex VII, Chapter 4.10..

			Paragraph 6. The applied level of surveillance shall not limit the discretion of the notified body to conduct for-cause surveillance measures at any time where justified by specific concerns or evidence. Irrespective of the applied level of surveillance, competent authorities may at any time require additional measures where necessary to address specific risks to health, safety or compliance with this Regulation. Notified bodies shall ensure the capacity to promptly re-escalate risk-adaptive surveillance.
Annex IX, **Section 3.3** conformity assessment based on a quality management system and on assessment of technical documentation	Notified bodies shall periodically, **at least once every 12 months,** 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. At the time of such on-site audits, 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.	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**	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 should ensure that the use of technology is implemented in auditing processes wherever feasible to enhance efficiency, accuracy, and overall audit quality.** 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 **according to the applicable level of risk-adaptive surveillance as specified in Article 52c., the audit approach may be adapted accordingly.**

		surveillance audits and assessments only once every 24 months.“	
Annex VII, Section 4.10, paragraph 1, indent 1	The notified body shall have documented procedures: — defining how and when surveillance activities of manufacturers are to be conducted. Those procedures shall include arrangements for unannounced on-site audits of manufacturers and, where applicable, subcontractors and suppliers carrying out product tests and the monitoring of compliance with any conditions binding manufacturers and associated with certification decisions, such as updates to clinical data at defined intervals,	No changes	The notified body shall have documented procedures: — (first indent) – defining how and when surveillance activities of manufacturers are to be conducted, **including how the notified body determines, documents and applies the relevant level of risk-adaptive surveillance in accordance with Article 52c.** Those procedures shall include arrangements for unannounced on-site audits of manufacturers and, where applicable, subcontractors and suppliers carrying out product tests and the monitoring of compliance with any conditions binding manufacturers and associated with certification decisions, such as updates to clinical data at defined intervals,
Annex VII, Section 4.10, Paragraph 3, indent 1	In relation to surveillance audits of manufacturers, the notified body shall have documented procedures to: — conduct surveillance audits of the manufacturer on at least an annual basis which shall be planned and conducted in line with the relevant requirements in Section 4.5,	In relation to surveillance audits of manufacturers, the notified body shall have documented procedures to: — conduct surveillance audits of the manufacturer **~~on at least an annual basis~~** which shall be planned and conducted in line with the relevant requirements in Section 4.5,	In relation to surveillance audits of manufacturers, the notified body shall have documented procedures to: — conduct surveillance audits of the manufacturer which shall be planned and conducted in line with the relevant requirements set out in Section 4.5, **and in accordance with the relevant level of risk-adaptive surveillance pursuant to Article 52c,**
2.	**Unnanounced Audits**		
	MDR	**MDR COMMISSION Draft Regulation**	**COMPLEMENTARY Proposal**
Annex VII, Section 4.5.1	The notified body and its personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical and scientific competence in the specific fields. The notified body shall have expertise, facilities and documented	The notified body and its personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical and scientific competence in the specific fields. The notified body shall have expertise, facilities and documented procedures that	The notified body and its personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical and scientific competence in the specific fields. The notified body shall have expertise, facilities and documented procedures that are sufficient to effectively conduct the conformity assessment activities for

	procedures that are sufficient to effectively conduct the conformity assessment activities for which the notified body in question is designated, taking account of the relevant requirements set out in Annexes IX to XI, and in particular all of the following requirements: […] — plan and periodically carry out appropriate surveillance audits and assessments, carry out or request certain tests to verify the proper functioning of the quality management system and to perform unannounced on site audits, — relating to the sampling of devices, verify that the manufactured device is in conformity with the technical documentation; such requirements shall define the relevant sampling criteria and testing procedure prior to sampling, — evaluate and verify a manufacturer's compliance with relevant Annexes. The notified body shall, where relevant, take into consideration available CS, guidance and best practice documents and harmonised standards, even if the manufacturer does not claim to be in compliance.	are sufficient to effectively conduct the conformity assessment activities for which the notified body in question is designated, taking account of the relevant requirements set out in Annexes IX to XI, and in particular all of the following requirements: […] **— plan and periodically carry out appropriate surveillance audits and assessments, carry out or request certain tests to verify the proper functioning of the quality management system and to perform unannounced on site audits,** **— (to be removed) relating to the sampling of devices, verify that the manufactured device is in conformity with the technical documentation; such requirements shall define the relevant sampling criteria and testing procedure prior to sampling,** — evaluate and verify a manufacturer's compliance with relevant Annexes. –'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**	which the notified body in question is designated, taking account of the relevant requirements set out in Annexes IX to XI, and in particular all of the following requirements: […] — plan and periodically carry out appropriate surveillance audits and assessments, carry out or request certain tests to verify the proper functioning of the quality management system and to perform unannounced on site audits**, each taking into account the level of risk-adaptive surveillance as described in Article 52c;** — relating to the sampling of devices, verify that the manufactured device is in conformity with the technical documentation; such requirements shall define the relevant sampling criteria and testing procedure prior to sampling, **taking into account the applicable level of risk-adaptive surveillance as specified in Article 52c.** — evaluate and verify a manufacturer's compliance with relevant Annexes. –'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**, also as further specified in Article 52c in order to determine the appropriate level of risk-adaptive surveillance.**

		The notified body shall, where relevant, take into consideration available CS, guidance and best practice documents and harmonised standards, even if the manufacturer does not claim to be in compliance.	The notified body shall, where relevant, take into consideration available CS, guidance and best practice documents and harmonised standards, even if the manufacturer does not claim to be in compliance.
Annex IX, Section 3.4, paragraph 1	The notified body shall randomly perform at least once every five years unannounced audits on the site of the manufacturer and, where appropriate, of the manufacturer's suppliers and/or subcontractors, which may be combined with the periodic surveillance assessment referred to in Section 3.3. or be performed in addition to that surveillance assessment. The notified body shall establish a plan for such unannounced on-site audits but shall not disclose it to the manufacturer.	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.	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 **at a frequency appropriate to the applicable level of risk-adaptive surveillance as specified in Article 52c** 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. **Unannounced audits for-cause, as referred to in Article 2 (77), shall remain applicable to all manufacturers where justified.** **The Notified Body shall establish and maintain a plan for unannounced audits; such plan shall not be disclosed to the manufacturer.**
3.	**Technical documentation sampling during surveillance**		
	MDR	**MDR COMMISSION Draft Regulation**	**COMPLEMENTARY Proposal**
Annex VII, Section 4.5.2(a), indent 4	— draw up and keep up to date, for class IIa and class IIb devices, a sampling plan for the assessment of technical documentation as referred to in Annexes II and III covering the range of such devices covered by the manufacturer's application. That plan	Delete from current legislation	— draw up and keep up to date **in accordance with the applicable level of surveillance referred to in Article 52c,** for class IIa and class IIb devices, a sampling plan for the assessment of technical documentation as referred to in Annexes II and III covering the range of such devices covered by the manufacturer's application. That plan shall ensure that the entire

	shall ensure that the entire range of devices covered by the certificate is sampled over the period of validity of the certificate, and		range of devices covered by the certificate is sampled **following certification and thereafter on an ongoing basis within the periodic review interval as referred to in Annex VII, Section 4.11, and**
Annex IX, Section 3.5, paragraph 1	In the case of class IIa and class IIb devices, the surveillance assessment shall also include an assessment of the technical documentation as specified in Section 4 for the device or devices concerned on the basis of further representative samples chosen in accordance with the rationale documented by the notified body in accordance with the third paragraph of Section 2.3. In the case of class III 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.	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 as specified in Section 4 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.	In the case of class IIa and class IIb devices, and of class III devices that are well-established technology devices, the surveillance assessment shall also include an assessment of the technical documentation **as referred to in Annex II and III,** as specified in Section 4 for the device or devices concerned on the basis of further representative samples chosen in accordance with the rationale documented by the notified body in accordance with the third paragraph of Section 2.3. **The technical documentation subject to assessment shall be determined according to the applicable level of surveillance pursuant to Art. 52c for each category and each generic device group.** **This assessment shall be conducted in addition to the relevant post-market surveillance documentation, including the post-market surveillance report referred to in Article 85 or the periodic safety update report referred to in Article 86, as applicable.**
4.	**Sampling during surveillance**		
	MDR	**MDR COMMISSION Draft Regulation** Annex IX 3.5	**COMPLEMENTARY Proposal**
Annex VII, Section 4.5.1., eleventh indent	4.5.1. General The notified body and its personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical and scientific competence in the specific fields.	4.5.1. General The notified body and its personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical and scientific competence in the specific fields.	4.5.1. General The notified body and its personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical and scientific competence in the specific fields. The notified body shall have expertise, facilities and documented procedures that are

	The notified body shall have expertise, facilities and documented procedures that are sufficient to effectively conduct the conformity assessment activities for which the notified body in question is designated, taking account of the relevant requirements set out in Annexes IX to XI, and in particular all of the following requirements: — […] eleventh indent— relating to the sampling of devices, verify that the manufactured device is in conformity with the technical documentation; such requirements shall define the relevant sampling criteria and testing procedure prior to sampling,	The notified body shall have expertise, facilities and documented procedures that are sufficient to effectively conduct the conformity assessment activities for which the notified body in question is designated, taking account of the relevant requirements set out in Annexes IX to XI, and in particular all of the following requirements: […] eleventh indent— [to be deleted: relating to the sampling of devices, verify that the manufactured device is in conformity with the technical documentation; such requirements shall define the relevant sampling criteria and testing procedure prior to sampling,	sufficient to effectively conduct the conformity assessment activities for which the notified body in question is designated, taking account of the relevant requirements set out in Annexes IX to XI, and in particular all of the following requirements: […] eleventh indent— relating to the sampling of devices, verify that the manufactured device is in conformity with the technical documentation; such requirements shall define the relevant sampling criteria and testing procedure prior to sampling, **taking into account the applicable level of risk-adaptive surveillance as specified in Article 52c.**
Annex IX Section 3.4, paragraph 2 and 3	Within the context of such unannounced on-site audits, the notified body shall 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). Prior to unannounced on-site audits, the notified body shall specify the relevant sampling criteria and testing procedure. Instead of, or in addition to, sampling referred to in the second paragraph, the notified body shall take samples of devices from the market to verify that the manufactured device is in conformity with the technical	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). Prior to unannounced on-site audits, the notified body shall specify the relevant sampling criteria and testing procedure. Instead of, or in addition to, the sampling referred to in the second paragraph, the notified body shall **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).	Within the context of such unannounced on-site audits, the notified body **may in accordance with the applicable level of risk-adaptive surveillance as specified in Article 52c** 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). Prior to unannounced on-site audits, the notified body shall specify the relevant sampling criteria and testing procedure. Instead of, or in addition to, the sampling referred to in the second paragraph, the notified body shall **may in accordance with the applicable level of risk-adaptive surveillance as specified in Article 52c** 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

	documentation, with the exception of the devices referred to in the second subparagraph of Article 52(8). Prior to the sampling, the notified body in question shall specify the relevant sampling criteria and testing procedure.	Prior to the sampling, the notified body in question shall specify the relevant sampling criteria and testing procedure. .	second subparagraph of Article 52(8). Prior to the sampling, the notified body in question shall specify the relevant sampling criteria and testing procedure.
5.	**Periodic review**		
	MDR	**MDR COMMISSION Draft Regulation**	**COMPLEMENTARY Proposal**
Annex VII Section 4.11, paragraph 1	The notified body shall have documented procedures in place relating to the re-certification reviews and the renewal of certificates. Re-certification of approved quality management systems or EU technical documentation assessment certificates or EU type-examination certificates shall occur at least every five years.	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. [...]	The notified body shall have documented procedures in place relating to the periodic reviews of the approved quality management systems or EU technical documentation assessment certificates or EU type-examination certificates. **The period reviews shall occur at least every three years.**
6.	**Small manufacturers with small device range and simple organisation**		
	MDR	**MDR COMMISSION Draft Regulation**	**COMPLEMENTARY Proposal**
Annex IX Section 2.3, paragraph 1	The notified body shall audit the quality management system to determine whether it meets the requirements referred to in Section 2.2. Where the manufacturer uses a harmonised standard or CS related to a quality management system, the notified body shall assess conformity with those standards or CS. The notified body shall assume that a quality management system which satisfies the relevant harmonised standards or CS conforms to the requirements	No changes	The notified body shall audit the quality management system to determine whether it meets the requirements referred to in Section 2.2. Where the manufacturer uses a harmonised standard or CS related to a quality management system, the notified body shall assess conformity with those standards or CS. The notified body shall assume that a quality management system which satisfies the relevant harmonised standards or CS conforms to the requirements covered by those standards or CS, unless it duly substantiates not doing so. **Audit time is dependent on factors such as the audit scope,**

	covered by those standards or CS, unless it duly substantiates not doing so.		**objectives, and specific regulatory requirements to be audited, as well as the range, class, and complexity of medical devices, and the size and complexity of the organization. The estimated audit time may be reduced where justified by objective and evidence-based considerations, such as low process complexity, demonstrated maturity and effectiveness of the quality management system, high-quality and readily available documentation, and a history of compliant performance.**
Annex IX, Section 2.3, paragraph 3	Moreover, in the case of class IIa and class IIb devices, the quality management system assessment shall be accompanied by the assessment of technical documentation for devices selected on a representative basis as specified in Section 4. In choosing representative samples, the notified body shall take into account the published guidance developed by the MDCG pursuant to Article 105 and in particular the novelty of the technology, similarities in design, technology, manufacturing and sterilisation methods, the intended purpose 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 samples taken.	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	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 Annexes 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. **In cases where the certificate contains very few devices and the technical documentations of these have been already reviewed, it is expected that**

		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.**	**during surveillance audits the notified body will focus on the review of the technical documentation related to post-market surveillance in accordance with Annex III.** **The notified body may include a 'for-cause' assessment, as referred to in Article 2 (77), of the technical documentation of additional representative devices or an in-depth technical documentation assessment on duly justified grounds identified during the quality management system assessment.**
7.	**Definition (New or update)**		
	MDR	**MDR COMMISSION Draft Regulation**	**COMPLEMENTARY Proposal**
Article 2(72) - WET	-	'well-established technology device' means a device that belongs to a generic device group, which fulfils the following criteria: (a) it has simple, common and stable design; (b) it has not been associated with safety issues in the past; (c) it has well-known clinical performance characteristics and comprises standard of care devices with little evolution in indications and the state of the art; (d) it has a long history on the Union market;	'well-established technology device' means a device that belongs to a generic device group, which fulfils the following criteria: a) it has simple, common and stable design **supported by common specifications or harmonised standards and does not incorporate novel design features, novel modes of action or recently developed materials or manufacturing processes that may impact safety or performance;** b) it has not been associated with safety issues in the past **including serious incidents, safety signals, safety corrective actions or systematic adverse trends, at Union or international level, during its period of market availability;** c) it has well-known **and predictable** clinical performance characteristics and **is widely recognised as part of the standard of care, and presents no significant evolution in intended purpose, indications, clinical use, performance claims or state of the art within the generic device group;** d) it has a **long, proven, stable and continuous** history on the Union market **demonstrated by safe clinical use and availability**

			within the same generic device group, without material changes affecting safety, performance or clinical benefit; **e) it does not include human or animal derived tissues or cells, medicinal substances, biologically active substances, pharmacological, immunological or metabolic agents, or software relying on artificial intelligence or machine learning based algorithms;** **f) it is supported by harmonised European standards and/or common specifications applicable to the generic device group, which adequately address its design, manufacture, safety and performance characteristics;** **g) it does not rely on new or emerging scientific evidence to substantiate its safety, performance or clinical benefit, beyond that which is already well established and generally accepted for the generic device group.** **A device shall not be considered a well-established technology device where any of the above criteria are not met.**
Article 2(77) – "for cause"	**-**	**-**	**Article 2(77) [New]** **'for-cause' means initiated by a notified body on the basis of specific, identified information indicating that the conformity of a device, the compliance or effectiveness of the manufacturer's quality management system, or the safety or performance of a device may be adversely affected, including information arising from serious incidents, field safety corrective actions, non-conformities, post-market surveillance data, or notifications of substantial changes to the quality management system or to the device range covered by the relevant certificate.**

8.	Use of technology to be implemented in auditing processes		
	MDR	**MDR COMMISSION Draft Regulation**	**COMPLEMENTARY Proposal**
Annex IX, Section 2.3, paragraph 2	The audit team of the notified body shall include at least one member with past experience of assessments of the technology concerned in accordance with Sections 4.3. to 4.5. of Annex VII. In circumstances where such experience is not immediately obvious or applicable, the notified body shall provide a documented rationale for the composition of that team. The assessment procedure shall include an audit on the manufacturer's premises and, if appropriate, on the premises of the manufacturer's suppliers and/or subcontractors to verify the manufacturing and other relevant processes.	No changes	The audit team of the notified body shall include at least one member with past experience of assessments of the technology concerned in accordance with Sections 4.3. to 4.5. of Annex VII. In circumstances where such experience is not immediately obvious or applicable, the notified body shall provide a documented rationale for the composition of that team. The assessment procedure shall include an audit on the manufacturer's premises and, if appropriate, on the premises of the manufacturer's suppliers and/or subcontractors to verify the manufacturing and other relevant processes. **The notified body should ensure that the use of technology is implemented in auditing processes wherever feasible to enhance efficiency, accuracy, and overall audit quality.**
Annex IX, Section 3.3	Notified bodies shall periodically, **at least once every 12 months,** 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. At the time of such on-site audits, the notified body shall, where necessary, carry out or ask for tests in	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	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 should ensure that the use of technology is implemented in auditing processes wherever feasible to enhance efficiency, accuracy, and overall audit quality.** The notified body shall, where necessary, carry out or ask for tests in order to check that the quality

	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.	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.“**	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 according to the applicable level of risk-adaptive surveillance as specified in Article 52c, the audit approach may be adapted accordingly.**
9.	**Periodic safety update report (‘PSUR’)**		
	MDR	**MDR COMMISSION Draft Regulation**	**COMPLEMENTARY Proposal**
Article 86(1)	Manufacturers of class IIa, class IIb and class III devices shall prepare a periodic safety update report (‘PSUR’) for each device and where relevant for each category or group of devices summarising the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan referred to in Article 84 together with a rationale and description of any preventive and corrective actions taken. Throughout the lifetime of the device concerned, that PSUR shall set out: (a) the conclusions of the benefit-risk determination;	Manufacturers of class IIa, class IIb and class III devices, other than custom-made devices, shall prepare a periodic safety update report (‘PSUR’) for each device, or where relevant for each category or group of devices, summarising the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post- market surveillance plan referred to in Article 84, together with a description of any preventive and corrective actions taken, including their rationale. Throughout the lifetime of the device concerned, that PSUR shall set out: (a) the conclusions of the benefit-risk determination; (b) the main findings of the PMCF; and	Manufacturers of class IIa, class IIb and class III devices, other than custom-made devices, shall prepare a periodic safety update report (‘PSUR’) for each device, or where relevant, for each category or group of devices, summarising the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan referred to in Article 84, together with a description of any preventive and corrective actions taken, including their rationale. Throughout the lifetime of the device concerned, that PSUR shall set out: (a) the conclusions of the benefit-risk determination; (b) the main findings of the PMCF; and (c) the volume of sales of the device and an estimate of the size and other characteristics of the population using the device and,

	(b) the main findings of the PMCF; and (c) the volume of sales of the device and an estimate evaluation of the size and other characteristics of the population using the device and, where practicable, the usage frequency of the device. Manufacturers of class IIb and class III devices shall update the PSUR at least annually. That PSUR shall, except in the case of custom-made devices, be part of the technical documentation as specified in Annexes II and III. Manufacturers of class IIa devices shall update the PSUR when necessary and at least every two years. That PSUR shall, except in the case of custom-made devices, be part of the technical documentation as specified in Annexes II and III. For custom-made devices, the PSUR shall be part of the documentation referred to in Section 2 of Annex XIII.	(c) the volume of sales of the device and an estimate evaluation of the size and other characteristics of the population using the device and, where practicable, the usage frequency of the device. **Manufacturers of class IIb and class III devices shall update the PSUR in the first year after the certificate is issued and every two years thereafter or when there is a significant change in the benefit-risk determination or in the acceptability of undesirable side-effects. The PSUR shall be part of the technical documentation as specified in Annex II and Annex III.** **Manufacturers of class IIa devices shall update the PSUR when necessary. The PSURs shall be part of the technical documentation specified in Annex III**.	where practicable, the usage frequency of the device. **Manufacturers of class III devices shall update the PSUR at least annually and whenever there is a significant change in the benefit-risk determination or in the acceptability of erroneous results.** **Manufacturers of class IIa and class IIb devices shall update the PSUR in the first year after the certificate is issued and every two years thereafter, or when there is a significant change in the benefit-risk determination or in the acceptability of erroneous results.** **In cases where a certificate has been issued subject to conditions, the manufacturer shall ensure that the PSUR is reviewed and updated at least annually, irrespective of the device's risk classification.** **Each PSUR shall form part of the technical documentation specified in Annex III.**
10.	**Clinical evidence**		
	MDR	**MDR COMMISSION Draft Regulation**	**COMPLEMENTARY Proposal**
Annex VI, **Part A_2**	**-**	**-**	**Annex VI, Part A 2.16. [New]** **2.16. method of clinical evidence generation, including whether equivalence has been claimed to an existing device on the Union market.**

Annex XIV, Section 3	A clinical evaluation may be based on clinical data relating to a device for which equivalence to the device in question can be demonstrated. The following technical, biological and clinical characteristics shall be taken into consideration for the demonstration of equivalence: — Technical: the device is of similar design; is used under similar conditions of use; has similar specifications and properties including physicochemical properties such as intensity of energy, tensile strength, viscosity, surface characteristics, wavelength and software algorithms; uses similar deployment methods, where relevant; has similar principles of operation and critical performance requirements; — Biological: the device uses the same materials or substances in contact with the same human tissues or body fluids for a similar kind and duration of contact and similar release characteristics of substances, including degradation products and leachables; — Clinical: the device is used for the same clinical condition or purpose, including similar severity and stage of disease, at the same site in the body, in a similar population, including as regards age, anatomy and physiology; has the same kind of user; has similar relevant critical performance in view of the expected	A clinical evaluation may be based on clinical data relating to a device for which equivalence to the device in question can be demonstrated. The following technical, biological and clinical characteristics shall be taken into consideration for the demonstration of equivalence: — Technical: the device is of similar design; is used under similar conditions of use; has similar specifications and properties including physicochemical properties such as intensity of energy, tensile strength, viscosity, surface characteristics, wavelength and software algorithms; uses similar deployment methods, where relevant; has similar principles of operation and critical performance requirements; — Biological: the device uses the same **or similar** materials or substances in contact with the same human tissues or body fluids for a similar kind and duration of contact and similar release characteristics of substances, including degradation products and leachables; — Clinical: the device is used for the same **or similar** clinical condition or purpose, including similar severity and stage of disease, at the same site in the body, in a similar population, including as regards age, anatomy and physiology; has the same kind of user; has similar relevant critical performance in view of the expected clinical effect for a specific intended purpose. The characteristics listed in the first paragraph shall be similar to the extent that there would be no clinically significant difference in the safety and clinical	A clinical evaluation may be based on clinical data relating to a device for which equivalence to the device in question can be demonstrated. The following technical, biological and clinical characteristics shall be taken into consideration for the demonstration of equivalence: — Technical: the device is of similar design; is used under similar conditions of use; has similar specifications and properties including physicochemical properties such as intensity of energy, tensile strength, viscosity, surface characteristics, wavelength and software algorithms; uses similar deployment methods, where relevant; has similar principles of operation and critical performance requirements; — Biological: the device uses the same **or similar** materials or substances in contact with the same human tissues or body fluids for a similar kind and duration of contact and similar release characteristics of substances, including degradation products and leachables; — Clinical: the device is used for the same ~~**or similar**~~ clinical condition or purpose, including similar severity and stage of disease, at the same site in the body, in a similar population, including as regards age, anatomy and physiology; has the same kind of user; has similar relevant critical performance in view of the expected clinical effect for a specific intended purpose. The characteristics listed in the first paragraph shall be similar to the extent that there would be no clinically significant difference in the safety and clinical performance of the device. Considerations of equivalence shall be based on proper scientific justification. **The device with which they are claiming equivalence must not have claimed equivalence to another device, and must have undergone clinical studies and generated clinical data for it's clinical evaluation.** It shall be

	clinical effect for a specific intended purpose. The characteristics listed in the first paragraph shall be similar to the extent that there would be no clinically significant difference in the safety and clinical performance of the device. Considerations of equivalence shall be based on proper scientific justification. It shall be clearly demonstrated that manufacturers have sufficient levels of access to the data relating to devices with which they are claiming equivalence in order to justify their claims of equivalence.	performance of the device. Considerations of equivalence shall be based on proper scientific justification. It shall be clearly demonstrated that manufacturers have sufficient levels of access to the data relating to devices with which they are claiming equivalence in order to justify their claims of equivalence.	clearly demonstrated that manufacturers have sufficient levels of access to the data relating to devices with which they are claiming equivalence in order to justify their claims of equivalence.