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: IVDR

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) 2017/746 on medical devices (IVDR)	
TOPIC: RISK-ADAPTIVE SURVEILLANCE	
Insertion point	**Function**
Article 48(13)(b)	Empower Commission to specify detailed criteria and modalities by implementing acts
New Article 48c	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) 2017/746

Regulation (EU) 2017/746 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 (79) 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.

III. Art. 29 paragraph 1 shall be replaced as follows:

For companion diagnostics, class C devices for self-testing **and near patient testing** and D devices, other than devices for performance studies, the manufacturer shall draw up a summary of safety and performance.

The summary of safety and performance shall be written in a way that is clear to the intended user.

The draft of the summary of safety and performance shall be part of the documentation to be submitted to the notified body involved in the conformity assessment pursuant to Article 48. The manufacturer shall ensure that the summary of safety and performance is available to the public in Eudamed and shall mention on the label or instructions for use where the summary is available.

IV. Art. 48 paragraph 13 shall be replaced as follows:

(b) criteria for the adoption of a risk-adaptive surveillance system as specified in Article 48c 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. 48c "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 48 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 48 paragraph 13(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 82 and 84 and post-market surveillance indicators, including trend reports under Article 83;

f. incomplete or untimely fulfilment of reporting and submission obligations, including to periodic safety update reports referred to in Article 81, post-market surveillance reports referred to in Article 80 and trend reports under Article 83; 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 81 shall be replaced as follows:

a. Paragraph 1. Manufacturers of class C and class D devices shall prepare a periodic safety update report ('PSUR') for each device, or where relevant, for each category or group of devices, summarising the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan referred to in Article 79, together with a description of any preventive and corrective actions taken, including their rationale. 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 PMPF; 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 D 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 C 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.

b. Paragraph 2. **For class C devices** and class D devices, the notified body shall review the PSUR during surveillance assessments. The manufacturer and notified body shall make such PSURs and the evaluation by the notified body available to competent authorities through the electronic system referred to in Article 87.

VII. Annex VI shall be amended as follows:

Part A, add 2.15

2.15. 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 48c;**

(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 48c.**

— 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;

–leverage evidence from previous assessments performed**, also as further specified in Article 48c 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 48c,** for class B and class C 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 48c.** 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 48c,**

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 B and class C 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 at least one** representative device selected as follows:

– for class B devices, **at least** one device **per category of device**;
– for class C devices, **at least** one device per generic device group.

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 device**(s)** 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 (79), 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 48c., 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 48c** 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 48c** 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. 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 48c** take samples of devices from the market to verify that the manufactured device is in conformity with the technical documentation. 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 B and class C 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. 48c for each category and each generic device group.**

For near-patient testing devices, sampling shall not be applied; instead, a focused review of performance and usability studies shall be conducted for each device.

This assessment shall be conducted in addition to the relevant post-market surveillance documentation, including the post-market surveillance report referred to in Article 80 or the periodic safety update report referred to in Article 81, as applicable.

g. Section 4.12 is replaced by the following:

To verify conformity of manufactured class D devices, the manufacturer shall carry out tests on each manufactured batch of devices. After the conclusion of the controls and tests, it shall forward to the notified body, without delay, the relevant reports on those tests. Furthermore, the manufacturer shall make the samples of manufactured batches of devices available to the notified body in accordance with pre-agreed conditions and detailed arrangements which shall include that manufacturer shall send samples of the manufactured batches of devices to the EU reference laboratory, where such a laboratory has been designated in accordance with Article 100, to carry out appropriate tests. The EU reference laboratory shall inform the notified body about its findings.

Where no EU reference laboratory has been designated in accordance with Article 100, those arrangements may include that the notified body conducts verification of samples or batches by alternative means.

The frequency of batch testing performed by the EURL after the initial testing, except transmissible agents first-line assays falling under the first indent of rule 1 section 2 Annex VIII, may be adjusted according to the applicable level of surveillance pursuant to Art. 48c, taking into account the number of lots produced in the previous year. Where the calculated number of batches to be tested is less than one, at least one batch per year shall be tested for every manufacturer.

X. Annex XI shall be amended as follows:

Section 5.1 is replaced by the following:

In the case of class D devices, the manufacturer shall carry out tests on each manufactured batch of devices. After the conclusion of the controls and tests, it shall forward to the notified body without delay the relevant reports on those tests. Furthermore, the manufacturer shall make samples of manufactured devices or batches of devices available to the notified body in accordance with pre-agreed conditions and detailed arrangements which shall include that the manufacturer, shall send samples of the manufactured devices or batches of devices to an EU reference laboratory, where such a laboratory has been designated in accordance with Article 100, to carry out appropriate laboratory tests. The EU reference laboratory shall inform the notified body about its findings.

Where no EU reference laboratory has been designated in accordance with Article 100, those arrangements may include that the notified body conducts verification of samples or batches by alternative means.

The frequency of batch testing performed by the EURL after the initial testing, except transmissible agents first-line assays falling under the first indent of rule 1 section 2 Annex VIII, may be adjusted according to the applicable level of surveillance pursuant to Art. 48c, taking into account the number of lots produced in the previous year. Where the calculated number of batches to be tested is less than one, at least one batch per year shall be tested for every manufacturer.

XI. Annex XIII shall be amended as follows:

Section 1.2.3 is replaced by the following:

2.3 Demonstration of the clinical performance

The manufacturer shall demonstrate the clinical performance of the device in relation to all the parameters described in point (b) of Section 9.1. of Annex I, unless any omission can be justified as not applicable.

Demonstration of the clinical performance of a device shall be based on one or a combination of the following sources:
–clinical performance studies, **including interventional and observational,** of the device concerned or of a device for which equivalence to the device concerned can be demonstrated;
–other studies published in scientific literature on the device concerned or of a device for which equivalence to the device concerned can be demonstrated;
–other clinical experience published in peer-reviewed scientific literature with the device concerned or a device for which equivalence to the device concerned can be demonstrated;
–clinically relevant information coming from post-market surveillance, in particular the PMPF;
–published experience gained by routine diagnostic testing.

Clinical performance studies shall be performed unless due justification is provided for relying on other sources of clinical performance data.

Clinical performance shall be demonstrated and documented in a dedicated section of the performance evaluation report, **in accordance to the outlined aims and methods for clinical performance demonstration in the performance evaluation report as referred to in Annex XIII, Part A 1.1.**
In line with the definition of equivalence provided in MDR Annex XIV, Part A, Section 3, the manufacturer shall demonstrate that the devices in question share comparable characteristics in terms of design and specifications relevant to analytical performance, intended purpose, target population and

target users, such that no clinically significant differences in safety and performance would be expected.

To allow conformity assessment, the manufacturer shall provide clear evidence that sufficient data related to the equivalent device is available and presented to adequately justify the equivalence claim. If these conditions are not fulfilled, analytical and/or clinical performance studies will be required to support the performance claims.

The notified body shall, where the clinical performance is based partly or totally on data from devices that are claimed to be equivalent to the device under assessment, assess the suitability of using such data.

ANNEX. SYNOPSIS OF THE LEGISLATIVE VERSIONS AND PROPOSAL

	IVDR Regulation (EU) 2017/746	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**		
	IVDR	**IVDR COMMISSION Draft Regulation**	**COMPLEMENTARY Proposal**
Article 48(13) **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,** […]	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 48c 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 48c	/	/	**Article 48c [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 48 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 48 paragraph 13(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 82 and 84 and post-market surveillance indicators, including trend reports under Article 83; f. incomplete or untimely fulfilment of reporting and submission obligations, including to periodic safety update reports referred to in Article 81, post-market surveillance reports referred to in Article 80 and trend reports under Article 83; 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 surveillance audits and assessments only once every 24 months.“**	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 48c., the audit approach may be adapted accordingly.**

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 48c.** 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 48c,**
2.	**Unnanounced Audits**		
	IVDR	**IVDR 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 procedures that are sufficient to effectively conduct the conformity assessment activities for which the notified body in	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	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:

	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.	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; **–leverage evidence from previous assessments performed** 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.	[…] — 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 48c;** — 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 48c.** — 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; –leverage evidence from previous assessments performed**, also as further specified in Article 48c 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.
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	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	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**

	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.	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.	**level of risk-adaptive surveillance as specified in Article 48c** 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 (79), 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**		
	IVDR	**IVDR COMMISSION Draft Regulation**	**COMPLEMENTARY Proposal**
Annex VII, Section 4.5.2(a), indent 4	— draw up and keep up to date, for class B and class C 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 over the period of validity of the certificate, and	– clearly identify, for class B and class C devices, the representative devices selected for the assessment of technical documentation as referred to in Annexes II and III, and;	— draw up and keep up to date **in accordance with the applicable level of surveillance referred to in Article 48c,** for class B and class C 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**
Annex IX, Section 3.5, paragraph 1	In the case of class B and C 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	In the case of class B and class C devices, during the surveillance assessment the notified body may include a 'for-cause' assessment of the technical documentation of representative devices where the notified body has identified potential concerns on the basis of post-market	In the case of class B and class C 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 rationale documented by the notified body in accordance with the third paragraph of Section 2.3.	surveillance data or other duly justified grounds.	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. 48c for each category and each generic device group.** **For near-patient testing devices, sampling shall not be applied; instead, a focused review of performance and usability studies shall be conducted for each device.** **This assessment shall be conducted in addition to the relevant post-market surveillance documentation, including the post-market surveillance report referred to in Article 80 or the periodic safety update report referred to in Article 81, as applicable.**
4.	**Sampling during surveillance**		
	IVDR	**IVDR COMMISSION Draft Regulation** Annex IX 3.5	**COMPLEMENTARY Proposal**
Annex VII, Section 4.5.1., tenth 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. 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: — […]	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: […]	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— relating to the sampling of devices, verify that the manufactured device is in conformity with the technical documentation; such requirements

	tenth 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,	tenth 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,	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 48c.**
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. 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 documentation. Prior to the sampling, the notified body in question shall specify the relevant sampling criteria and testing procedure.	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. 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. Prior to the sampling, the notified body in question shall specify the relevant sampling criteria and testing procedure. .	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 48c** 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. 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 48c** take samples of devices from the market to verify that the manufactured device is in conformity with the technical documentation. Prior to the sampling, the notified body in question shall specify the relevant sampling criteria and testing procedure.
5.	**Periodic review**		
	IVDR	**IVDR 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.	The notified body shall have documented procedures in place relating to periodic reviews of approved quality management systems or EU technical documentation	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

	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.	assessment certificates or EU type-examination certificates. [...]	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**		
	IVDR	**IVDR 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 covered by those standards or CS, unless it duly substantiates not doing so.	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, 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 B and C devices, the quality management system assessment shall be accompanied by the assessment of the technical documentation	Moreover, in the case of class B and class C devices, the quality management system assessment shall be accompanied by the assessment of the technical documentation, as referred to	Moreover, in the case of class B and class C 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

	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 99 and in particular, the novelty of the technology, the potential impact on the patient and standard medical practice, similarities in design, technology, manufacturing and, where applicable, sterilisation methods, the intended purpose and the results of any previous relevant assessments that have been carried out in accordance with this Regulation. The notified body in question shall document its rationale for the samples taken.	in Annexes II and III, as specified in Sections 4.3. to 4.8., for a representative device selected as follows: – for class B devices, **one device;** – for class C devices, one device per generic device group. 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 novelty of the technology, the novelty of the analyte and/or marker being detected, the potential impact on the patient and standard medical practice, similarities in design, technology, manufacturing and, where applicable, 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 that have been carried out in accordance with this Regulation. The notified body in question shall document its rationale for the representative device taken. 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.	Sections 4.3. to 4.8., **for at least one** representative device selected as follows: – for class B devices, **at least** one device **per category of device;** – for class C devices, **at least** one device per generic device group. 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 device**(s)** 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 (79), 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)**		
	IVDR	**IVDR COMMISSION Draft Regulation**	**COMPLEMENTARY Proposal**

Article 2(79) – "for cause"	**-**	**-**	**Article 2(79) [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**		
	IVDR	**IVDR 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 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 surveillance audits and assessments only once every 24 months.“**	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 48c., the audit approach may be adapted accordingly.**
9.	**Periodic safety update report (‘PSUR’)**		
	IVDR	**IVDR COMMISSION Draft Regulation**	**COMPLEMENTARY Proposal**
Article 81(1)	Manufacturers of class C and class D devices shall prepare a periodic safety update report (‘PSUR’) for each device and where	Manufacturers of class C and class D devices shall prepare a periodic safety update report (‘PSUR’) for each device, or where relevant, for	Manufacturers of class C and class D devices shall prepare a periodic safety update report (‘PSUR’) for each device, or where relevant, for each category or group of devices,

	relevant for each category or group of devices summarising the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan referred to in Article 79 together with a 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; (b) the main findings of the PMPF; 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 C and D devices shall update the PSUR at least annually. That PSUR shall be part of the technical documentation as specified in Annexes II and III.	each category or group of devices, summarising the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan referred to in Article 79, together with a description of any preventive and corrective actions taken, including their rationale. 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 PMPF; 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 C and class D devices shall update the PSUR in the first year after the certificate is issued and every two years thereafter or when there is a significant change in the benefit-risk determination or in the acceptability of erroneous results. That PSUR shall be part of the technical documentation specified in Annex III.**	summarising the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan referred to in Article 79, together with a description of any preventive and corrective actions taken, including their rationale. 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 PMPF; 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 D 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 C 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.**
Article 81(2)	Manufacturers of class D devices shall submit PSUR by means of the electronic system referred to in Article 87 to the notified body involved in	**For class D devices**, the notified body shall review the PSUR during the surveillance assessment. The manufacturer and notified body shall make such PSURs	**For Class C devices and Class D devices**, the notified body shall review the PSUR during surveillance assessments. The manufacturer and notified body shall make such PSURs and the

	the conformity assessment of such devices in accordance with Article 48. The notified body shall review the report and add its evaluation to that electronic system with details of any action taken. Such PSUR and the evaluation by the notified body shall be made available to competent authorities through that electronic system.	and the evaluation by the notified body available to the competent authorities through the electronic system referred to in Article 87.	evaluation by the notified body available to competent authorities through the electronic system referred to in Article 87.
10.	**Clinical evidence & equivalence**		
	IVDR	**IVDR COMMISSION Draft Regulation**	**COMPLEMENTARY Proposal**
Annex VI, Part A_2	**-**	**-**	**<u>Annex VI, Part A 2.15. [New]</u>** **<u>2.15. method of clinical evidence generation, including whether equivalence has been claimed to an existing device on the Union market.</u>**
Annex XIII, Section 1.2.3	Demonstration of the clinical performance The manufacturer shall demonstrate the clinical performance of the device in relation to all the parameters described in point (b) of Section 9.1. of Annex I, unless any omission can be justified as not applicable. Demonstration of the clinical performance of a device shall be based on one or a combination of the following sources: — clinical performance studies; — scientific peer-reviewed literature; — published experience gained by routine diagnostic testing.	Demonstration of the clinical performance The manufacturer shall demonstrate the clinical performance of the device in relation to all the parameters described in point (b) of Section 9.1. of Annex I, unless any omission can be justified as not applicable. **Demonstration of the clinical performance of a device shall be based on one or a combination of the following sources:** **– clinical performance studies of the device concerned or of a device for which equivalence to the device concerned can be demonstrated;** **– other studies published in scientific literature on the device concerned or of a device for which**	Demonstration of the clinical performance The manufacturer shall demonstrate the clinical performance of the device in relation to all the parameters described in point (b) of Section 9.1. of Annex I, unless any omission can be justified as not applicable. Demonstration of the clinical performance of a device shall be based on one or a combination of the following sources: –clinical performance studies, **<u>including interventional and observational,</u>** of the device concerned or of a device for which equivalence to the device concerned can be demonstrated; –other studies published in scientific literature on the device concerned or of a device for which equivalence to the device concerned can be demonstrated;

	Clinical performance studies shall be performed unless due justification is provided for relying on other sources of clinical performance data. Clinical performance shall be demonstrated and documented in the clinical performance report.	**equivalence to the device concerned can be demonstrated;** **– other clinical experience published in peer-reviewed scientific literature with the device concerned or a device for which equivalence to the device concerned can be demonstrated;** **– clinically relevant information coming from post-market surveillance, in particular the PMPF;** **– published experience gained by routine diagnostic testing.** **Clinical performance studies shall be performed unless due justification is provided for relying on other sources of clinical performance data.** **Clinical performance shall be demonstrated and documented in a dedicated section of the performance evaluation report.**	–other clinical experience published in peer-reviewed scientific literature with the device concerned or a device for which equivalence to the device concerned can be demonstrated; –clinically relevant information coming from post-market surveillance, in particular the PMPF; –published experience gained by routine diagnostic testing. Clinical performance studies shall be performed unless due justification is provided for relying on other sources of clinical performance data. Clinical performance shall be demonstrated and documented in a dedicated section of the performance evaluation report**, in accordance to the outlined aims and methods for clinical performance demonstration in the performance evaluation report as referred to in Annex XIII, Part A 1.1.** **In line with the definition of equivalence provided in MDR Annex XIV, Part A, Section 3, the manufacturer shall demonstrate that the devices in question share comparable characteristics in terms of design and specifications relevant to analytical performance, intended purpose, target population and target users, such that no clinically significant differences in safety and performance would be expected.** **To allow conformity assessment, the manufacturer shall provide clear evidence that sufficient data related to the equivalent device is available and presented to adequately justify the equivalence claim. If these conditions are not fulfilled, analytical and/or clinical performance studies will be required to support the performance claims.** **The notified body shall, where the clinical performance is based partly or totally on data from**

			devices that are claimed to be equivalent to the device under assessment, assess the suitability of using such data.
11.	**Summary of safety and performance**		
	IVDR	**IVDR COMMISSION Draft Regulation**	**ALTERNATIVE Proposal**
Article 29(1)	For class C and D devices, other than devices for performance studies, the manufacturer shall draw up a summary of safety and performance. The summary of safety and performance shall be written in a way that is clear to the intended user and, if relevant, to the patient and shall be made available to the public via Eudamed. The draft of the summary of safety and performance shall be part of the documentation to be submitted to the notified body involved in the conformity assessment pursuant to Article 48 and shall be validated by that body. After its validation, the notified body shall upload the summary to Eudamed. The manufacturer shall mention on the label or instructions for use where the summary is available.	For companion diagnostics, class C devices for self-testing and D devices, other than devices for performance studies, the manufacturer shall draw up a summary of safety and performance. The summary of safety and performance shall be written in a way that is clear to the intended user. The draft of the summary of safety and performance shall be part of the documentation to be submitted to the notified body involved in the conformity assessment pursuant to Article 48.The manufacturer shall ensure that the summary of safety and performance is available to the public in Eudamed and shall mention on the label or instructions for use where the summary is available.	For companion diagnostics, class C devices for self-testing **and near patient testing** and D devices, other than devices for performance studies, the manufacturer shall draw up a summary of safety and performance. The summary of safety and performance shall be written in a way that is clear to the intended user. The draft of the summary of safety and performance shall be part of the documentation to be submitted to the notified body involved in the conformity assessment pursuant to Article 48. The manufacturer shall ensure that the summary of safety and performance is available to the public in Eudamed and shall mention on the label or instructions for use where the summary is available.
12.	**Batch testing**		
	IVDR	**IVDR COMMISSION Draft Regulation**	**ALTERNATIVE Proposal**
Annex IX, Section 4.12	To verify conformity of manufactured class D devices, the manufacturer shall carry out tests on	To verify conformity of manufactured class D devices, the manufacturer shall carry out tests on each	To verify conformity of manufactured class D devices, the manufacturer shall carry out tests on each manufactured batch of

	each manufactured batch of devices. After the conclusion of the controls and tests, it shall forward to the notified body, without delay, the relevant reports on those tests. Furthermore, the manufacturer shall make the samples of manufactured batches of devices available to the notified body in accordance with pre-agreed conditions and detailed arrangements which shall include that the notified body or the manufacturer shall send samples of the manufactured batches of devices to the EU reference laboratory, where such a laboratory has been designated in accordance with Article 100, to carry out appropriate tests. The EU reference laboratory shall inform the notified body about its findings.	manufactured batch of devices. After the conclusion of the controls and tests, it shall forward to the notified body, without delay, the relevant reports on those tests. Furthermore, the manufacturer shall make the samples of manufactured batches of devices available to the notified body in accordance with pre-agreed conditions and detailed arrangements which shall include that the manufacturer shall send samples of the manufactured batches of devices to the EU reference laboratory, where such a laboratory has been designated in accordance with Article 100, to carry out appropriate tests. The EU reference laboratory shall inform the notified body about its findings. Where no EU reference laboratory has been designated in accordance with Article 100, those arrangements may include that the notified body conducts verification of samples or batches by alternative means.	devices. After the conclusion of the controls and tests, it shall forward to the notified body, without delay, the relevant reports on those tests. Furthermore, the manufacturer shall make the samples of manufactured batches of devices available to the notified body in accordance with pre-agreed conditions and detailed arrangements which shall include that manufacturer shall send samples of the manufactured batches of devices to the EU reference laboratory, where such a laboratory has been designated in accordance with Article 100, to carry out appropriate tests. The EU reference laboratory shall inform the notified body about its findings. Where no EU reference laboratory has been designated in accordance with Article 100, those arrangements may include that the notified body conducts verification of samples or batches by alternative means. **The frequency of batch testing performed by the EURL after the initial testing, except transmissible agents first-line assays falling under the first indent of rule 1 section 2 Annex VIII, may be adjusted according to the applicable level of surveillance pursuant to Art. 48c, taking into account the number of lots produced in the previous year. Where the calculated number of batches to be tested is less than one, at least one batch per year shall be tested for every manufacturer.**
Annex XI, **Section 5.1**	In the case of class D devices, the manufacturer shall carry out tests on each manufactured batch of devices. After the conclusion of the controls and tests, it shall forward to the notified body without delay the relevant reports on those tests. Furthermore, the manufacturer shall make samples of manufactured	In the case of class D devices, the manufacturer shall carry out tests on each manufactured batch of devices. After the conclusion of the controls and tests, it shall forward to the notified body without delay the relevant reports on those tests. Furthermore, the manufacturer shall make samples of manufactured devices or batches of devices	In the case of class D devices, the manufacturer shall carry out tests on each manufactured batch of devices. After the conclusion of the controls and tests, it shall forward to the notified body without delay the relevant reports on those tests. Furthermore, the manufacturer shall make samples of manufactured devices or batches of devices available to the notified body in accordance with pre-agreed conditions and detailed

	devices or batches of devices available to the notified body in accordance with pre-agreed conditions and detailed arrangements which shall include that the notified body or the manufacturer, shall send samples of the manufactured devices or batches of devices to an EU reference laboratory, where such a laboratory has been designated in accordance with Article 100, to carry out appropriate laboratory tests. The EU reference laboratory shall inform the notified body about its findings.	available to the notified body in accordance with pre-agreed conditions and detailed arrangements which shall include that the manufacturer, shall send samples of the manufactured devices or batches of devices to an EU reference laboratory, where such a laboratory has been designated in accordance with Article 100, to carry out appropriate laboratory tests. The EU reference laboratory shall inform the notified body about its findings. Where no EU reference laboratory has been designated in accordance with Article 100, those arrangements may include that the notified body conducts verification of samples or batches by alternative means.	arrangements which shall include that the manufacturer, shall send samples of the manufactured devices or batches of devices to an EU reference laboratory, where such a laboratory has been designated in accordance with Article 100, to carry out appropriate laboratory tests. The EU reference laboratory shall inform the notified body about its findings. Where no EU reference laboratory has been designated in accordance with Article 100, those arrangements may include that the notified body conducts verification of samples or batches by alternative means. **The frequency of batch testing performed by the EURL after the initial testing, except transmissible agents first-line assays falling under the first indent of rule 1 section 2 Annex VIII, may be adjusted according to the applicable level of surveillance pursuant to Art. 48c, taking into account the number of lots produced in the previous year. Where the calculated number of batches to be tested is less than one, at least one batch per year shall be tested for every manufacturer.**