The European Association of Medical devices Notified Bodies

MD/IVD targeted revision of EU rules

"Have your say"

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1. Introduction

This document presents the outcome of a structured notified body review in response to the proposed targeted revision of the EU Medical Devices and In Vitro Diagnostic Regulations. Approximately 50 notified body experts, representing a broad range of technical, clinical and regulatory expertise, contributed to this work.

The experts were organised into four dedicated task forces, each focusing on one of the key thematic areas affected by the proposed revision. The work was carried out through coordinated drafting, technical exchanges and iterative consolidation across task forces to ensure consistency and coherence of the overall message. The work was coordinated by Team-NB, while participation in the taskforces was open to all notified bodies, including non-Team-NB members.

The four task forces addressed the following core topics:

- **Governance**, including Union-level coordination, expert panel structures and system-level efficiency;
- **Safety**, with a focus on maintaining preventive regulatory safeguards across the device lifecycle;
- **Clinical evaluation**, including well-established technologies (WET), Article 61(10) and equivalence;
- **Notified Body requirements**, covering designation, monitoring, surveillance, competency and sustainability of the notified body system.

The proposals, concerns and suggested solutions developed by the task forces have been consolidated into this document. Together, they reflect the collective experience of notified bodies gained through MDR and IVDR implementation and aim to support a revision framework that maintains patient safety, regulatory robustness and legal certainty, while improving predictability and operational efficiency.

2. Governance

2.1. Strengthening Union governance through a Medical Devices Coordination Office (MDCO)

Purpose and scope

Persistent structural inefficiencies in the implementation of the MDR and IVDR affect predictability, consistency, and timeliness of Union-level processes. To address these issues, Team-NB proposes the establishment of a **Medical Devices Coordination Office (MDCO)**.

MDCO would consolidate and professionalise **procedural, logistical, and operational activities** that are currently distributed across multiple structures, including MDCG and its working groups, Commission services, EMA secretariats, and national authorities. MDCO would not assume regulatory decision-making, policy-setting, or scientific responsibilities.

MDCO in the EU Governance Architecture

MDCO serves as the **administrative backbone** of the EU medical device and IVD system. While MDCG retains strategic and policy-setting functions, MDCO provides:

- day-to-day coordination of regulatory workflows
- structured procedural support for regulatory and scientific processes
- management of timelines, documentation and workflows
- long-term stable operational infrastructure

NBCG-Med is integrated into the MDCG architecture. MDCO provides the operational framework enabling NBCG-Med to function effectively, deliver harmonised technical coordination and report systematically into the MDCG structure.
The idea for MDCO was inspired by the AI Act's governance framework. In comparison, we noticed that the MDR/IVDR framework doesn't include a body equivalent to the AI Office by means of role and centrally provided resources. A gap that the MDCO would close.

Role allocation (applies throughout Sections 1.1–1.8):

- **Member States and the Commission** retain full regulatory authority and decision-making responsibility.
- **NBCG-Med** provides notified body coordination and harmonisation, supported operationally by MDCO.
- **EMA and Expert Panels** retain all scientific, methodological and clinical responsibilities.
- **MDCO** covers all non-scientific operational tasks and ensures coherence across the system.

This reflects a stable structure based on **policy (MDCG) – science (Expert Panels & EMA) – operations (MDCO)**.

Integration of NBCG-Med Technical Secretariat Into MDCO

Integrating the EU4Health-funded NBCG-Med technical secretariat into MDCO ensures a stable and coherent foundation for Union-level NB coordination. MDCO supports NBCG-Med by providing:

- long-term continuity for NB coordination
- strengthened methodological alignment across NBs
- harmonised templates, procedures and workflows
- facilitation of cross-NB exchange of best practices
- a coherent procedural interface between NBs and Expert Panels
- integrated operational support for NB experts' contributions to
    - borderline and classification cases
    - Breakthrough (BtX) and Orphan processes
    - scientific advice procedures
- support for literature-screening methodologies and tools as described in **section 1.7**

Structured, non-scientific support enables NBCG-Med to fulfil its role in the MDCG-ecosystem.

All assessment of evidence and conformity-assessment judgements remain exclusively with NBs.

A Coherent Procedural Interface Between NBs and Expert Panels

To ensure transparency, proportionality and consistency in Union-level regulatory processes, MDCO would establish and maintain a **coherent procedural interface** between NBs and Expert Panels. This would include:

- secure and structured channels for exchange between notified body experts and Expert Panels in borderline/classification, BtX/Orphan and scientific advice workflows
- a pre-opinion procedural dialogue mechanism for CECP (Clinical Evaluation Consultation Procedure) enabling mutual clarification in complex cases
- supporting structured follow-up on Expert Panel opinions in CECP (excluding any scientific involvement)
- alignment of timelines and document formats to avoid procedural bottlenecks
- routing NB questions to Expert Panels on the regulatory status of a product (MDR art 4a (1))
- ensuring independence safeguards and conflict-of-interest rules while enabling efficient cooperation

Scientific positions remain under the exclusive responsibility of the Expert Panels, supported by EMA.

MDCO Support for other Union-level operational tasks that fall outside the remit of notified bodies

These activities reflect potential improvements to EU-level procedural efficiency.
Note: these **are suggestions only**, as defining MDCG, Member State or sandbox support is not within the remit of notified bodies.

- **Procedural and logistic support to MDCG and its subgroups,** including organisation of meetings, agenda preparation, document management, minutes and follow-up actions, coordination of timelines, and maintenance of shared working platforms.

This support should ensure continuity, transparency and efficiency of MDCG activities, without interfering with policy-setting, regulatory decision-making or the substantive content of discussions.

- **Procedural support for NB designation, joint assessments and monitoring**, including organisation of Joint Assessment Teams, coordination of expert availability, management of assessment documentation, consistent use of templates, support for remote or hybrid assessments, maintenance of NB information (scope, performance history, monitoring status), and tools for sampling, case selection and risk-based monitoring
  Relevant MDR/IVDR provisions: MDR: Art. 38–44 (designation, JATs, monitoring), Annex VII; IVDR: Art. 31 (designation, monitoring), Annex VII)
- **Procedural support for Member State and Commission derogation mechanisms** supporting the procedural organisation, documentation pathways and coordination steps linked to Member State derogations under MDR Articles 59 and 59a, IVDR Articles 54 and 54a, including structured communication channels, harmonised templates, secure information exchange and optional MDCO-facilitated coordination among Member States when a derogation has cross-border relevance; ensuring alignment of timelines, document formats, and procedural notifications while fully respecting that **derogation decisions remain exclusively within Member State and Commission authority**.
  Relevant MDR/IVDR provisions: MDR Articles 59 -59a, IVDR Articles 54-54a.
- **Procedural support for Member State vigilance coordination**, including harmonised templates, structured cross-border workflows and secure platforms for information exchange.
  Relevant MDR/IVDR provisions: MDR: Art. 87–90; IVDR: Art. 82–86
- **Union-wide training and harmonisation support for national authorities**, including coordinated training programmes, common guidance libraries, harmonisation workshops and structured knowledge-exchange platforms.
- **Coordination of regulatory sandboxes**, including intake and validation of applications, facilitation of Member State cooperation, maintenance of sandbox documentation and coordination of reporting to MDCG and the Commission.
  Relevant MDR/IVDR provisions: MDR: Art. 59b–59c; IVDR: Art. 54b–54c.

Summary of operational benefits of establishing MDCO

By consolidating currently fragmented operational activities, MDCO would support

- predictable and efficient Union-level processes
- reduced fragmentation across Member States
- more consistent NB coordination
- more coherent support for Expert Panels
- clearer processes for manufacturers, including SMEs

2.2. Establish a clear governance model for expert panels

Clear governance arrangements for Expert Panels are essential to ensure transparency, predictability, and consistent integration of scientific advice into Union-level processes. To achieve this, Team-NB proposes that the new governance model should clarify:

- **The interaction between Expert Panels and NBCG-Med**, describing that NBCG-Med provides a forum for coordination and exchange.
- **How expert panel outputs are integrated into Union processes**, including classification, qualification, and the evaluation of applications for Breakthrough and Orphan designations, in a manner that ensures proportionality, consistency, and timely decision-making.

This structure would ensure transparency, reinforce the independence of scientific advice, and provide a clear and coherent framework for the participation of NB experts in Expert Panel activities.

2.3. Allow NB personnel to contribute under strict independence and impartiality safeguards

Notified body personnel possess validated regulatory and technical expertise assessed by national designating authorities. Their participation can strengthen the scientific and regulatory robustness of Expert Panels, provided strict safeguards ensure independence and impartiality.

Team-NB proposal

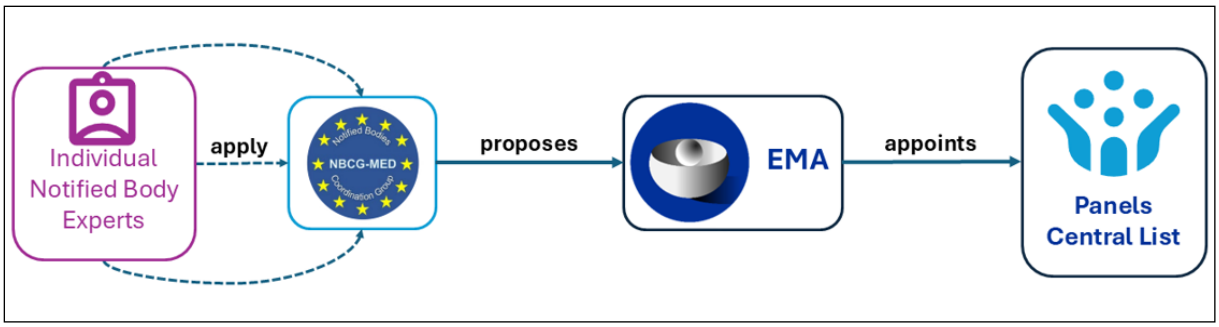
1) **NB experts apply and are appointed as individual professionals**, not as representatives of their notified body;
2) **Nomination via NBCG-Med**, which compiles a balanced shortlist ensuring no NB is over-represented.
3) **Appointment by EMA and/or Commission**
4) **Strict role separation** applies, including:
   To ensure independence and avoid conflicts of interest while maintaining NB operational capacity, the following principles apply:

- **No involvement in directly related cases**
  An NB expert who has contributed to an Expert Panel opinion shall not be involved in any procedure directly relating to that specific Expert Panel opinion, including subsequent assessments for the same device. (Note - this must not preclude other experts from that NB working on subsequent submissions for the same device or from the same manufacturer).
- **No assessment of devices previously assessed by the expert's NB**
  NB experts must not participate in Expert Panel discussions or opinions concerning devices that have been assessed by their own NB in the context of conformity assessment.

5) **Transparency requirements** apply equally to NB experts and other panel members.
6) **Regulatory Adjustments Needed**
   As a prerequisite for any scheme involving NB personnel in expert panels, existing policies and procedures of the Commission and EMA would need to be revised to reflect the impartial and independently supervised nature of NBs, such as EC Decision 2019/1396, Art. 12 (2): "Advisor shall not have financial or other interests in the medical device industry or in a notified body [...]").

Please be referred to Figure 1 for schematic reflection of the process

Fig 1. Overview of NB experts' route for appointment into Expert Panels



Team-NB draft text (Article 106(2) (MDR only)):
"Expert panels may include personnel from notified bodies, appointed as individual experts. Such experts shall comply with the applicable independence and impartiality requirements, including recusal from any procedure directly related to an opinion to which they have contributed and from expert panel activities concerning devices assessed or to be assessed by their notified body. These limitations apply solely to the individual expert and shall not restrict the notified body from conducting conformity assessment through other qualified personnel. All notified body experts shall be subject to the transparency rules applicable to expert panel members." (see Table, Ref. no. 39)

2.4. Standing expert panels for BtX, Orphan, and Borderline & Classification Functions

Borderline & Classification Standing Expert Panel (Articles 4a, 51a, 51b MDR) (3a, 47a, 47b IVDR)
The new **Article 4a MDR (3a IVDR)** establishes a formal pathway for determining whether a product or group of products falls within the definition of a medical device or accessory, or within the scope of Annex XVI. As per paragraphs 1 and 2, Expert Panel opinions issued under **Article 106** form the scientific basis for subsequent regulatory determinations.

Proposed articles **51a and 51b MDR (47a and 47b IVDR)** introduce an additional pathway for resolving disputes and challenges related to the **classification of CE-marked devices**, including:

- identification of potential misclassification following an evaluation under **Article 94 MDR (89 IVDR)**;
- mandatory coordination and consultation among Member States **(Art 51b(1)–(2) MDR) (47b(1)-(2) IVDR)**;
- referral to an Expert Panel under **Art 51b(3) (47b(3) IVDR)** where a substantiated disagreement is raised;
- adoption of the Member State decision giving **utmost consideration** to the Panel opinion (**Art 51b(4)) (47b(4) IVDR)**.

Additional task for borderline and classification could be:

- Providing feedback to update MDCG classification guidance documents (e.g., Manual on Borderline and classification under EU 2017/756 and 2017/746, MDCG 2021-24 and MDCG 2020-16). Given these responsibilities, the B&C Standing Expert Panel must operate under the full governance framework of **proposed MDR Article 106**.

Because borderline/classification work requires broad regulatory judgement, the NB experts contributing to the B&C Standing Panel should be **seasoned generalists with long-standing**

cross-cutting experience (“eminences grises”), distinct from the technology-specific experts used in thematic clinical or technical panels.

This Standing Panel ensures:

- consistent Union-level interpretation of regulatory status and classification
- timely decisions in the strict deadlines under Article 51b(3) (47b(3) IVDR)
- scientific robustness to support Commission implementing acts
- coherence between Member State practice, MDCG coordination and Expert Panel advice

Standing Expert Panels for Breakthrough (BtX) and Orphan Designations (Article 52a MDR) (48a IVDR)

The **proposed MDR Article 52a** and **proposed IVDR Article 48a** introduce Union-level mechanisms for the designation of:

- **Breakthrough devices / breakthrough IVDs**, and
- **Orphan devices / orphan IVDs**.

These mechanisms are intended to promote access to technologies addressing unmet medical needs, rare conditions, or serious clinical challenges, and may involve **priority review, rolling review and adapted evidence pathways**.

Because BtX and Orphan designations have a *higher regulatory significance* than standard Article 106 advice, and because the proposed MDR/IVDR foresee that Expert Panel recommendations may form the basis for **Union-level regulatory decisions**, Team-NB proposed that the BtX/Orphan Standing Panel:

- has **stable membership**, including **Member State representatives**, ensuring continuity and legitimacy;
- includes academic and NB experts selected under **Article 106(6)** independence rules;
- provides **scientific recommendations capable of being transformed into Union-level legally binding decisions**, similar to the Orphan medicinal product pathway;
- operate under governance rules aligned with Article 106 of the MDR/IVDR.

This Standing Panel should serve **both the MDR and the IVDR**, reflecting that BtX/Orphan mechanisms are introduced in **both proposed Article 52a MDR** and **Article 48a IVDR**. The binding decisions, similar to the orphan medicinal product pathway ensure that NBs are **not exposed to undue liability risks** when certifying devices supported by emerging or incomplete clinical data.

Clinical Expert Panels (Article 61(2) MDR, 56 IVDR)

Under **Article 61(2) MDR**, manufacturers of class IIb and III devices may seek **early scientific advice** on their clinical development strategy. Under **Article 56 IVDR**, manufacturers of class C and D IVDs may seek similar advice on performance evaluation strategies.

These advisory activities represent the role foreseen in **Article 106(1)(e) and 106(7)(a)** and are distinct from the CECP/PECP procedures. Per **Article 106(6)**, NB experts participating in these advisory panels **shall not** be involved in CECP (Article 54 MDR). Thus, Figure 2 correctly shows these Clinical Panels as **ad-hoc advisory groups**, not CECP review panels.

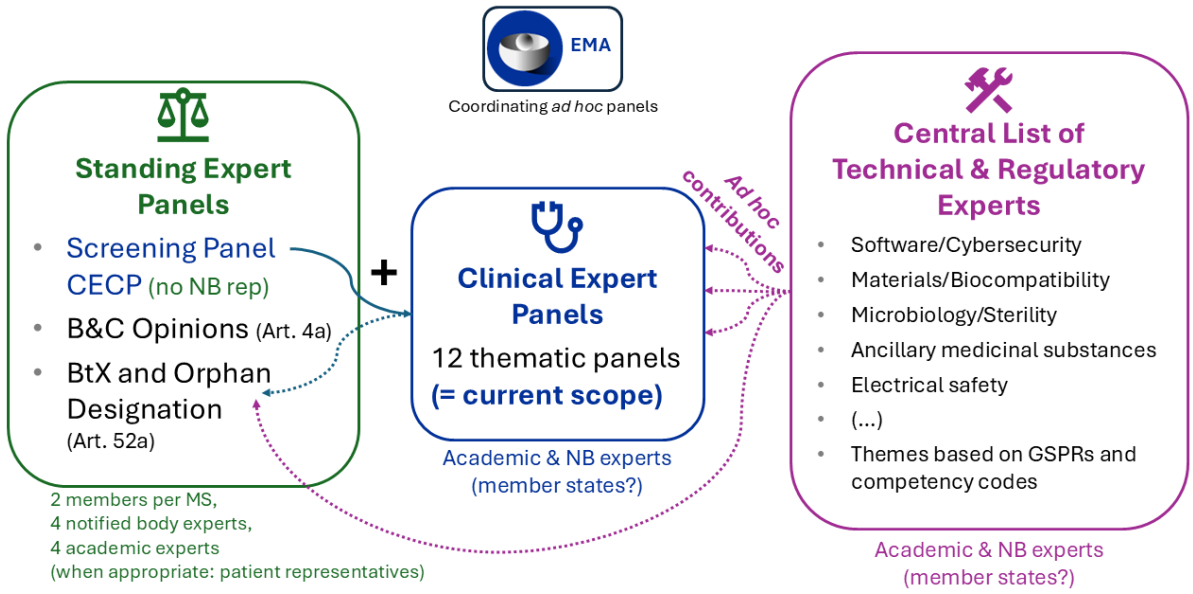
Central List of Technical & Regulatory Experts (Article 106(2))

The central expert pool foreseen in **Article 106(2)** supports Standing Panels and Clinical Panels in domains such as:

- software, cybersecurity
- biocompatibility and materials science
- sterilisation and microbiology
- ancillary medicinal substances
- electrical safety
- GSPR-related horizontal competencies

These experts are mobilised **ad hoc** across all Expert Panel functions.

Figure 2: Proposed structure of expert panels



Integrated Explanation of Figure 2 (Articles 4a, 51a, 51b, 52a MDR, 48a IVDR)

Figure 2 illustrates the architecture of Expert Panel activities under the proposed MDR/IVDR:

Standing Expert Panels (green box)

- Screening Panel (CECP)
- **Borderline & Classification Standing Panel (Articles 4a, 51a, 51b MDR)**
- **BtX and Orphan Standing Panels (Article 52a MDR) (48a IVDR)**

Shared characteristics:

- stable membership
- Member State representation
- academic and NB experts under Article 106(6)
- ability to support **Commission implementing acts** (Articles 4a(3), 51a(6), 51b(6) MDR) (3a(3), 47a(6), 47b (6) IVDR)

Clinical Expert Panels (blue box)
Advisory functions under:

- **Article 61(2) MDR** – early scientific input on clinical development
- **Article 56 IVDR** – early scientific input on performance evaluation

Explicitly **not CECP**, consistent with Article 106(6).

Central Expert List (purple box)
Article 106(2) pool of cross-cutting technical and regulatory experts.

Overall Interaction
The structure ensures:

- consistent classification and borderline decisions (Articles 4a, 51a, 51b MDR) (3a, 47a, 47b IVDR)
- structured BtX/Orphan pathways (Articles 52a MDR) (48a IVDR)
- consistent scientific advice for clinical/performance development
- access to specialised expertise across all panels
- EMA secretariat support under Article 106(4)
- Relevant NB experts can contribute without affecting NB organisational capacity.

2.5. Allow utilization of external expertise for rare or highly specialised IVDs and medical devices

For rare or highly specialised devices where EU expertise is limited, Expert Panels should be permitted to engage external experts, subject to documented justification and EMA approval, to ensure appropriate scientific competence.

2.6. Allow transparency and exchange between NBs and Expert Panels

Experience shows that limited interaction between expert panels and NBs can lead to divergent scientific views, particularly in complex cases or where an expert panel intends to issue a negative opinion. The absence of a structured exchange mechanism may result in misunderstandings and reduced confidence in the consistency of assessments.

Team-NB proposal:

- **An optional structured pre-opinion exchange**, allowing the expert panel to request clarifications from the NB—and vice versa—before the panel adopts a negative or significantly divergent scientific opinion.
- **A formal mechanism for exchange of views in complex cases**, ensuring both bodies can explain the evidence base and its interpretation before positions become final.
- **Publication of anonymised summaries** of such exchanges to support consistency and predictability across the system. *(see Table, Ref. no. 39a)*

2.7. Reconsider methodology for literature screening and NBCG-Med work sharing

While enhanced coordination on literature screening can support greater consistency, several practical considerations need to be taken into account:

- NBs differ significantly in **scope, designation, and manufacturer portfolios**, which means that individual literature screening activities must ultimately be performed within each NB.
- the sheer **breadth of device types and clinical applications** makes a fully centralised or uniform screening system impractical without substantial and stable resources.
- **copyright constraints** may limit the extent to which journal access or full-text articles can be shared across organisations when not all have paid for access to the information.
- **AI-based tools** can support screening workflows but cannot replace expert regulatory judgement or contextual clinical assessment.

These factors indicate that coordination is valuable but **cannot substitute for NB-specific screening responsibilities** aligned with their designation and client base.

Team-NB Proposal:

Team-NB supports enhanced coordination while ensuring that final literature screening remains the responsibility of each NB. To balance harmonisation with operational feasibility, Team-NB proposes:

1) **A risk-based prioritisation approach** to literature surveillance, using EMDN codes to focus shared efforts on higher-risk categories and/or emerging technologies.
2) **Development of common best-practice methodologies**, templates, and search strategies through NBCG-Med, enabling convergence without requiring identical screening outputs.
3) **An EU-funded, optional support tool** that can assist NBs in identifying relevant publications and safety signals, without imposing mandatory centralised screening.
4) **Retention of expert human review** within each NB, ensuring that literature assessment remains aligned with the NB's designation, clinical specialties, and specific manufacturer portfolios.

This approach promotes **harmonisation, efficiency, and proportionality**, while respecting the fundamentally decentralised structure of the NB system.

2.8. Clarification of role of NBCG-Med within the MDCG Structure

Team-NB supports the Commission's intention to formalise the role of the Notified Bodies Coordination Group (NBCG-Med) within the overall MDCG governance architecture, as foreseen in the proposed Article 49 MDR. A clearer structural anchoring of NBCG-Med can promote coherence, improve transparency and strengthen the Union-level coordination of notified bodies.

At the same time, it is important to ensure that this integration does not inadvertently limit NBCG-Med's ability to perform one of its core functions: development of **technical, operational and methodological guidance for notified bodies**. Such work often requires:

- highly specialised technical expertise,

- rapid drafting and iteration, and
- targeted discussion among NB experts with deep, practical experience in conformity assessment.

Because MDCG operates at a broader policy-oriented and Commission and Member-State-led level, and because detailed technical NB documents usually require more specialised knowledge than is available within MDCG, it would be neither efficient nor proportionate to require MDCG approval for purely technical NBCG-Med documents. This could risk slowing down urgently needed harmonisation work and delaying practical solutions.

For these reasons, Team-NB respectfully proposes that:

- NBCG-Med becomes formally part of the MDCG structure, with appropriate reporting lines allowing two-way communication and transparency obligations.
- NBCG-Med retains the ability to develop and adopt technical, NB-internal documents autonomously, without mandatory MDCG endorsement, provided such documents:
    - are clearly identified as NBCG-Med outputs,
    - remain consistent with Union law and MDCG guidance, and
    - support harmonised practices across notified bodies.
- documents of broader Union-level relevance or general policy impact continue to be submitted to MDCG, as today, for endorsement or further consideration.

This balanced approach ensures:

- coherent integration of NBCG-Med into the MDCG framework,
- preservation of NB operational efficiency,
- continued rapid development of technical guidance,
- appropriate transparency and alignment with Member State and Commission priorities.

Team-NB believes this model both respects the governance role of MDCG and safeguards the technical depth and agility required for high-quality and harmonised conformity assessment across the Union.

3. Clinical – WET – Equivalence – Art 61(10)

3.1. High-level summary

Clinical data is central to ensuring that medical devices demonstrate robust safety and performance, forming the scientific foundation of a credible conformity assessment process. While strong evidence is essential for protecting patients, a pragmatic and proportionate approach is needed–one that recognises that regulatory risk classifications do not always mirror the true clinical risks faced by patients. Meaningful reform of the MDR and clinical evaluation requirements must therefore introduce flexibility without weakening the core scientific principles that safeguard patient safety. Such improvements should enhance transparency and ensure patients have access to clear, relevant clinical evidence supporting the devices they rely on.

3.2. Clinical Data Definition (Article 2 (48))

Team-NB welcomes the Commission's efforts to clarify what qualifies as clinical data but believes the proposed amendment does not reflect the full range of sources which can be used to generate clinically relevant data. The proposed definition risks exclusion of real-world data derived from sources such as retrospective studies, surveys, registries, case studies and unpublished clinical experience, in addition to system level clinical data which in some cases can indirectly inform on safety and performance.

There is also an ongoing concern that the requirement for clinical experience to be published in "peer-reviewed scientific literature" creates an artificial threshold regarding the quality of clinical data, that is not reflected in the current academic publishing environment, such that a potentially misleading narrative is constructed where the "peer-reviewed" automatically indicates the source of clinical data to be reliable. Based on the collective experience of Team-NB, a more reliable and predictable indicator of how a device performs in the clinical setting requires consideration of all potential data sources, including patient reported data where available. The quality, reliability and relevance of which is subject to appraisal via the clinical evaluation process.

Proposed Amendment: Impact on Patients

- Delayed access to devices due to higher evidence-generation burden.
- Exclusion of unpublished real-world data may slow detection of real-use performance and safety issues.

Proposed Amendment: Impact on Manufacturers

- More restrictive definitions may force manufacturers to generate new data unnecessarily, increasing cost and delaying access.
- Potentially important real-world evidence may be disregarded, weakening predictability of conformity assessment process.

Team-NB Proposal

Team-NB proposes adopting a globally aligned definition of clinical data, consistent with IMDRF and MEDDEV 2.7/1 Rev. 4, ensuring broader acceptance of real-world evidence. This approach promotes global converge of regulations as outlined in point 5 of the MDR preamble[1]. We also propose incorporating system-level data into the definition to enable its use where relevant (e.g., surgical instruments intended for use with a specific implant).

Team-NB proposed text (Article 2(48)):
'clinical data' means safety or performance information that is generated from clinical and/or investigational use of a device, or where relevant arising from use of a device within a system, on humans for treatment, diagnosis, patient management or public health purposes. (see Table, Ref. no. 2)

[1] To the extent possible, guidance developed for medical devices at international level, in particular in the context of the Global Harmonization Task Force (GHTF) and its follow-up initiative, the International Medical Devices Regulators Forum (IMDRF), should be taken into account to promote the global convergence of regulations which contributes to a high level of safety protection worldwide, and to facilitate trade, in particular in the provisions on Unique Device Identification, general safety and performance requirements, technical documentation, classification rules, conformity assessment procedures and clinical investigations.

3.3. Clinical Data Deemed Inappropriate - Article 61.10

Team-NB recognises that the medical device sector has experienced persistent inconsistency and debate around Article 61(10) since MDR implementation. We welcome clarification on the types of non-clinical data which are considered acceptable (in silico, in vitro, ex vivo, modelling) but believe the proposed amendments will increase ambiguity rather than reduce it.

Key concerns include:

- Removing the word "exception" broadens use of non-clinical-only routes, risking misuse for Class IIa/IIb non-implantable devices and potentially making absence of clinical data the default for low-medium risk devices, contrary to the underlying principles of the regulation as outlined in point 63 of the MDR preamble[2].
- Adding "data available for the generic device group" introduces uncertainty and may push article 61(10) toward reliance on similar device data which may not accurately reflect the actual safety and performance of the subject device, rather than applying robust evidence-based decision-making principles.
- Lack of clarity around "not deemed appropriate" raises concern that manufacturers might claim article 61(10) in instances where sufficient pre-market clinical data is possible but difficult to obtain.

Proposed Amendment: Impact on Patients

- Greater risk of devices entering market without device-specific clinical evidence.
- Potentially catastrophic consequences if medium risk devices default to evidence-light pathways.
- Delayed detection of harms that only emerge through clinical use.

Proposed Amendment: Impact on Manufacturers

- Increased uncertainty and divergent notified body interpretations.
- May lead manufacturers to adopt the non-clinical route prematurely → later delays when NBs reject insufficient justification.
- Risk of inefficient planning and repeated clinical strategy rework.

Team-NB Proposal

Team-NB proposes a structural change:

1) Remove Article 61(10) entirely, and
2) Remove the reference to paragraph 10 in the proposed amended text for article 61.1

This would shift the focus back to:

[2] To ensure a high level of safety and performance, demonstration of compliance with the general safety and performance requirements laid down in this Regulation should be based on clinical data that, for class III devices and implantable devices should, as a general rule, be sourced from clinical investigations that have been carried out under the responsibility of a sponsor. It should be possible both for the manufacturer and for another natural or legal person to be the sponsor taking responsibility for the clinical investigation

- Assessing sufficiency of all available clinical and/or non-clinical evidence for each device
- Reducing debate over article interpretation and improving transparency and predictability.

In addition, at the time of publication of the amendment, the Commission must provide manufacturers and notified bodies with proper guidance to ensure consistent interpretation and implementation of the criteria for justifying the necessary level of clinical data, clearly reinforcing point 63 of the MDR preamble[3], that normally some clinical data should be provided and that reliance on non-clinical data alone should only apply to devices where clinical data does not inform on safety and/or performance. *(see Table, Ref. no. 33)*

3.4. Equivalence (Article 61 (5) and Annex XIV Part A (3))

Team-NB welcomes the Commissions efforts to introduce greater pragmatism to demonstration of equivalence and supports expansion of biological equivalence to allow for consideration the same or similar materials or substances. However, it is important to emphasise that permitting the use of similar materials may lead to the introduction of unforeseeable medium-to-long-term risks to the patient. Thus, to support patient safety and ensure consistent interpretation and implementation, it is critical that the Commission provide manufacturers and notified bodies with proper guidance at the time of publication of the amendment.

Regarding clinical equivalence, the proposal to broaden the criteria for demonstration of clinical equivalence by allowing for the use of the "same or similar clinical condition" raises several concerns:

- Allowing "same or similar" clinical conditions will lower the requirement to below that of the medical device directives and thereby undermines MDR's core intent to improve patient safety
- "Similar" clinical conditions may share pathology but differ significantly in treatment strategy and outcomes–leading to inappropriate equivalence conclusions (e.g., peripheral vs. coronary artery disease stent behaviour).
- If all three equivalence criteria (technical, biological, and clinical) can be based on similarity, it brings into question how the claimed equivalent device's data can be considered to accurately reflect the safety and performance of the device under evaluation. Indeed, it can be argued that such an approach could annul the validity and robustness of the equivalence claim.

Proposed Amendment: Impact on Patients

- Increased probability that devices enter the market without evidence relevant to their intended population, leading to safety and performance failures.

[3] To ensure a high level of safety and performance, demonstration of compliance with the general safety and performance requirements laid down in this Regulation should be based on clinical data that, for class III devices and implantable devices should, as a general rule, be sourced from clinical investigations that have been carried out under the responsibility of a sponsor. It should be possible both for the manufacturer and for another natural or legal person to be the sponsor taking responsibility for the clinical investigation.

- Greater inconsistency between notified bodies creates unequal patient protection across the EU.
- Devices with substantially different risk profiles could be approved based on relaxed equivalence criteria.

Proposed Amendment: Impact on Manufacturers

Positive short-term:

- It may be simpler to justify equivalence and reduce the need for new clinical investigations.
- Negative long-term:
- Increased unpredictability in NB acceptance of equivalence rationale.
- Potential misalignment with international regulators (e.g., FDA does not accept "similar" for clinical equivalence), risking global market strategy complications.

Team-NB Proposal:

1) Retain the current wording of the clinical characteristics specified by Annex XIV Part A (3), thereby preserving a scientifically defensible basis for using another device's data.

"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"

2) Biological equivalence:

At the time of publication of the amendment, the Commission must provide manufacturers and notified bodies with proper guidance to ensure consistent interpretation and implementation of the criteria for demonstration of similarity. *(see Table, Ref. no. 32)*

3.5. Clinical Evaluation Consultation Procedure (CECP) & Scrutiny (Articles 54 & 55)

This section examines proposed revisions to the EU MDR/IVDR, focusing on changes to the Clinical Evaluation Consultation Procedure (CECP), the scrutiny mechanism, and expert panel involvement. It highlights practical challenges arising from harmonised standards, transparency gaps, and unclear operational processes. The document also evaluates the implications of revised scrutiny pathways and the role of expert laboratories. Finally, it outlines opportunities to improve early expert engagement to support innovation and ensure consistent, predictable conformity assessment.

In the first paragraph of Article 54, the requirement to perform CECP is reduced to class III implantable devices only.

In Article 54(2), it is outlined that CECP is not required in the following cases:

a) for a renewal of a certificate issued under this Regulation;
b) where the device has been designed by modifying a device already marketed for the same intended purpose, provided that the manufacturer has demonstrated to the

satisfaction of the notified body that the modifications do not adversely affect the benefit-risk ratio of the device;

c) where the principles of the clinical evaluation of the device type or category have been addressed in a harmonised standard referred to in Article 8 or in CS referred to in Article 9, and the notified body confirms that the clinical evaluation of the manufacturer for this device is in compliance with the relevant harmonised standard or CS for clinical evaluation of that kind of device.

Concerns

There are no specific comments on (a) and (b). Item (c) is of concern.

- It needs to be outlined that the process of harmonising standards and the publication of CS was not effective during the initial phase of the MDR. We believe that the Commission should focus on resolving this weakness before establishing new exceptions based on harmonised standards and CS.
- Furthermore, even if a harmonised standard includes clauses related to clinical aspects, this does not mean that it covers all clinical aspects and all clinical claims.
- Product standards usually address standard medical devices, but not the specific claims of the manufacturer for their specific device.

Related to the CECP and the experience to date:

Expert panel opinions are published after certificates are issued, but the information might not be current anymore. In cases where the views and recommendations are not followed, the substantiated justification of the notified body is not published together with the expert panel opinion.

A platform to share the substantiated justification with the authority responsible for notified bodies of the Member State in which it is established, with the expert panel that issued the opinion, and with the Commission is not available and is not mentioned in Article 54(4).

Patients should have all data related to the evaluation of a device available. The justification of a notified body for not following recommendations of the expert panel should be publicly available on the same platform as the expert panel's opinions.

Publication of the MDCG opinion only may infringe upon the reputation of notified bodies in general or even in particular.

In Annex IX, 5.1(g), the platform is referenced: *"the substantiated justification provided by the notified body shall be publicly available via Eudamed without any confidential information."* This Eudamed reference should also be added to the CECP / scrutiny Articles 54 and 55.

Scrutiny (Article 55)

The revised mechanism for scrutiny reflects post-market surveillance based on reasonable product-specific concerns of the MDCG or the Commission, but the header indicates scrutiny of conformity assessments.

As the header should fit the content of the article, "conformity assessments" should be deleted, and it should read "mechanism of scrutiny" or "mechanism of scrutiny of devices."

It is stated that notified bodies may be requested to submit to expert laboratories their clinical evaluation assessment report and any subsequent surveillance assessment reports regarding that device. The purpose of providing the clinical evaluation assessment report to the expert

laboratories does not become clear, as the expert laboratories may not employ clinical experts for the particular device.

Regarding device testing by expert laboratories, the following concerns apply:

- There is a limited number of device-specific harmonised standards reflecting standardised test methods with suitable device specifications available, or CS in general and
- in particular, based on which test procedures or test results may an expert laboratory decide whether or not device specifications are met? Furthermore, expert laboratories related to medical device testing are not yet available.

Referring to Article 55(3):

- No timelines are identified for expert panel advice or expert laboratory testing which, as scrutiny is due to reasonable concerns, is problematic.
- The article indicates that the notified body shall give utmost consideration to the advice provided by the expert panel or the expert laboratory and, where needed, take any appropriate measures.
  Due to this, delays in appropriate measures may occur, as manufacturers might reject actions of the notified body with the argument that the device is under scrutiny by expert panels or laboratories in parallel.

3.6. Expert panel (Article 61(2))

The article refers to class IIb and class III devices only, but a voluntary process should also be established for lower-risk class devices in cases where novel technologies give rise to residual clinical considerations. Supporting innovation in these cases is essential for patient benefit and for fostering the development of the European market.

Such consultations are known as pre-submission meetings between the manufacturer, the notified body, and the competent authority for drug/device combination consultation procedures (pre-submission in the sense of pre-Technical Documentation submission).

A similar process could be beneficial for Article 61(2) and the subsequent CECP, where applicable.

Upon request of the manufacturer, the notified body should attend meetings with the expert panel. Such consultations or meetings should be held prior to submission of the technical documentation to the notified body.

Such pre-submission meetings may help to duly address the expectations of the expert panels in cases where CECP is required. Involving expert panels for the first time at the latest stage of the conformity assessment procedure may lead to unexpected requests, which may cause delays in device market access. Such delays could potentially be avoided by involving the expert panel at an earlier stage.

The article states that the notified body shall give due consideration to the advice of the expert panel and, where they do not follow the advice, they shall provide duly justified reasons. Therefore, the notified body should also be able to attend such meetings of manufacturers with the expert panel.

A voluntary process should also be established for lower-class devices in cases where novel technologies give rise to residual clinical considerations. Supporting innovation in these cases is essential for patient benefit and for fostering the development of the European market.

3.7. PMCF Evaluation Report & Updates (Article 61 (11) and Annex XIV Part B)

The removal of the PMCF evaluation report, together with a risk-based approach to updating clinical evaluations, presents a valuable opportunity to reduce administrative burden while ensuring that evidence generation reflects the actual clinical risk of the device rather than regulatory formality. However, clearer guidance or an alternative framework is needed to prevent manufacturers from extending update timelines beyond what is acceptable and to support notified bodies in holding manufacturers accountable.

3.8. Well Established Technologies (Article 2 & Article 61 (6b), 61 (8)

The regulation made a list (screws, plates etc.) of simple implantable devices that are exempt from some of the requirements for most permanently implanted devices. These are named well-established technology (WET) devices.

MDCG 2020-6 interpreted the text to mean other similar devices could also use these exemptions if they were similar enough though not listed in the regulation. That guidance also significantly reduced the clinical data requirements that apply to these devices by introducing the interpretation that clinical data from non-equivalent but similar devices can be used as if it were clinical data on the device for these well-established technology devices. This is Level 6 data. The proposal is to remove the list of well-established technology devices from the regulation and replace it with the general definition from MDCG 2020-6 with some changes so any device meeting the definition can use the exemptions. It also introduces several new explicit exemptions. It does not propose to alter the interpretation that these devices can rely on clinical data of similar devices in the MDCG 2020-6 guidance.

3.8.1. Concerns

The definition of well-established technology devices proposed to be included in the regulation is largely a copy of the definition in MDCG 2020-6, so we have several years' experience of implementing this definition. This is the source of concerns. An example is a smart phone app for processing and displaying diagnostic ultrasound images that had been on the market in USA for 18 months claimed to be well-established, because 18 months was a long time and the application was only displaying diagnostic images. The definition is excessively open to interpretation, and this results in lack of harmonisation, a decrease in predictability of the outcome of notified body assessment of these claims and delay in market access for some of these devices when the claim is not agreed.

Further the combination of both a broad definition with the uncertainly broad interpretation of MDCG on the clinical data requirements creates a double risk that both a large number of devices might use this route and that they will rely on very weak clinical data, in a disproportionate way that re-introduces patient safety risk that has been reduced by the MDR. There will be temptation for a "race to the bottom" with notified bodies being forced to underbid one another when deciding on accepting WET claims potentially undermining independence, impartiality and integrity of the notified bodies as well as leading to high-risk devices not undergoing proper scrutiny possibly compromising patient safety.

The proposal includes that high-risk devices meeting the definition of well-established technologies will be subject to the conformity assessment procedure according to Annex IX, Chapters I and III only. As a consequence, high-risk devices will be placed on the Union market without scrutiny of their technical documentation by the notified bodies. The manufacturers of these devices would no longer be required to submit notifications of design changes. The combination of these two factors reduces the level of oversight on high-risk well-established technology devices to a level even lower than that under the former Directive re-introducing risks to patient safety within the Union market.

We think there is a set of permanently implantable devices, like screws, that can safely be marketed with lower clinical data requirements than most permanent implants. We agree with some of the additional exemptions, like removing the need for an implant card for every single screw. We support the move to a definition in principle but oppose the current proposed definition because it will lead to excessively many devices on the market with inadequate clinical data that will harm patients. A definition that is clear enough that it includes the current list, but not many more types of devices would be ideal. Further clarity on the benefits that accrue to a device meeting the definition is needed.

3.8.2. Summary of notified body proposals on well established technologies

Based on implementation experience, notified bodies consider that the current and proposed approach to well-established technologies requires targeted corrections to ensure legal certainty, harmonised application and patient safety.

Notified bodies propose, as a priority, that the framework for well-established technologies be **clearly constrained and legally predictable**. The definition should be sufficiently precise to allow manufacturers and notified bodies to determine, at an early stage, whether a device qualifies as well-established, thereby avoiding late-stage disagreements and inconsistent outcomes across Member States.

Where such a precise and restrictive legal definition cannot be established, notified bodies propose that the Commission adopt a **binding and exhaustive list of devices qualifying as well-established technologies**, through implementing acts. **Such lists should explicitly indicate both devices that qualify as well-established technologies and devices for which applications have been assessed and rejected**, in order to ensure transparency and avoid repeated, duplicative submissions.

The well-established technology lists should be maintained and updated at regular intervals through a predictable and clearly defined procedure, allowing timely adaptation to technical and scientific developments while preserving legal certainty for manufacturers, notified bodies and competent authorities.

Furthermore, notified bodies propose that **well-established technology status should not, by itself, justify reduced monitoring or technical documentation assessment for higher-risk devices**. In particular, class III devices should not benefit from reduced oversight solely on the basis of WET classification, given the potential impact on patient safety.

Finally, where regulatory relief is granted for well-established technologies, the **scope and limits of that relief should be explicitly defined in the Regulation**, to ensure that core principles—such as demonstration of safety and performance for the specific device under assessment—remain fully preserved. *Proposed solutions are reflected in Table entry 4,5, and 6.*

3.9. Summary of Safety and Clinical Performance (MDR Article 32)/Summary of Safety and Performance (IVDR Article 29)

The Summary of Safety and Clinical Performance (SSCP), for MDR, and the Summary of Safety and Performance (SSP), for IVDR, was introduced by these regulations. It is the only document a manufacturer must openly publish and make available to the general public and therefore the only opportunity for the public to see into the medical device system. It is a vital tool for transparency and public accountability. It is only required for a small proportion of implantable devices.

The proposal is to exempt some of these devices from the requirement to publish this information. The argument put forward is that it is burdensome to produce these summaries. This argument does not bear scrutiny when the proposal already includes several measures to reduce the burden, and with digitalisation this can be reduced further.

Concerns

The SSCP/SSP is a vital tool for transparency of the medical devices system. It is one of very few ways that the public, lay people, academic researchers, patients and professionals, can get genuine insight into the medical devices available on the market. Reducing the already small group of devices on which an SSCP/SSP must be published reduces the transparency of the system and increases risk. It sends a message that the sector does not welcome public involvement.

The argument put forward is that SS(C)Ps production is burdensome. There are several measures already proposed to reduce this burden and we would suggest further reduction in the burden would be a preferable step to removing the need to publish them. There is insufficient guidance that SSCPs/SSPs should be a true summary of the clinical evaluation or performance evaluation report. Many SSCPs and SSPs we see are excessively long and complex – not really summaries but completely new documents that are so long they become inaccessible to the layperson - who in the case of IVD near-patient and self-tests is also the end user - and therefore defeat their purpose. Further clarity that the SSCP/SSP is to be truly a summary in layperson readable form would both reduce the supposed burden and increase their utility.

Another argument presented is that the SSCP must be validated by the notified body and therefore only those devices where the notified body is undertaking a full assessment of the technical file should have an SSCP/SSP. But this is putting the cart before the horse. The purpose of the SSCP is not to be validated by the notified body, it would be preferable to publish SSCPs that have not been validated by notified bodies to not having SSCPs.

3.10. Suggested input for IVDs

Notified bodies are broadly aligned with the proposed revisions to the IVDR articles and annexes related to performance evaluation. However, several elements require clarification. For example, the proposal allows manufacturers to demonstrate clinical performance using data from clinically equivalent devices, yet it does not define *equivalence*. Likewise, while criteria are outlined for high-risk procedures, the proposal does not define which procedures fall into this category. To support consistent implementation, notified bodies propose definitions for both *equivalence* and *high-risk procedures*.

4. Safety concerns

4.1. High-level summary

The proposed MDR/IVDR revisions would substantially reduce the level of regulatory scrutiny by limiting notified body involvement across certification and surveillance activities. Several proposed changes—such as the removal of unannounced audits, less frequent review of safety-related reports, and reduced systematic documentation assessments—would lower oversight below the standards applied even prior to the MDR/IVDR.
Such a reduction in scrutiny would lessen the effectiveness of established preventive controls and constrain the system's ability to identify safety and performance issues as early and consistently as under the current framework.

From a notified body perspective, these developments could lead to an overall increase in risk for patients and healthcare professionals. A structured assessment of the key issues—together with constructive alternative solutions designed to maintain regulatory robustness while supporting implementation efficiency—is provided in Annex I of this document.

4.2. Safety concerns

The proposed revisions to the MDR and IVDR would significantly lower the level of regulatory scrutiny applied to medical devices and IVDs across both pre-market and post-market phases, thereby increasing the potential risk to public health.
A key concern is the substantial reduction in notified body involvement throughout the conformity assessment lifecycle—from initial certification activities to ongoing surveillance. Such a shift would weaken core elements of the EU's medical device safety framework.
The cumulative impact of the proposed measures is particularly noteworthy.
The proposed revisions introduce a series of measures that collectively reduce the depth and consistency of regulatory oversight. These include:

- Reduction of systematic audit activities (see Table Ref. no 57, with specific example)
- Removal of product-specific unannounced audit requirements (see Table Ref. no 58, with specific examples)
- Reduction of mandatory technical documentation assessments for representative product groups (see Table Ref. no 55,56)
- Elimination of standalone product- or group-specific PSUR reviews (see Table Ref. no 34,35)
- Increased reliance on "for-cause" assessments rather than on systematic oversight (see Table Ref. no 56)
- Down-classification of certain high-risk products (see Table Ref. no 27,54)
- Broad and loosely defined WET categorization, disproportionately affecting higher-risk devices (see Table Ref. no 5, 55)
- Removal of re-certification requirements and the introduction of periodic reviews and extended certificate validity periods (see Table Ref. no 53)

Viewed cumulatively, these changes would significantly limit the system's ability to detect safety and performance issues at an early stage, thereby weakening safeguards intended to prevent harm before it occurs. The proposed changes are shifting the EU regulatory model from a proactive, preventive framework to a predominantly reactive one, where issues are identified only after serious incidents or widespread complaints arise.

Such a shift would undermine the preventive intent of the MDR/IVDR and could reduce the level of protection to below that which existed prior to their implementation. This, in turn, increases the likelihood that unsafe or non-compliant devices remain in clinical use, with potential consequences for patient and healthcare-professional safety and for public confidence in the regulatory system.

As an example, under the current system, the Technical Documentation for medium-risk devices is reviewed proportionally, with only 5 to 15% of each device group assessed by the notified body during surveillance. The proposed revision would reduce this to a single product assessment initially without any further systematic risk-based Technical Documentation sampling, even though these groups often contain more than 100 devices. Furthermore, specifically for IVDs, around 80% of products have never undergone third-party assessment. Notified bodies observe that many devices previously placed on the market under self-certification show very poor-quality technical documentation, and a significant number will not be submitted for IVDR assessment because they cannot meet the required performance and safety criteria.

In this context, returning to a Directive-like structure could allow such poorly performing devices back onto the market.

4.2.1. Notified body access to EUDAMED as enabler of patient safety

Effective implementation of notified body oversight tasks under the MDR and IVDR requires **direct and comprehensive access to EUDAMED**, commensurate with the notified bodies' legal responsibilities.

Under **Articles 83 to 86 MDR**, manufacturers are required to generate and report post-market surveillance, vigilance and periodic safety update data through Union systems. **Annex III** establishes that these data form an integral part of the technical documentation and are subject to notified body assessment. **Annex IX** requires notified bodies to verify continued conformity through surveillance activities, including review of post-market data and corrective actions.

Without adequate access to EUDAMED, notified bodies cannot effectively:

- independently review vigilance reports, trend reports and PSURs,
- assess the completeness and consistency of manufacturers' post-market systems,
- detect cross-manufacturer or cross-border safety signals,
- substantiate or challenge "for-cause" triggers, or
- conduct meaningful periodic reviews of continued conformity.

As the Commission proposal increases reliance on **post-market data, for-cause mechanisms and periodic review**, the absence of explicit legal clarification on notified body access to EUDAMED would directly undermine the preventive safeguards foreseen by the MDR.
Team-NB therefore considers it essential that **all notified bodies designated under the MDR and IVDR have direct access to the relevant EUDAMED modules**, in line with their tasks under Articles 83–86 and Annexes III and IX. This access should be explicitly anchored in the Regulation to ensure consistent and uniform application across Member States.
This concern and proposed solution are reflected in Table entry 37.

4.3. Alternative solution – Performance-based regulatory incentives

Rather than reducing regulatory scrutiny across the board and relying predominantly on "for-cause" interventions once deficiencies have already materialised, Team-NB proposes an alternative model that **rewards sustained regulatory compliance and high-quality manufacturer performance**, while preserving robust safeguards for patient safety.

Under the MDR and IVDR, conformity assessment and surveillance are designed to be preventive. This preventive character is most effective when regulatory effort is applied **predictably and proportionately over time**, and when manufacturers have a clear incentive to invest in strong quality management systems, robust technical documentation, and proactive post-market surveillance.

4.3.1. Rewarding good compliance rather than reacting to failures

Instead of lowering the overall level of scrutiny, Team-NB proposes that **reduced regulatory intensity should be earned**, not assumed. A meaningful incentive could be introduced once a manufacturer has successfully completed **two periodic reviews (e.g. six years)** under the MDR or IVDR, without major non-conformities, significant unresolved CAPAs, or repeated safety-related findings.

For such manufacturers and devices, a **proportionately reduced surveillance intensity** may be justified, for example through:

- streamlined sampling approaches,
- reduced frequency of certain routine assessments, or
- increased reliance on desk-based or remote activities.

This approach would **reward good regulatory behaviour**, strengthen trust in high-performing manufacturers, and encourage early and continuous investment in compliance, rather than incentivising a minimum-effort approach followed by reactive corrections.

4.3.2. Early lifecycle focus: where most issues arise

Experience from notified bodies shows that the **"childhood diseases" of medical devices** typically become apparent during the **initial phase following market entry and the first periodic review cycles**, either through design maturity issues, initial market feedback, or early post-market surveillance data. Strong scrutiny during this initial phase is therefore essential and should not be diluted.

Maintaining comprehensive oversight during the first periodic review cycles allows:

- early identification of design or usability weaknesses,
- validation of clinical assumptions in real-world use, and
- timely corrective action before large-scale exposure.

Only once this early lifecycle phase has been successfully completed through **compliant periodic reviews** should proportional regulatory relief be considered.

4.3.3. Late-lifecycle risks: ensuring continued state of the art

Conversely, experience also shows that risks tend to increase again as devices approach **later lifecycle stages or obsolescence**. Changes in clinical practice, evolving standards, emerging cybersecurity threats, or outdated materials and manufacturing processes may progressively erode the original safety and performance assumptions.

For this reason, Team-NB recommends that **periodic reviews conducted at later lifecycle stages place increased emphasis on state-of-the-art considerations**, regardless of prior compliance history. This can be achieved by applying a **more focused and, where appropriate, more intensive periodic review**, concentrating in particular on:

- continued conformity with current state-of-the-art technical and clinical requirements;
- relevance and continued applicability of existing standards and specifications;
- cumulative post-market surveillance and vigilance data; and
- evidence that device design and performance have not undergone unnoticed drift over time.

Such an approach ensures that regulatory oversight remains **preventive rather than reactive**, addressing emerging risks before they result in patient harm.

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4.3.4. Benefits of a performance-based oversight model

A regulatory framework that differentiates oversight based on demonstrated performance would:

- incentivise manufacturers to maintain consistently high compliance standards;
- reduce unnecessary administrative burden for proven, well-performing devices;
- allow notified bodies and authorities to focus resources where risk is highest;
- preserve patient safety by maintaining strong scrutiny in early and late lifecycle phases; and
- improve predictability and trust in the regulatory system.

In this way, efficiency gains would be achieved **through better targeting of regulatory effort**, rather than by reducing the level of protection embedded in the MDR and IVDR.

5. Change in Notified Bodies requirements tasks

5.1 High-level summary

Europe is at a critical juncture in regulatory history. Decisions made today will either deliver devices to help solve health crises and improve patient outcomes across member states, or encourage manufacturers to first place those devices on offshore markets.

Notified bodies are a critical part of the infrastructure that currently delivers medical innovation to the European market. This is, in part, because they possess the necessary expertise and resource to make an informed assessment as to whether a given device is safe, performant, and effective.

Team-NB supports many aspects of the Commission's proposal in respect of the changes to notified body requirements and tasks (see below) but identifies concerns over implementation as is. However, the following aspects, when viewed as a package, rather than in a vacuum, present a serious system-level risk to the viability of notified bodies. Team-NB's view is that this will lead to crisis in terms of device delivery.

5.2 Financial components

Overview

- Ensure clarity on liabilities and prevent spiralling insurance costs.
- Protect capacity, competition, and expertise: Avoid measures that accelerate consolidation and exit by ensuring oversight is predictable and proportionate, safeguarding notified body capacity, retaining specialised expertise, and maintaining timely access to conformity assessment services across the EU.

Cost Increases

Under the Commission's proposal, notified bodies would face a material increase in the cost of delivering conformity assessment services while simultaneously constraining revenue, creating an unviable operating model.

The cost increase related to the introduction of fees payable by the notified body to authorities for designation and ongoing surveillance activities under the proposed Article 40a will impact

notified bodies differently, as not all notified bodies are required to pay their competent authorities for these types of services.

Of greater significance is the cost that notified bodies will face in preparing for, attending, and completing post audit activities following a joint assessment every two years, as proposed by Article 44 (4)(a) of the draft text. This requires material resource that cannot be allocated to improving, supporting, or delivering the core conformity assessment services to manufacturers.

In addition to the audit days required for a joint assessment, there is a material amount of administrative burden on notified bodies, which includes:

Preparation stage, including, for example, the completion of forms, provision of documentation.

- Scheduling delays for manufacturer audits, as joint assessment audit dates are held prior to being confirmed.
- Several streams of assessment to manage during the joint audit itself, and across a longer time frame due to translation, and lack of context (that would otherwise be held by the competent authority).
- Follow up CAPA processes that (from experience) extend beyond 12 months after the audit dates, and would overlap with annual assessments.

The Commission has also proposed the removal of Article 10 (16), which currently provides clarity on manufacturer liability and insurance obligations:

- European patients and people can claim compensation for damage caused by a defective device; and
- Manufacturers shall carry insurance that provides sufficient financial coverage in respect of their potential liability.

While we appreciate that the intent of the proposal is to simplify regulation, and many of the principles in Article 10(16) already apply implicitly or explicitly across other Union law, this statement in Article 10 makes it clear where primary liability falls in the event of a defective device. Where that liability is less clear, and where a manufacturer carries insufficient insurance to cover their own liability, claimants will inevitably turn to other stakeholders e.g., healthcare providers or notified bodies. Therefore, by removing this clause, all stakeholders will need to carry higher indemnity levels in their own insurance policies (triggering higher premiums), and will face greater costs in defending unwarranted claims, for example, in the event of an insolvent manufacturer.

Impact on Notified Bodies

For many notified bodies, designation under Regulations (EU) 2017/745 and 746 is a loss leader. The proposed financial regulation in draft Article 50 presents an increased risk for notified bodies, particularly a loss of predictability:

- First, imposing up to 50% reduction in pricing for small and micro enterprises, alongside mandatory deferred payment schedules will present material cost-recovery and severe cashflow problems for smaller and medium notified bodies. A recent Team-NB study demonstrated that the portfolio of small and micro enterprises among notified bodies is over [77% of the clients of Team-NB members (PressRelease-Team-NB-20241024.pdf)], which means the vast majority of notified body customer revenue will be impacted. If, for example, a manufacturer is required to spend some time generating additional

clinical data, it could be many months until a notified body is paid for the assessment work done. In that time, notified bodies still need to pay staff, and meet operational expenses. Many notified bodies simply do not have the cash reserves to make ends meet during this time.

- Second, empowering the Commission to set the level and structure of fees undermines an otherwise functioning competitive market, without clear evidence of price-driven market failure – particularly where notified body fees are estimated to constitute ca <7% of manufacturers' total regulatory costs (mte-ivdr-mdr-survey-report-highlights-march.2025.pdf). All measures should be a proportionate response and follow a reliable market analysis, which would include an assessment of the downstream consequences of any pricing regulation. Due consideration should be given to both the implications of reduced notified body capacity and the loss of a highly specialised skill set from the EU jurisdiction.

It is worth noting that today notified bodies are required to publish their fees and manufacturers routines request multiple proposals to compare costs and assess services, driving competition and keeping costs at a minimum. Complaints usually arise due to the accumulating costs where the submissions by manufacturers do not meet the Regulatory requirements, in a background of considerable regulatory costs (approaching 90% on the manufacturer's personnel costs; mte-ivdr-mdr-survey-report-highlights-march.2025.pdf).

Downstream Impact

The down steam impact of higher costs for notified bodies, constrained pricing and financial unpredictability will accelerate consolidation, deter new entrants, and drive notified bodies out of the market. The impact will be critical: bottlenecks, reduced capacity, and higher staff turnover due to inadequate remuneration. It is worth noting that within the past 5 years' the Commission itself has raised concerns about notified body capacity, leading to extended transition timelines for the implementation of the new Regulations, as well as direct investment in notified body capacity in a number of EU member states. Thus, the measures stated herein contradict former positions and the proposal's stated objectives of improving availability of medical devices and patient safety.

The resultant reduction and consolidation of notified bodies, and a sector shift away from the European market, will also erode the EU's competitiveness in the MedTech sector. The EU has gone from the jurisdiction of choice for market launch to a 3rd or 4th in line market, as the costs rise for approval under the Regulations and EU businesses are disproportionately impacted. If notified bodies are to serve the public interest, they must be financially sustainable, with regulatory oversight that is proportionate, predictable, and evidence-based.

Fundamentally, there is no notified body "fee problem" that requires solving: the Commissions' proposal does not present a sufficiently detailed impact analysis or substantive proportionality argumentation, to support the position taken in proposed Article 50.

Alternative Solution

The proposed alternative measures listed below provide a balanced solution. They allow notified bodies to absorb necessary cost increases without triggering system-wide failure, while preserving competition, capacity, and access to safe medical devices across the EU.

Note: many of these measures affect both the MDR and IVDR, even if only the MDR Article or Annex has been listed.

5.3 Change in NB Monitoring and Surveillance

Overview

- Ensure proportionate surveillance that prevents duplication and inefficiencies, focusing resources on medical device innovation and safety.
- Promote harmonisation in a structured manner, without leading to ambiguity and "limbo" situations for notified bodies that undermine public confidence.

Monitoring and surveillance of the proposed changes and their impact on notified bodies

The proposed amendments to Article 44 of the MDR intensify the monitoring and Joint Assessment framework for notified bodies through biennial Joint Assessments. While these measures are intended to enhance harmonisation and confidence in the conformity assessment system, their cumulative effect raises serious concerns regarding proportionality, legal certainty, and the long-term operational and financial sustainability of notified bodies.

The removal of the five-year full re-designation is a positive development as the delay between Joint Assessments can lead to drift between interpretations of Competent Authorities. The biennial approach promotes harmonisation and removes any "shock" at the 5 year full re-assessment. However, this benefit is offset by the proposal to conduct Joint Assessments every two years and there is concern over the timelines given delays in issuing and following up on findings raised during Joint Assessments, particularly where there is difference of opinion between team members. In practice, this proposed change implements a near-continuous and overlapping oversight regime, monopolising significant resources and capacity away from core conformity assessment activities and other designation management activities, including adapting to regulatory change.

Experience under the current framework demonstrates that diverging opinions and approvals on corrective and preventive actions often remain unresolved for more than two years. As a result, implementing a two-year Joint assessment cycle risks creating a perpetual CAPA loop for notified bodies, Designating Authorities and the European Commission. This would demand continuous capacity and timely engagement from all involved parties, increasing the likelihood of systemic delays and prolonged uncertainty.

Importantly, the more frequent Joint Assessment regime does not replace existing oversight but adds to it. Notified bodies are already subject to annual surveillance, witness audits, and other supervisory activities by national authorities. Adding biennial Joint Assessments, even if these have partial scope, increases duplication and disruption: rotating Joint Assessment audits require notified bodies to repeatedly re-explain foundational elements of their systems, structures, and interpretations of the Regulations and would only tend towards harmonisation where replacing national competent authority surveillance. Otherwise, repetition adds limited incremental oversight value and, in practice, reduces efficiency, consistency, and regulatory focus that risks undermining the capacity and stability of the conformity assessment system as a whole.

Note: Notified bodies should not be required to finance the participation, training, or capacity building of Joint Assessment Team members. Where the Union framework requires Joint Assessments, any related training and operational preparedness of assessors should be funded

and organised by the competent public authorities (Commission/Member States) and not cross-subsidised via notified body fees.

Downstream Impact

The down steam impact of the increased surveillance, which risks locking notified bodies, Competent Authorities, Joint Assessment Teams, and the Commission into a recurring, resource-intensive surveillance cycle and disputes around diverging opinions and overlapping/contradicting findings, and that duplicates and potentially contradicts activities, with questionable added value, is a risk to patient safety. The mandatory two-year Joint Assessment running along-side existing national oversight, raises material concerns regarding proportionality, efficiency, and long-term system sustainability.

Alternative Solution

The proposed alternative measures are based on a risk- and performance-based hybrid oversight model - combining desk-based reviews with targeted "for cause" on-site assessments – that would provide a more proportionate and sustainable solution, without compromising on the value of surveillance.

- *Model 1 – "for cause" Joint Assessments*

In this model, Joint Assessments would be triggered by clearly defined criteria, such as major systemic nonconformities, significant scope extensions, or substantial organisational changes. National surveillance would continue on an annual basis.

Harmonisation is primarily strengthened through common guidance, joint interpretation, targeted peer-learning, and risk-based "for-cause" oversight, making full use of knowledge already held at MDCG/Commission level from prior JAT designations and re-assessments, rather than duplicative monitoring cycles.

- *Model 2 – "for cause" national surveillance*

In this model, the biennial Join Assessment is implemented and fully replaces national surveillance, except when triggered by defined criteria (see above) to avoid duplication, ensure proportionality. Re-designation/re-assessment Join Assessments would be abolished.

Models 1 and 2 represent proportionate and efficient means to enhance harmonisation of notified body practices preventing than increasing the frequency and cumulative burden of assessments.

5.4 Competency

Overview

- Reduced notified body activity (sampling, surveillance, reviews) conflicts with NBOG 2017-2 expectations for maintaining state-of-the-art competence through regular conformity assessment work.

- Declining activity risks erosion of technical expertise, reduced availability for specialised codes, and certification bottlenecks that delay patient access to beneficial devices.

The interdependence of competency on conformity assessment activity volume

A reduction in notified body involvement and oversight activities does not appear to align with existing expectations regarding the maintenance of state-of-the-art competence. In particular, the NBOG 2017-2 guidance (current and draft) emphasises that assessors must maintain up-to-date technical knowledge through a minimum number of conformity assessment activities per scope code and per individual. Competence under the MDR/IVDR framework is therefore not static or purely qualification-based; it is activity-dependent and practice-driven.

Downstream Impact

If the volume and breadth of assessment activities decline, there is a real risk of progressive erosion of state-of-the-art technical and clinical expertise. Such a loss of competence could directly affect the quality and consistency of conformity assessments, with potential downstream implications for patient safety. The impact is across the industry as personnel move between notified bodies and industry, creating a system-wide competence gap across the EU, with direct downstream implications for the medtech sector, innovation, market growth, and investment, as well as patient safety, regulatory credibility, and trust in the conformity assessment system.

In addition, reduced activity levels may limit the availability of notified bodies for certain highly specialised codes. This directly contradicts prior Commission concerns about notified body capacity following the introduction of MDR/IVDR and undermines the stated objectives of improving availability of medical devices and safeguarding patient safety. Where assessors cannot maintain the minimum activity needed to retain competence, notified bodies may be forced to withdraw from certain codes altogether. This leads to certification bottlenecks, longer time-to-market, and reduced access to conformity assessment services - especially for innovative, niche, or high-risk technologies. In a market already experiencing significant barriers due to the additional data required under the Regulations, these dynamic risks triggering functional market failure, where manufacturers are unable to secure timely certification despite regulatory demand.

Alternative Solution

The proposed alternative measures is to consider broadening and/or combining device codes in a manner that reduces dependence on narrowly qualified personnel, while still ensuring that assessors retain the necessary depth of technical and clinical competence.

5.5 Patient Safety

Overview

- Increased procedural oversight (e.g. biennial Joint Assessment Teams under Art. 44) adds significant administrative burden without clear evidence of improved patient safety, risks delaying maintenance of designation, and may drive defensive or overly conservative certification decisions instead of balanced, risk-based assessments.

- Accelerated review timelines combined with stricter qualification and limited scope codes (Annex VII; Art. 52; Annex IX 3.3 & 3.5), alongside reduced sampling and surveillance, risk diminishing notified body capacity and assessor competence—particularly for complex or innovative technologies—leading to fewer products reaching the market.
- A move toward predominantly for-cause assessments, reduced proactive surveillance, cost-driven measures (Art. 50(2)), and prescriptive conformity assessment approaches (Art. 50(6)) weakens early detection of safety and performance issues, constrains risk-based judgment, and undermines long-term patient confidence and market stability.

Proportional surveillance

The proposed amendments introduce a combination of increased procedural oversight (e.g. biennial Joint Assessment Teams) and reduced substantive conformity assessment activity that risks creating a disproportionate administrative burden without clear evidence of added patient safety benefits, potentially pushing notified bodies toward defensive or overly conservative certification decisions rather than balanced, risk-based assessments. In turn, these changes will destabilize the MDR/IVDR system.

Increased costs / administration such as

- biennial Joint Assessment Teams (Article 44),
- accelerated review timelines
- stricter training and qualification requirements
- stricter designation requirements (including limited scope codes) place pressure on notified body viability, in turn reducing capacity and expert availability, resulting in fewer products reaching the market, including devices that could offer improved safety or clinical benefit.

The concurrent reduction in fee-earning activities - reduced sampling and surveillance activities – adds to the financial pressure whilst simultaneously challenging maintaining assessor qualifications.

A shift toward predominantly for-cause assessments, with fewer proactive and systematic conformity assessment activities, risks limiting early identification of safety and performance issues (i.e. tends towards reactive rather than proactive safety).

Downstream Impact

The downstream impact on patient safety is significant and systemic. Collectively, the proposals increase administrative burden while constraining the ability of notified bodies to deliver balanced, risk-based assessments. These measures are introduced without clear evidence of added patient safety benefit and, in practice, risk delaying maintenance of designation, reducing capacity, and weakening the very safeguards the Regulations are intended to strengthen.

With reduced notified body oversight, potential early signs of non-compliance, safety concerns, or performance degradation across a manufacturer's devices and QMS unlikely to be detected in a timely manner, ultimately weakening preventive oversight and increasing reliance on reactive measures after issues have already materialised.

There is a concern amongst notified bodies that the current model for continual surveillance approach, which is based largely on PMS activities, would not fully replace the objectives of a recertification review. The recertification review does not serve to perform a full initial product review, and thereby duplicate activities; rather it serves to perform a state of the art assessment to ensure that the product has a) been updated and re-tested according to the state of the art and b) has not undergone design drift such that the original approval data is invalid. Whilst PMS would feedback changes required based on clinical data, it does not necessarily encompass technical standard updates impacting, for example, tensile testing or cybersecurity until there is a breach impacting PMS. As such, it moves safety to reactive rather than proactive and places a greater emphasis on manufacturers taking the initiative to ensure that their products remain conformity without oversight.

A proposal focussed predominantly on cost savings and efficiency, without a corresponding assessment of impacts on patient safety, risks weakening key MDR/IVDR safeguards and shifting attention away from robust conformity assessment, potentially undermining long-term patient confidence and healthcare outcomes (SME fee reduction, Art. 50 (2)).

The proposal to impose specific conformity assessment approaches raises unresolved questions regarding liability, impartiality, and notified body independence, and risks constraining the application of risk-based judgment foreseen under the MDR/IVDR; prescriptive imposition rather than adherence to existing regulatory requirements may reduce flexibility needed to ensure appropriate, device-specific safety evaluations and market stability. à Art. 50(6).

Alternative Solution

The proposed alternative measures listed below provide a balanced approach to conformity assessment aspects using proportionality to balance the regulatory burden of placing the product on the market with risks and clinical outcome, overall balancing availability of devices with risks to ensure public safety.

6. Conclusion

This document sets out the consolidated position of Team-NB on the proposed targeted revision of the MDR and IVDR. Drawing on the collective expertise of notified bodies actively involved in conformity assessment under the Regulations, it aims to support improvements to the regulatory framework while safeguarding patient safety, legal certainty and system sustainability.

Across all thematic areas examined—governance, safety, clinical evaluation (including well-established technologies, Article 61(10) and equivalence), and notified body requirements—a consistent conclusion emerges: efficiency gains must not be achieved through uniform reduction of preventive regulatory safeguards. Experience from MDR and IVDR implementation shows that patient safety and system robustness are best preserved through proportionate, risk- and performance-based oversight, applied across the full device lifecycle.

Team-NB therefore concludes that:

- Preventive controls, particularly in early and late lifecycle phases, remain essential and cannot be replaced solely by reactive, “for-cause” mechanisms. Any regulatory relief, including reductions in oversight or administrative burden, should be earned, justified, time-limited and reversible, based on demonstrated compliance performance;

- Governance structures should be strengthened through clearer roles, improved coordination and procedural support at Union level, without diluting regulatory accountability;
- Clinical evaluation pathways, including those for well-established technologies and equivalence, require clear, restrictive and legally predictable frameworks to ensure harmonised application and continued patient protection;
- The notified body system must remain viable, competent and sufficiently resourced to fulfil its role as a core preventive safeguard of the EU medical device system.

In order to ensure transparency and traceability between high-level conclusions and concrete regulatory proposals, this document includes an accompanying tabular annex. The main text provides contextual explanation, rationale and system-level perspective for each topic, while the table presents the corresponding detailed comments, references to specific legislative provisions, and proposed amendments in a structured format aligned with the Commission's proposals published on 16 December 2025 with reference COM(2025)1023 final. Together, the text and the table form a single, coherent body of input: the text explains why changes are needed, and the table specifies what changes are proposed.
Team-NB submits this document as a constructive contribution to the revision process and remains committed to continued dialogue with the Commission and co-legislators Member States and Parliament, to ensure a regulatory framework that protects patients, supports innovation and remains operationally robust.

7. Annex I: Legislative proposals

Ref	Page no. Proposal	Art /Annex	Clause/ Subclause - Proposal	Point and Paragraph - Regulation	Comments	Proposed change
1	36	1	2	b	The generic device group definition is too imprecise and widely cast. It is applied in widely differing ways which leads to lack of harmonisation. Which devices can be grouped is subject of prolonged discussions which decreases predictability and slows timelines. As it is also now to become a key part of the definition of a well-established technology device, there is a need for accurate benchmarking to set a clear threshold directly in the regulation for this definition. There is guidance in MDCG 2019-13 that could be helpfully moved into the regulation to achieve this.	Team NB proposed text (Art 2(7)): *"'generic device group' means a set of devices having the same or similar intended purposes and a commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics.* ***There must be at least three devices in a group and they have the same EMDN code down to at least the fourth level;"***
2	36	1	2	d	There is a concern that the proposed sources are overly prescriptive and do not reflect the wealth of safety and performance related data and information which can be obtained from other data sources. For example, clinical data generated from real world clinical use of a device can be sourced via retrospective studies, survey studies, registry studies, case studies and unpublished reports on clinical experience. This is not clearly reflected in the proposed definition, potentially leading to their exclusion as data sources. Additionally, there is no consideration of the role of system level clinical data which in some cases can indirectly inform safety and performance. For example, in the case of instruments designed for use with a specific implant. There is concern that the introduction of the requirement for clinical experience to be published in "peer-reviewed	The definition for clinical data should be more closely aligned with the widely accepted definitions used by the global regulatory community (for example, IMDRF MDCE WG/N56FINAL:2019, MEDDEV 2.7/1 Rev 4), thereby promoting greater harmonization across international regulatory agencies, in accordance with point 5 of the preamble to the regulation and acceptance of a wider range of clinical data sources. In addition, the definition should be updated to reflect the potential use of system level data where relevant. Team NB proposed text (Art 2(48)): *"'clinical data' means* ***safety or performance information*** *that is generated from* ***clinical and/or investigational*** *use of a device****, or where relevant arising from use of a device within a system, on humans for treatment, diagnosis, patient management or public health purposes."***

Ref	Page no. Proposal	Art /Annex	Clause/ Subclause - Proposal	Point and Paragraph - Regulation	Comments	Proposed change
					scientific literature" creates an artificial threshold regarding the quality of clinical data, such that a potentially misleading narrative is constructed where the "peer-reviewed" in "peer-reviewed scientific literature" automatically indicates the source of clinical data to be reliable. Based on the collective experience of Team NB, a more reliable and predictable indicator of how a device performs in the clinical setting requires consideration of all potential data sources. Via the clinical evaluation process, the quality, reliability and relevance of the clinical data, irrespective of its source, must be appraised. This appraisal is subject to scrutiny, ensuring any data which is inappropriate to support device safety and performance is excluded from further analysis. By failing to consider all potential sources of data and information generated from clinical use of a device, there is a concern that patient access to certain devices may be delayed due to: 1. The need for manufacturers to generate new data and information via the sources prescribed by the MDR rather than relying on alternative and meaningful sources of real-world data 2. Inappropriate application of Art 61(10) for lower risk devices due to a lack of availability of clinical data from the specific sources defined by the proposed amendment, rather than its appropriate application	

Ref	Page no. Proposal	Art /Annex	Clause/ Subclause - Proposal	Point and Paragraph - Regulation	Comments	Proposed change
					(i.e., when clinical data are deemed not appropriate to demonstrate compliance with the GSPRs) 3. Prioritization, by manufacturers, of other global jurisdictions over the EU due to the perception that other jurisdictions accept a wider range of alternative clinical data sources	
3	36	1	2	e(72)	A significant risk comes from the combination of MDCG 2020-6 with this newly expanded definition of well-established technology (WET). This guidance introduced the idea of 'level 6' clinical data in Annex III and in the text, sections 6.2.2, 6.5.e. This is widely interpreted to both include new as well as legacy devices. It is also interpreted to mean if a device is a WET device, it can use clinical data from a similar, but not equivalent, device as if it were data about the device. This means that WET devices effectively only have to show similarity, not equivalence, to gain the benefits of demonstrating equivalence. If this is intended, it should be specifically written into the MDR. More likely this is not intended, and MDCG 2020-6 should be withdrawn or re-written to clarify this point.	**Either:** Withdraw and/or rewrite MDCG 2020-6 so that it does not give the impression that WET devices can use clinical data on other devices in the generic device group as if it were equivalent data without having demonstrated equivalence. **Or (not preferred!):** Add to Annex XIV (3): "*For devices that are well-established technology devices all members of the same generic device group can be assumed to have demonstrated equivalence to each other*."
4	36	1	2	e(72)	The current definition is too vague. It is currently in use via the MDCG guidance and experience shows that attempts to apply it in very wide circumstances have been made. For example, a software product that is 18 months old: to the manufacturer this is simple and old software. The current definition is too difficult to benchmark. This leads to decrease in predictability because a manufacturer may believe they have a WET device until the late stage of conformity assessment, and the late revelation of non-	Team NB suggestions for improvement of the text: "'*well-established technology device' means a device that belongs to a generic device group. The group fulfils all the following criteria:* *a) it has simple, common and stable design supported by common specifications or harmonised standards;*

Ref	Page no. Proposal	Art /Annex	Clause/ Subclause - Proposal	Point and Paragraph - Regulation	Comments	Proposed change
					applicability can cause significant delay, for example, because new clinical data must be generated. The definition should be refined to give a clear indication of how long on the market, how simple, etc., meets the threshold. We note that Ann VIII (5.4), rule 8, retains the words screws, wedges, plates and instruments. We think this is a good benchmark that should extend to the definition. The proposed definition includes reference to generic device group, which definition we think should also be further refined as a part of this.	*b) it has not been associated with safety issues in the past and there is good scientific justification that safety issues are unlikely to arise in future;* *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 similarly long history on the Union market as screws, wedges, plates and instruments* *e) it is not an active device* *f) there is no requirement for any special consultation or other relevant procedure* g) *it is not a class III device, other than those devices explicitly listed in …"*
5	36	1	2	e(72)	The definition (72) of WET is ambiguous. It is left to the interpretation of manufacturers and notified bodies to determine where exactly the boundaries of the a-d in the definition. Additionally, the "generic device group" definition does not concern a specific product, but rather a large number of products that a manufacturer may not even produce itself, but for which it must provide the relevant evidence. Many manufacturers will not be able to meet this requirement, and the lack of clear guidelines will lead to inconsistent implementation by the notified bodies. We consider it very risky in terms of patient safety to allow class III devices to benefit from reduced monitoring requirements. A lot of products that have caused problems	Definition of WET in Art 1 (2) (e) – (72) to be improved. See entry 4 above. In case impossible to draft an unambiguous and restrictive legal definition, a binding and unambiguous list of all products considered WET devices by application of the definition under Art 1 (2) (e) – (72) shall be drawn up by the Commission via an implementing act in accordance with the examination procedure referred to in Art 114(3). The Commission could be supported by the expert panels as established under MDR art 106. The Commission shall also establish a procedure to amend this list at predictable and regular intervals. Applications for amendments shall only be accepted for devices that clearly fulfil the definition of WET under Art 1 (2) (e) – (72).

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					in the past would have met these requirements for classification as WET. The simplifications should be limited to class IIa and IIb devices. Class III devices classified as WET should continue to benefit only from the relief provided for in Art 61 (6).	Class III devices classified as WET should not benefit from reduced monitoring requirements but continue to benefit only from the relief provided for in Art 61(6). Art 1(43)(a) to be amended, and Annex I(7)(e) to be adjusted.
6	37	1	3		Commission proposal: 1. "*The Commission is empowered to adopt delegated acts in accordance with Art 115 in order to amend the definition of well-established technology device set out in Art 2, point (72), in the light of technical and scientific progress and taking into account definitions agreed at Union and international level.* 2. *The Commission may, by means of implementing acts, draw up non-exhaustive lists of devices that fall under, or of devices that do not fall under the definition of well-established technology device in Art 2, point (72).* *Those implementing acts shall be adopted in accordance with the examination procedure referred to in Art 114(3).*"	A list of all products considered to be WET devices to be drawn up by the European Commission. See entry 5. In addition, devices, for which a valid application to be included in the WET list is rejected, shall also be included in the list as "devices <u>not</u> considered a WET device". Team NB proposed text (Art 3): "*The Commission may, by means of implementing acts, draw up lists of devices that* ***are a or are not a*** *well-established technology.* *Those implementing acts shall be adopted in accordance with the examination procedure referred to in Art 114(3).*"
7	38, 60, 80, 83, 92, 103, 104, 121	MDR: 1 IVDR: 2	MDR: 4, 42, 75, 86 IVDR: 4, 28, 61		The new Art MDR (3a IVDR) establishes a formal pathway for determining whether a product or group of products falls within the definition of a medical device or accessory, or within the scope of Ann XVI. As per paragraphs 1 and 2, Expert Panel opinions issued under Art 106 form the scientific basis for subsequent regulatory determinations. Proposed Arts 51a and 51b MDR (47a and 47b IVDR) introduce an additional pathway for resolving disputes and	

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					challenges related to the classification of CE-marked devices, including: • identification of potential misclassification following an evaluation under Art 94 MDR (89 IVDR); • mandatory coordination and consultation among Member States (Art 51b(1)–(2) MDR) (47b(1)-(2) IVDR); • referral to an Expert Panel under Art 51b(3) (47b(3) IVDR) where a substantiated disagreement is raised; • adoption of the Member State decision giving utmost consideration to the Panel opinion (Art 51b(4)) (47b(4) IVDR). Given these responsibilities, the B&C Standing Expert Panel must operate under the full governance framework of proposed MDR Art 106. Because borderline/classification work requires broad regulatory judgement, the NB experts contributing to the B&C Standing Panel should be seasoned generalists with long-standing cross-cutting experience (“eminences grises”), distinct from the technology-specific experts used in thematic clinical or technical panels. This Standing Panel ensures: • consistent Union-level interpretation of regulatory status and classification • timely decisions in the strict deadlines under Art 51b(3) (47b(3) IVDR)	

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					• scientific robustness to support Commission implementing acts • coherence between Member State practice, MDCG coordination and Expert Panel advice	
8	38, 60, 65, 83, 92, 103, 114, 115	MDR: 1 IVDR: 2	MDR: 4, 42, 46, 86 IVDR: 4, 28, 38, 39			A Coherent procedural interface between NBs and Expert Panels including: secure and structured channels for exchange between NB experts and Expert Panels; pre-opinion procedural dialogue mechanism and supported structured follow-up on Expert Panel opinions for CECP; alignment of timelines and document formats; routing of NB questions to Expert Panel
9	41	1	9		The original MDR Art 10(9)/IVDR Art 10(8) provided a clear, standardized reference for QMS components—from risk management to CAPA and post-market surveillance—ensuring consistency across manufacturers reflecting relevance to EN ISO 13485 clause and subclauses. Removing it creates ambiguity and increases interpretive variability among stakeholders involved in conformity assessment, potentially leading to inconsistent audit outcomes. The IVDR Art 10(8) third subparagraph fills the gaps which are not covered by ISO 13485 for certain elements such as UDI registration, Regulatory strategy, PMS etc. This could lead to de-harmonisation with MDSAP that could result in future misalignment.	Reinstate existing MDR Art 10(9)/ IVDR Art 10(8) third paragraph.
10	41	1	9	f,g	Commission proposal: "*Where manufacturers have their devices designed and manufactured by another legal or natural person the information on the identity of that person shall be part of the*	Team NB proposed text (Art 10(15)): "*Where a manufacturer has its device designed and/or manufactured by another legal or natural person, the identity of that person shall form part of the information submitted in accordance with Art 26(3).*

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					information to be submitted in accordance with Art 26(3). In those cases, the manufacturer shall ensure that the relevant parts of the technical documentation are drawn up, kept up to date and, upon request, made available to the competent authorities in accordance with paragraphs 4 and 7 by the legal or natural person that has designed and manufactured the device. In addition, the manufacturer shall draw up, keep up to date and, upon request, make available to the competent authorities the remaining parts of the technical documentation, in particular those referred to in Section 2 of Annex II and in Annex III." This text makes the OEM (i.e. devices designed and manufactured by another legal entity) responsible for authoring and maintaining parts of documentation, but: • the legal manufacturer retains full compliance liability • authorities can request documentation from either party • contractual enforcement becomes critical but is not addressed This results in unclear accountability during nonconformities and legal manufacturers having limited control over critical design evidence. From a regulatory drafting perspective, the main problems are: • artificial partitioning of Annex II • no concept of "documentation system delegation" • no explicit alignment with QMS control model; and • no safeguard ensuring legal manufacturer access and oversight	*The manufacturer shall ensure that a single, coherent set of technical documentation in accordance with Annex II and Annex III is established, maintained, and kept up to date within a controlled documentation system.* *The manufacturer may mandate the legal or natural person that designs and manufactures the device to draw up, update and maintain specified parts or the entirety of the technical documentation on its behalf, provided that:* • *the manufacturer retains full responsibility for conformity with this Regulation* • *the arrangements are governed by a written agreement defining responsibilities, access rights, change control, and regulatory availability, and* • *the manufacturer ensures continuous access to and oversight of the technical documentation.* *Upon request, the manufacturer shall ensure that the complete technical documentation is made available to the competent authorities, and if applicable to the Notified Body, within the timelines specified in paragraphs 4 and 7, irrespective of where or by whom the documentation is maintained.*"

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11	42	1	9	h	The express statement that individuals can claim compensation for defective devices against manufacturers, and manufacturers shall carry appropriate insurance, is an important statement of liability and should be retained.	Reinstate existing Art 10(16).
12	43	1	13	a,d	Commission proposal: Art 15(1): "*Manufacturers shall have available within their organisation at least one person responsible for regulatory compliance who possesses the requisite expertise in the field of in vitro diagnostic medical devices*" Art 15 (6): "*Authorised representatives shall have permanently and continuously at their disposal at least one person responsible for regulatory compliance who possesses the requisite expertise regarding the regulatory requirements for in vitro diagnostic medical devices in the Union*." Removing the qualification requirement would allow any individual to be designated, even without the necessary expertise, which weakens compliance oversight. Without clear competence standards, the likelihood of incorrect regulatory decisions increases, raising the risk of non-compliance, product recalls, and potential patient harm. The MDR and IVDR introduced the PRRC role specifically to reinforce accountability and ensure that regulatory responsibilities are handled by qualified professionals. Eliminating the qualification criteria contradicts this original	Reinstate the existing qualification criteria for PRRC.

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					intent and risks fragmenting EU wide harmonization. Deleting the requirement ultimately reduces the robustness of the regulatory compliance system, increases patient safety risks, and creates uncertainty for both notified bodies and manufacturers.	
13	46	1	21		Commission proposal: 3. "*For devices that are the subject of a conformity assessment as referred to in Art 52(3) and in Art 52(4), second and third subparagraphs, the notified body shall confirm in Eudamed that the information referred to in Part B of Annex VI is correct.*" In Art 52(4) there is no third subparagraph in the proposal. To limit effort, costs and administrative burden the essential information to be confirmed by NB should be limited.	For devices that are the subject of a conformity assessment as referred to in Art 52(3) and in Art 52(4), second and third subparagraphs, the notified body shall confirm in Eudamed that the information is correct as referred to in Ann VI, Part B: • point 2, • point 5, • point 6, • point 7, • point 8, • point 9, • point 19, • point 21, • point 22, • - point 23.
14	47	1	22		Commission proposal: *"The Commission, after consulting the MDCG, shall set up and manage an electronic system to create the single registration number referred to in Article 31(2) and to collate and process information that is necessary and proportionate to identify the manufacturer and, where applicable, the authorised representative, the importer and the person referred to in Article 22(1). The details regarding the information to be provided to that electronic system by the economic operators are laid down in Part A, Section 1, of Annex VI."*	Team NB proposed text: "*The Commission, after consulting the MDCG, shall set up and manage an electronic system to create the single registration number referred to in Article 31(2) and to collate and process information that is necessary and proportionate to identify the manufacturer and, where applicable, the authorised representative, the importer and the person referred to in Article 22(1). The details regarding the information to be provided to that electronic system by the economic operators are laid down in Part A, Section 1, of Annex VI.* ***In addition to the information referred to in Part A of Annex VI, manufacturers***

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					SME status should be documented in Eudamed. This would be a more sustainable option than utilising the monthly NB surveys.	***and authorized representatives shall provide the information required to determine size as per 2003/361/EC**."*
15	48, 101	MDR : 1 IVDR: 2	MDR: 24 IVDR: 22		The purpose of a SSCP/SSP is not for it to be validated by a NB, and the proposal already removes the requirements for validation. It would be possible to require a SSCP/SSP be published without ever having been reviewed by a notified body. The primary consideration should be whether the SSCP/SSP provides value to the intended audience: the public, patients and their carers. The SSCP/SSP cannot be reviewed other than alongside the CER, since it is a summary of the CER. The cost could be reduced by only requiring NB review when the NB would anyway be reviewing the CER. This does not mean that the SSCP cannot be published without this review. As the SSCP/SSP is a summary of the CER/PER, the cost is already low and will decrease further over time due to automation and digitalisation,. The SSCP and SSP are precious tools for transparency and coordination across the healthcare system. They provide patients, the public, healthcare professionals and	Maintain the proposed changes that remove the requirement for validation by notified bodies of SSCP/SSPs. Specify that SSCP and SSP should only be reviewed by the NB when they would have been reviewing the relevant CER/PER anyway, according to a sampling schedule if necessary. Require the SSCPs and SSPs be published by the manufacturer whether they have been reviewed by the NB or not. Increase clarity that SSCP and SSP are a summary of the CER/PER, and therefore minimal additional work should be undertaken, that automated summarisation should be possible. Maintain the requirement for a lay person readable version, if necessary, at the expense of the professional readable version. Do not reduce the range of devices for which an SSCP/SSP is required; increase this to include more devices, e.g. all class III and IIb devices.

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					researchers valuable information that they otherwise cannot access. They provide a valuable method of accountability. The range of devices for which an SSCP/SSP is published should be increased, and if further reductions in NB review are needed to make it viable, that would be preferable. For similar reasons the removal of the requirement for a lay person readable version will lead to a significant deterioration in the value of those SSCP/SSPs that are published and should be reconsidered.	
16	48	1	24		Commission proposal (Art 31(1)(2)): "*For **class IIb implantable** devices and for class III devices, **other** than custom-made or investigational devices **and well-established technology devices**, the manufacturer shall draw up a summary of safety and clinical performance.* *The summary of safety and clinical performance shall be written in a way that is clear to the intended user and, if relevant, to the patient and shall be made available to the public via Eudamed.*" It is not clear why the "lay-person" language versions are deleted in the proposal.	Reinstate the existing second paragraph of Art. 32. The summary of safety and clinical performance shall be written in a way that is clear to the intended user and, if relevant, to the patient. This shall be made available to the public via Eudamed.
17	54	1	35		Biennial Joint Assessments risk placing NBs in continuous audit state (preparation, duration, and responses) and recurring CAPA cycles, diverting resources away from device-	

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					specific assessments with limited incremental oversight benefit. A more proportionate risk- and performance-based hybrid oversight model (desk-based reviews with targeted on-site visits triggered by defined criteria) would strengthen harmonisation while preserving capacity and predictability. Where the legal framework proceeds with bi-annual Joint Assessments, routine annual surveillance audits should be removed to avoid duplication. This would ensure proportionality and maintain the capacity of NBs to perform their core conformity assessment tasks. Interim involvement by authorities should be limited to clearly defined "for-cause" triggers. Re-designation/re-assessment audits should not be required. This approach safeguards harmonisation objectives while preventing cumulative and duplicative assessment burdens that detract from Notified Bodies' core conformity assessment activities.	
18	55	1	35	e	The involvement of the joint assessment team (JAT) every two years is a material resource burden.	Team NB proposed text (Art 44(4)): "*Only in the event that the relevant authority reasonably suspects a material breach of this Regulation, the authorities responsible for Notified Bodies shall assess whether each Notified Body established on their respective territory and, where appropriate, the subsidiaries and subcontractors under the responsibility of those Notified Bodies*

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					Monitoring by competent authorities (i.e. annual audits) that take place between the bi-annual reviews should be dropped from the proposal and only be actioned "for cause". The specific scope of JAT involvement should be made very clear to ensure that it is limited to monitoring rather than re-assessment; and should be proportionate to NB size (based on, for example, number of active certificates).	*still satisfy the requirements and fulfil their obligations set out in this Regulation, in particular Annex VII.*" Team NB proposed text (Art 44(4a)): **Model 1 – Preferred (Hybrid, risk-based; retains national surveillance)** **"***At least every five years, the assessments referred to in Art 44(4) shall be monitored off-site by a Joint Assessment Team including two experts from the list referred to in Art 40(2), appointed by the Commission in consultation with the MDCG.* *At least one of those experts shall represent the Commission. The Joint Assessment Team shall be coordinated by the expert representing the Commission.* *In duly justified cases, as referred to in Art 44(6), monitoring by the Joint Assessment Team may be performed more frequently and may include for-cause on-site assessments, where necessary to address specific issues or verify compliance during the annual assessment of a Notified Body.* *Where consensus cannot be reached within the Joint Assessment Team, any member may refer the matter to the MDCG, which shall provide its views without undue delay and no later than 60 days from referral.*"

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						Rationale: This model preserves preventive oversight, avoids continuous audit readiness, and ensures Joint Assessments are targeted to risk, while maintaining national annual surveillance and protecting NB capacity. **Or** **Model 2 – Alternative (Biennial JAT replaces national surveillance)** *"Every two years, the assessments referred to in Art 44(4) shall be monitored by a Joint Assessment Team including two experts from the list referred to in Art 40(2), appointed by the Commission in consultation with the MDCG.* *At least one of those experts shall represent the Commission. The Joint Assessment Team shall be coordinated by the expert representing the Commission.* *In duly justified cases, as referred to in Art 44(6), monitoring by the national Competent Authority may be performed more frequently and may include for-cause on-site assessments, where necessary to address specific issues or verify compliance.* *Where consensus cannot be reached within the Joint Assessment Team, any member may refer the matter to the MDCG, which shall provide its views without undue delay and no later than 60 days from referral."*

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						Rationale: This model avoids duplication by replacing national surveillance with Joint Assessments but still requires strict proportionality and clear triggering criteria to prevent continuous oversight.
19	58, 63, 71, 83, 106, 114, 115 / 6, 31	MDR: 1 / Ann I IVDR: 2 / Ann II	MDR: 40, 44, 52, 86 / 5 IVDR: 30, 38, 39 / 5			Integration of NBCG-Med Technical Secretariat Into Medical Device Coordination Office: support from MDCO would be provided with NB coordination, strengthened methodological alignment across NBs, harmonisation of workflows, cross-NB exchange of best practices, integrated operational support for NB expert contributions, and support for literature-screening methodologies.
20	58	1	40		This text should be adapted to allow Notified Bodies more flexibility in how they accommodate the interests of small/micro enterprises. Examples could include working more closely with state-backed innovation and enterprise development agencies, reduction in training fees, increased availability of structured dialogues, or greater flexibility in conformity assessment timelines.	Team NB proposed text (Art 50(2)): "*Notified bodies shall adopt documented procedures to safeguard the interests of small and micro enterprises within the meaning of Recommendation 2003/361/EC when setting fees and delivering services. Following the end of each financial year, Notified Bodies shall publish reports on their websites outlining the support they have provided to small and micro enterprises.*"
21	58	1	40		The proposal focusses predominantly on cost savings and efficiency, without a corresponding assessment of impacts on patient safety, risks weakening key MDR/IVDR safeguards and shifting attention away from robust conformity assessment, potentially undermining long-term patient confidence and healthcare outcomes	Any proposed procedural or financial amendments should be accompanied by a structured assessment of their impact on patient safety and overall system performance, ensuring that efficiency measures do not compromise the preventive safeguards established under the MDR/IVDR.
22	59	1	40		The current proposed wording in Art 50(3) is highly detrimental without any demonstrable benefit and therefore should be removed. NBs have committed to a) publishing	Remove Art 50(3).

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					fees on their website; and b) reporting on fees to their designating authorities in response to the proposed Ann VII implementing act.	
23	59	1	40		The proposal to impose specific conformity assessment approaches raises unresolved questions regarding liability, impartiality, and NB independence, and risks constraining the application of risk-based judgment foreseen under the MDR/IVDR; prescriptive imposition rather than adherence to existing regulatory requirements may reduce flexibility needed to ensure appropriate, device-specific safety evaluations and market stability.	Remove or clarify provisions that impose prescriptive conformity assessment structures, ensuring NBs retain independence, impartiality, and the ability to apply risk-based judgment, with clear alignment to existing MDR/IVDR principles.
24	61 / 14, 15	1 / Ann I	43 / 7	7c, 7e	Acceleration of review timelines combined with stricter training, qualification, and designation requirements (including limited scope codes) may reduce NB capacity and expert availability, resulting in fewer products reaching the market, including devices that could offer improved safety or clinical benefit.	Allow NBs to determine proportionate review times that reflect the quality of the technical documentation and the risk of the devices. Allow flexibility for qualification of resource, acknowledging that the role of the conformity assessment is to provide a proportionate, risk-based review that considers boarder concepts and leverages wider knowledge of medical devices to challenge the safety and performance demonstrated by manufacturers and the clinical claims.
25	61 / 14,15	1 / Ann 1	43 / 7	7c,7e	Reduced sampling and surveillance activities, together with challenges in maintaining assessor qualifications under the proposed framework, may undermine the ability of NBs to sustain the necessary depth of technical and clinical competence, particularly for complex or innovative technologies.	Maintain minimum proactive sampling and surveillance levels necessary to support assessor competence and robust clinical/technical oversight, particularly for high-risk and innovative devices, rather than reducing systematic activities to infrequent intervals.
26	61 / 14,15	1 / Ann I	43 / 7	7c,7e	A shift toward predominantly for-cause assessments, with fewer proactive and systematic conformity assessment activities, risks limiting early identification of safety and	Ensure that oversight remains preventive and systematic, with for-cause assessments used as a supplement rather than a substitute,

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					performance issues. With reduced NB oversight, potential early signs of non-compliance, safety concerns, or performance degradation across a manufacturer's devices and QMS is unlikely to be detected in a timely manner, ultimately weakening preventive oversight and increasing reliance on reactive measures after issues have already materialised.	preserving early detection mechanisms for noncompliance, safety concerns, and performance degradation.
27	62	1	43	e(ii)	Art 52.7c states that manufacturers may not involve a NB if the manufacturer self-declares that relevant harmonized standards or CS have been applied. If they do not self-declare this, they must involve a NB for conformity assessment. This suggested approach is not comprehensible as the NB has to consider the relevant harmonized standards, and CS or state-of-the-art criteria. Specifically in combination with the proposed down-classification in Annex VIII, rule 6 and 7 "regardless of the body part with which they come into contact" the proposed removal of scrutiny for those devices is concerning for patient's safety (practical experiences of NBs and laboratories regarding reprocessing data below). Furthermore, no impact analysis could be found that estimates the potential costs for the overall European healthcare system that may arise from dismantling the enhanced infection protection introduced by the current MDR requirements for instrument-related surgical interventions.	Remove addition of "*Where the manufacturer of class I reusable surgical instruments has applied harmonised standards or CS covering all relevant aspects referred to in the first subparagraph, point (c), the involvement of a notified body is not required*." Reinstate existing Art 52(7c).

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					Practical experiences of NBs and laboratories regarding reprocessing data: • majority of lifetime data including biocompatibility are lacking full evidence • 50-80% of manufacturers outside of the central European region abandon a disinfection step before sterilization in IFU and efficacy testing thereof According to well-established accredited test laboratories recognized for ISO 17664, the majority of MDR triggered reprocessing validations are insufficient and do not comply with the claimed harmonized standard EN ISO 17664. Specifically, the manufacturer is not able to present an IFU with correct reprocessing instructions complying with ISO 17664 and related standards and guidelines. That does not support the thesis that proposed change of Art 52.7c can be considered as a reliable approach to safeguarding a high level of patient safety.	
28	63, 106	MDR: 1 IVDR: 2	MDR: 44 IVDR: 30		The proposed MDR Art 52a and proposed IVDR Art 48a introduce Union-level mechanisms for the designation of: • Breakthrough devices / breakthrough IVDs, and • Orphan devices / orphan IVDs. These mechanisms are intended to promote access to technologies addressing unmet medical needs, rare conditions, or serious clinical challenges, and may involve	The BtX/Orphan Standing Panel should: • have stable membership, including Member State representatives, ensuring continuity and legitimacy • include academic and NB experts selected under Art 106(6) independence rules • provide scientific recommendations capable of being transformed into Union-level legally binding decisions, similar to the Orphan medicinal product pathway • operate under governance rules aligned with Art 106 of the MDR/IVDR.

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					priority review, rolling review and adapted evidence pathways. BtX and Orphan designations have a higher regulatory significance than standard Art 106 advice, and the proposed MDR/IVDR foresee that Expert Panel recommendations may form the basis for Union-level regulatory decisions.	This Standing Panel should serve both the MDR and the IVDR, reflecting that BtX/Orphan mechanisms are introduced in both proposed Art 52a MDR and Art 48a IVDR. The binding decisions, similar to the orphan medicinal product pathway ensure that NBs are not exposed to undue liability risks when certifying devices supported by emerging or incomplete clinical data.
29	63	1	44		A new Art, Art 52(c) should be introduced which lists of all products that are considered WETs needs to be drawn up by the European Commission.	Team NB proposed text (Art 52(c)): 1. *"Upon a duly substantiated request by a manufacturer or a notified body, MDCG shall provide a decision within 30 days as to whether device is a well-established technology.* *2. The decision shall be published on a dedicated website without disclosing any confidential information as referred to in Art 109.* *3. The decision shall be binding for the manufacturer and the notified body.* *4. Only devices listed in accordance with Art 3 or for which a decision according to paragraph 1 of this Art is available are considered to be a well-established technology."*
30	65, 83, 85, 114, 115	MDR: 1 IVDR: 2	MDR: 46, 86, 87 IVDR: 38, 39			Introduction of MDCO (Medical Device Coordination Group), serving as the administrative backbone of the system providing: • Interaction of MDCO with Member States, Commission, NBCG-Med and EMA, functioning as central procedural interface: MS and Commission would maintain full responsibility for regulatory decisions; NBCG-Med provides NB coordination; EMA and Expert Panels retain scientific,

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						methodological and clinical responsibilities; MDCG covers all non-scientific operational tasks and ensures coherence Procedural (not scientific) coordination for Expert Panels through: dossier validation and completeness checks; scheduling and workflow management; Member State consultation coordination; independence and confidentiality safeguards; structured communication with NBs and national authorities
31	72, 114	MDR: 1 IVDR: 2	MDR: 52 IVDR: 38		Under Art 61(2) MDR, manufacturers of class IIb and III devices may seek early scientific advice on their clinical development strategy. Under Art 56 IVDR, manufacturers of class C and D IVDs may seek similar advice on performance evaluation strategies. These advisory activities represent the role foreseen in Art 106(1)(e) and 106(7)(a) and are distinct from the CECP/PECP procedures. Per Art 106(6), NB experts participating in these advisory panels shall not be involved in CECP (Art 54 MDR).	
32	71 / 23	1 / Ann I	52 / 12	52b / 12b	The proposal to broaden the criteria for demonstration of clinical and biological equivalence by allowing for the use or "same or similar materials" and "same or similar clinical condition" raises concerns. 1. Clinical Equivalence: • Broadening of the criteria allows for certain clinical conditions to be considered as "similar" based solely on underlying pathology, even when the actual clinical management or expected patient	Reinstate the current wording of clinical characteristics specified by Annex XIV Part A (3).

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					outcomes differ substantially. It may be claimed that certain clinical conditions are “similar” without a unifying underlying pathology but instead based on some other unvalidated measure (e.g., patient symptoms). • A clear example can be seen in atherosclerosis. Although the physiological process of plaque formation in peripheral arteries and in coronary arteries may be broadly similar, the clinical implications and treatment strategies differ markedly. For instance, drug-eluting stents offer established and substantial clinical benefit in the treatment of coronary artery disease. In contrast, the same intervention provides minimal benefit and increases risk substantially for patients with flow-limiting plaque in the lower limb. This demonstrates that, despite similarities in pathology, clinical condition and associated therapeutic value cannot be considered equivalent. • Under the MDD, the requirement to demonstrate clinical equivalence relied on use of the device for the same clinical condition and intended purpose. By amending the criteria to allow for use of “similar” clinical condition, the requirements fall below MDD requirements, which is contrary to the underlying founding principles of the MDR to enhance patient safety. It is further noted that reliance on the criterion of ’similar clinical conditions’ is not permitted by other global regulatory agencies, for example the FDA, and may lead to lack of recognition of CE-marked devices based on equivalence for entry to certain global markets.	

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					2. Biological Equivalence: Introduction of 'similar' materials is welcomed as it provides greater flexibility and pragmatism for acceptance of certain material differences based on scientific evidence and appropriate justifications. For example: • Low-risk, non-contacting devices • Introduction of minor material changes to a device with an established history of safety and performance • Modification of a device because of material supply issues Caution is advised regarding the interpretation of 'similar' particularly in the case of implantable devices and substance-based devices, as diverging opinions amongst and between NBs and manufacturers may arise – for example, differences in grade of titanium vs differences in formulations and proportions of non-active ingredients. It is important to emphasise that use of similar materials may lead to the introduction of unforeseeable mid-long-term risks to the patient Supporting guidance from the Commission will therefore be essential to ensure consistent, pragmatic, and patient-safe decision-making.	

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					3. Recertification: In cases whereby initial CE marking was based on equivalence, recertification is a point in time when NBs have the best opportunity to review the clinical data generated for the subject device and in accordance with the manufacturer's approved PMCF plan. The proposed changes to recertification remove the opportunity to perform a detailed review of the subject device's PMCF data. This further reinforces the need for equivalence claims to be based on a solid, evidence-based rationale and justification that adequately informs the consideration of long-term safety and performance. 4. Inconsistent Interpretation of 'Similar': The proposed change will result in all three equivalence criteria–technical, biological, and clinical–to require only 'similar' characteristics. 'Similarity' is a subjective concept, and manufacturers as well as NBs are highly likely to interpret it differently. Inconsistent interpretation and acceptance of what is considered 'similar' could potentially lead to devices with substantially different safety profiles reaching the market with inadequate regulatory scrutiny. Additionally, the purpose of equivalence is to demonstrate safety and performance of a device based on another device's clinical data (i.e., the data is equally relevant to both devices as they are essentially the same device). If a device is compared to another device with similar technical, biological and clinical characteristics–i.e., where none of	

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					these three aspects are the same–it brings into question how the claimed equivalent device's data can be considered to accurately reflect the safety and performance of the device under evaluation. It can be argued that such an approach could annul the validity and robustness of the equivalence claim.	
33	73	1	52	f	Clarification is needed on the requirements for supporting device safety and performance based on non-clinical data in cases where clinical data is deemed to be not appropriate. Team NB supports the recognition of the additional non-clinical testing methods such as in-silico testing, ex-vivo, in-vitro testing and computational modeling. There is a concern that in the absence of any guidance from the Commission regarding the types of devices for which Art 61(10) is considered acceptable, the proposed changes will further exacerbate the inconsistent use and acceptance of this clinical evaluation route. As a result, NBs and manufacturers will continue to engage in onerous and time-consuming discussions regarding interpretation of the specific wording of the Art, rather than focusing on what data is needed to support a device and whether the available data is considered sufficient. Concerns: • The removal of the word "exception" implies that a greater number of class IIa and IIb non-implantable devices may become eligible for Art 61(10). This	Delete Art 61(10). Team NB proposed text (Art 61(1)): • "*Manufacturers shall plan, conduct and document a clinical evaluation in accordance with this Art and with Part A of Annex XIV to confirm the safety and performance of the device under normal conditions of use in accordance with the intended purpose of the device, and shall evaluate any undesirable side-effects and the acceptability of the benefit-risk- ratio referred to in Sections 1 and 8 of Annex I.* • *The manufacturer shall specify and justify the level of clinical evidence necessary to confirm the safety and performance of the device. That level of clinical evidence shall be appropriate in view of the characteristics of the device and its intended purpose.* • *The clinical evaluation, its results and the clinical evidence derived from it shall be documented in a clinical evaluation report as referred to in Section 4 of Annex XIV, which, except for custom-made devices, shall be part of the technical documentation referred to in Annex II relating to the device concerned.*"

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					approach moves away from the underlying principles of the medical device regulation outlined in point 63 of the preamble, whereby the focus of the regulation is to ensure patient safety by emphasizing the important role played by clinical data when it comes to demonstrating device safety and performance. Rather than focusing on ensuring that sufficient evidence is available to demonstrate that a device is safe for use and will perform as intended, this change is likely to increase ambiguity and lead to greater inconsistency and disagreement between manufacturers and NBs, when determining the acceptability of such an approach. • The addition of "data available for the generic device group" potentially adds further ambiguity. It is not clear what 'data' the proposed wording is referring to. For example, is Art 61(10) considered to be unacceptable if clinical data is available for other devices within the same generic device group? Alternatively, in the absence of clinical data on the device under evaluation, does the proposed amendment intend for safety and performance to be demonstrated using generic device group clinical data for certain devices? This approach	In addition, at the time of publication of the amendment, the Commission must provide manufacturers and NBs with proper guidance to ensure consistent interpretation and implementation of the criteria for justifying the necessary level of clinical data, clearly reinforcing point 63 of the MDR preamble[4], that normally some clinical data should be provided and that reliance on non-clinical data alone should only apply to devices where clinical data does not inform on safety and/or performance.

[4] To ensure a high level of safety and performance, demonstration of compliance with the general safety and performance requirements laid down in this Regulation should be based on clinical data that, for class III devices and implantable devices should, as a general rule, be sourced from clinical investigations that have been carried out under the responsibility of a sponsor. It should be possible both for the manufacturer and for another natural or legal person to be the sponsor taking responsibility for the clinical investigation

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					implies that Art 61(10) is moving towards a more lenient equivalence-type route. • There is a lack of clarity regarding what is meant by "not deemed appropriate" in relation to "the confirmation of safety and performance based on clinical data". Is it foreseeable that the term "not deemed appropriate" could be interpreted to mean that clinical data is "not available prior to initial certification for the device under evaluation". It must be acknowledged that there are situations in which certain devices are unlikely to obtain sufficient clinical data prior to initial certification, however once on the market, real world clinical data can be more readily generated. This may arise for several reasons, including the challenges in performing clinical studies (including ethical concerns, feasibility and excessive timelines) for some emergency use devices, limited reporting in the peer-reviewed scientific literature for routine standard-of-care medical devices, or a genuinely low appetite among clinicians to undertake clinical data-generation activities for certain standard-of-care or routine devices. Clear guidance for NBs on when such circumstances justify reliance on alternative non-clinical evidence would introduce greater pragmatism and consistency in evaluations	
34	76	1	67	a	Annual PSURs enable early detection of trends in adverse events, erroneous results, and performance degradation. Extending the interval to two years increases the likelihood	Team NB proposed text: "*Manufacturers of Class III devices or novel/orphan/breakthrough devices shall update the PSUR at least annually and whenever there is*

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					that emerging safety signals remain undetected for longer, delaying necessary corrective actions. Extending PSUR update intervals has a materially greater impact where standalone notified body PSUR review is also reduced or eliminated. Class III devices present the highest individual and public health risk and annual updates are essential to ensure timely identification of safety concerns. Class IIb devices that are not novel/orphan/breakthrough devices may retain a reduced frequency for administrative relief but still require updates following major changes. This approach preserves alignment with MDR principles of proportionality and risk-based oversight.	*a significant change in the benefit–risk determination or in the acceptability of erroneous results*. *Manufacturers of class IIb devices shall update the PSUR in the first year after the certificate is issued and every two years thereafter, or earlier if there is a significant change in the benefit–risk determination, in the acceptability of erroneous results, or when the notified body has raised concerns and it has been agreed that these will be addressed through increased PSUR scrutiny.* *Each PSUR shall form part of the technical documentation as specified in Annex III.*
35	77	1	67	b	For class III devices or class IIb implantable devices, other than well-established technology devices, the NB shall review the PSUR during the surveillance assessment. The manufacturer and the NB shall make such PSURs and the evaluation by the NB available to competent authorities through the electronic system referred to in Art 92. It shall be clarified that by which qualified role, auditor or product reviewer, the PSUR assessment is meant to be conducted.	Team NB proposed text: “PSUR review by the notified body shall enable an independent benefit–risk assessment and shall not be reduced to an incidental audit activity where this would prevent sufficient depth of review.”

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					In case the proposal means to eliminate standalone PSUR reviews by product reviewers in exchange of conducted the review during surveillance audits by auditors: this proposal increases pressure on auditors to assess PSURs during audits. They are unlikely to have sufficient time to compare them with previous PSURs and the state of the art for complaint and vigilance rates. Further the qualification of auditors is technology related and not product related. Please clarify that during the surveillance assessment, it is meant that the PSUR review shall be done in the context of the surveillance the audit conduction, but not necessarily onsite by the auditor. The review shall be done by a product reviewer, either onsite or offsite. Further, clear timeframes need to be given to harmonize the approach across the mfr and NBs, as for the first surveillance audit after the certification most likely no PSUR reviews can be conducted, as the PSUR data collection period is due after 12 months after the certification plus approximately 60-90 days for report preparation. Therefore, for the first surveillance we propose that the data collection period shall be less than the exact 12 months to be able to combine it with the surveillance activities, or alternatively the audit shall be planned at the outer limit of the maximum allowed time window (see MDCG below*). *MDCG 2019-6, IV.10: In order to take in consideration, the necessity for contingent scheduling adjustments, surveillance audits can be	

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					conducted w**ithin a limited window of +/- three months** from the due date without particular concern.	
36	77, 118	MDR: 1 IVDR: 2	MDR: 68 IVDR: 54	MDR: 68b IVDR: 54b	Commission proposal: *"Manufacturers shall report any serious incident as referred to in paragraph 1, first subparagraph, point (a), immediately after they have established that there is a causal relationship between that incident and their device or that such causal relationship is reasonably possible, and not later than 30 days after they become aware of the incident."*	The amendment would be acceptable if the current NB oversight (such as systematic initial and surveillance TD assessments, PSUR reviews) remain unchanged. If not, this would further cumulatively weaken the protection of patient safety.
37	80	1	73		Notified bodies' tasks under Articles 83–86 MDR, Annex III and Annex IX require independent and timely access to post-market surveillance, vigilance and PSUR data. Without direct access to EUDAMED, notified bodies cannot effectively perform surveillance, benefit–risk assessment, trend analysis, for-cause evaluations or periodic reviews of continued conformity. In light of the increased reliance on post-market data and reactive mechanisms in the Commission proposal, lack of explicit access risks weakening the preventive intent of the MDR and creating inconsistent practices across Member States.	Team-NB text proposal for MDR: *"For the purposes of Articles 83 to 86 and Annexes III and IX, notified bodies designated under this Regulation shall have direct access to the relevant modules of the electronic system referred to in Article 92, to the extent necessary to perform their conformity assessment, surveillance and periodic review tasks."* For IVDR, analogous text is proposed.
38	83, 85, 123	MDR: 1 IVDR: 2	MDR: 86, 87 IVDR: 70		The governance of expert panels shall be clearly defined, including the respective roles of the Commission and EMA in oversight and secretariat support, and the relationship between expert panels, MDCG, EMA and NBCG Med. Team NB believes clear governance provisions would enhance predictability and transparency for all actors involved in expert panel activities.	Team NB proposed text: **"***In order to ensure consistent, transparent and independent scientific advice at Union level, the governance of expert panels should be clearly delineated. It is therefore appropriate to specify the respective roles of the Commission and the European Medicines Agency in the oversight and operational support of Expert Panels, the reporting obligations towards the Medical Device Coordination Group, and the*

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					The existing governance model should be extended with: • The interaction between Expert Panels and NBCG Med, clarifying that NBCG Med provides a forum for coordination and exchange. • How expert panel outputs are integrated into Union processes, including classification, qualification, and the evaluation of applications for Breakthrough (BtX) and Orphan designations, in a manner that ensures proportionality, consistency, and timely decision making. This structure would ensure transparency, reinforce the independence of scientific advice, and provide a clear and coherent framework for the participation of NB experts in Expert Panel activities.	*modalities for interaction with NBCG Med. Clarifying these elements would enhance predictability for manufacturers, notified bodies and other stakeholders, while safeguarding the independence and technical integrity of Expert Panel opinions issued under this Regulation."*
39	83	1	86		NB personnel have demonstrable expertise validated by national designating authorities. Their contribution increases the technical and regulatory depth of Expert Panels while ensuring consistency with conformity assessment practice. Safeguards are necessary to preserve impartiality: 1. NB experts apply as individual professionals, not representing their NB	Team NB proposed text: *"Expert panels may include personnel from notified bodies, appointed as individual experts. Such experts shall comply with the applicable independence and impartiality requirements, including recusal from any procedure directly related to an opinion to which they have contributed and from expert panel activities concerning devices assessed or to be assessed by their notified body. These limitations apply solely to the individual expert and shall not restrict the notified body from conducting conformity assessment through other qualified personnel. All notified body experts shall be subject to the transparency rules applicable to expert panel members."*

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					2. Nomination via NBCG Med, which compiles a balanced shortlist ensuring no NB is over-represented 3. Appointment by EMA/Commission 4. Strict role separation To ensure independence and avoid conflicts of interest while maintaining NB operational capacity, the following principles apply: • No involvement in directly related cases An NB expert who has contributed to an Expert Panel opinion shall not be involved in any procedure directly relating to that specific Expert Panel opinion, including subsequent assessments for the same device • No assessment of devices previously assessed by the expert's NB NB experts must not participate in Expert Panel discussions or opinions concerning devices that have been assessed by their own NB in the context of conformity assessment. • Mandatory transparent publication of expert names and affiliations. For transparent publication, NB experts shall be subject to the same rules as the experts of the existing expert panels. • Regulatory adjustments needed to permit NB expert participation as a prerequisite for any scheme involving NB personnel in expert panels, existing policies and procedures of the Commission and EMA would need to be revised to reflect the	

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					impartial and independently supervised nature of NBs, such as EC Decision 2019/1396, Art. 12 (2): "Advisor shall not have financial or other interests in the medical device industry or in a notified body […]").	
40	83	1	86		The central expert pool foreseen in Art 106(2) supports Standing Panels and Clinical Panels in domains such as: • software, cybersecurity • biocompatibility and materials science • sterilisation and microbiology • ancillary medicinal substances • electrical safety • GSPR-related horizontal competencies These experts are mobilised ad hoc across all Expert Panel functions.	Introduction of: **Standing Expert Panels** • Screening Panel (CECP) • Borderline & Classification Standing Panel (Arts 4a, 51a, 51b MDR) • BtX and Orphan Standing Panels (Art 52a MDR) (48a IVDR) Shared characteristics: • stable membership • Member State representation • academic and NB experts under Art 106(6) • ability to support Commission implementing acts (Arts 4a(3), 51a(6), 51b(6) MDR) (3a(3), 47a(6), 47b (6) IVDR) **Clinical Expert Panels** Advisory functions under: • Art 61(2) MDR – early scientific input on clinical development • Art 56 IVDR – early scientific input on performance evaluation Explicitly not CECP, consistent with Art 106(6).

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						Central Expert List Art 106(2) pool of cross-cutting technical and regulatory experts. **Overall interaction** The structure ensures: • consistent classification and borderline decisions (Arts 4a, 51a, 51b MDR) (3a, 47a, 47b IVDR) • structured BtX/Orphan pathways (Arts 52a MDR) (48a IVDR) • consistent scientific advice for clinical/performance development • access to specialised expertise across all panels • EMA secretariat support under Art 106(4) • Relevant NB experts can contribute without affecting NB organisational capacity.
41	90	2	1		Commission proposal: *"Any device which, when placed on the market or put into service, incorporates, as an integral part, a medical device as defined in Art 2, point (1), of Regulation (EU) 2017/745 that has an action ancillary to that of the in vitro diagnostic medical device, the integral product shall be governed by this Regulation. In that case, the relevant general safety and performance requirements set out in Annex I to Regulation (EU) 2017/745 shall apply as far as the safety and performance of the medical device part are concerned. However, if the action of the medical device is principal and not ancillary to that of the in vitro diagnostic medical device, the integral product shall be governed by Regulation (EU) 2017/745. In that case, the relevant general safety and*	Team NB proposed text: "*In cases where a single integral product combines an in vitro diagnostic medical device and a medical device, and both components have principal actions that are not ancillary to each other, the product shall comply with both Regulation (EU) 2017/746 and Regulation (EU) 2017/745. In such cases, the manufacturer shall demonstrate conformity with the applicable general safety and performance requirements set out in Annex I of both Regulations for the respective parts of the device. The conformity assessment shall ensure that the combined use does not compromise the safety, performance, or intended purpose of either component."*

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					performance requirements set out in Annex I to this Regulation shall apply as far as the safety and performance of the in vitro diagnostic medical device part are concerned." The proposal provides better explanation for integral part MD/IVD in IVD/MD Device. This does not cover all scenarios. For example: There is 2-in-1 blood glucose meter and blood pressure meter as a single medical device, where the action of IVD part is principal for IVD and the action of MD part is principal for MD. This scenario is not clearly covered by the text and would be helpful to include it.	
42	96	2	9	d	Commission proposal: Removal of "*The information supplied in accordance with Section 20 of Annex I with devices for self-testing or near-patient testing shall be easily understandable and provided in the official Union language(s) determined by the Member State in which the device is made available to the user or patient."* By removal of this phrase self-users or users of NPT tests can end up with an IFU that is not understandable due to too complex words or technical language etc. This will pose a significant risk to the usability of these tests.	Reinstate the existing text and the requirement to provide information in a format that is easily understandable for users.
43	100	2	18	d	Commission proposal:	Correction of this reference.

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					"*3a. For devices that are the subject of a conformity assessment as referred to in Art 48(3) and (4), Art 48(7), second ';subparagraph, Art 48(8), and Art 48(9), second subparagraph, the assignment of a Basic UDI-DI referred to in paragraph 1 of this Art shall be done before the manufacturer applies to a notified body for that assessment."* There are no second paragraphs for Art 48(7) and 48(9) in the revised text.	
44	100	2	19		Commission proposal: "*2. For devices that are the subject of a conformity assessment as referred to in Art 48(3) and (4), Art 48(7), second subparagraph, Art 48(8), and Art 48(9), second subparagraph, the notified body shall confirm in Eudamed that the information referred to in Part B of Annex VI is correct.'"* The current version of IVDR text refers to conformity assessment routes applicable for product certificates (class D, CDx, ST and NPT), whereas the revised text refers to in general class D, class C and class B. This is not possible. NBs can only confirm Basic UDI-DI on certificates for product certificate relevant conformity assessment.	Team NB proposed text: "*For devices that are the subject of a conformity assessment as referred to in Art 48(3) and (4), Art 48(7) in combination Art 48(10a) and/or Art 48 (10b), Art 48(8), and Art 48(9) in combination Art 48(10a) , the notified body shall confirm in Eudamed that the information referred to in Part B of Annex VI is correct."*
45	101	2	22	a	In general, Class C devices include tissue typing, genetic testing, cancer diagnostic, specific disease, and infectious disease diagnostic tests, where there is high individual risk. SSPs are public-facing documents for the public. Without a clear, easy-to-understand summary in Eudamed for certain	From a safety perspective, if the requirement for SSP for Class C devices were removed, manufacturers should at minimum be required to make their IFU easily searchable on their website (ideally retrievable by entering the device name or marker name) and accessible to both healthcare professionals and patients. This would

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					class C devices, healthcare providers and patients lose quick access to critical information on safety, performance, risks, and post-market data. This undermines the IVDR objective of fostering informed use of high-risk devices. SSP serves a supplementary, distilled format tailored to professionals and patients, which IFUs alone may not cover.	help ensure that users can readily identify the intended purpose and limitations of the device, even in the absence of SSP oversight.
46	101	2	22	b	SSPs were designed to present information in plain language for intended users. The pared-down version may not cater to non-professionals or self-testers effectively. IFUs often involve dense technical language and lengthy narratives, making it harder for lay users to locate and understand key safety and performance information. IFUs are not always online publicly available. A more concise SSP provides less insights into device limitations (potentially affecting trust from clinicians, patients, and purchasers). Reducing content may erode public trust in regulations thoroughness. The full SSP, publicly uploaded to Eudamed, enhances accountability. Moreover, the suggested approach is not aligned with revised text of MDR.	Reinstate Art 29 (2) concerning the text for SSP content.
47	104	2	29	a	Commission proposal: *"(a) in paragraph 3, the second and third subparagraphs are deleted;* *First sub-paragraph: "Manufacturers of class D devices, other than devices for performance study, shall be subject to*	Team NB proposed text: **Option A: Clarify NB Inclusion** "*Manufacturers of Class D devices (excluding performance study devices) must undergo conformity assessment under Chapters I, II (excluding Section 5), and III of Annex IX, conducted by a Notified Body officially designated for all three chapters. Certificate(s) issued by the*

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					*a conformity assessment as specified in Chapters I, II except for Section 5, and in **Chapter III of Annex IX**."* Chapter III is not currently overseen by NBs under the IVDR, creating a gap in formal conformity coverage. Publicly available NB certificates for IVDR are limited to Chapters I and II; there's no trackable NB certificate for Chapter III under IVDR.	*Notified Body must specify compliance with Annex IX Chapters I, II, and III, and be registered in EUDAMED accordingly."* **Or** **Option B: Limit Scope to Chapters I and II** "*Manufacturers of Class D devices (excluding those for performance studies) must undergo conformity assessment under Chapters I and II of Annex IX. Notified Bodies designated under Annex IX Chapters I and II shall audit QMS and technical documentation as required, with certificates duly"*
48	105	2	29	h	A significant patient-safety concern arises for Class A sterile IVDs, such as blood collection tubes used with an open connection to a venous or arterial puncture needle (classified as Class IIa under the MDR). Studies have demonstrated that these tubes must be sterile due to the risk of backflow of blood into the patient's venous system. This can happen due to changes in the pressure if the tourniquet is released while the tube is still connected and the vacuum is exhausted, the sudden drop in venous pressure can pull fluid back from the tube. It can also happen by holding the tube above the puncture site which allows gravity to facilitate the movement of contents back into the vein. Significant lack of experience among IVD manufacturers with sterile products in general, and particularly with a sterile	Reinstate 48(10).

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					validation, already now resulting in a relatively high number of safety issues.	
49	105 / 25	2 / Ann II	29 / 6	29i / 6n	These sections should also be applicable for the near-patient testing (NPT) devices. Users of NPT devices often lack experience with IVD devices and have only limited knowledge on specimen handling, not typically a trained laboratory professional. There are also high country-to-country differences in educational and training background. Therefore, it is important that these devices meet the same requirement as the self-testing devices. In addition, the risk management section, usability and Labelling (IFU) of NPT shall always be verified by a NB. Especially since the use environment (storage conditions, temperature, humidity, emergency situations (stress), manual input is required sometimes, manual read-out, transcription errors) of the NPT test can have a big effect on the performance of the device. As an example, a NB assessed a device that could not tolerate any vibration during use. However, the intended use environment also included an ambulance. The risk associated with operating the device in a moving ambulance was not addressed in the risk management file.	The current sampling requirements for Class C and Class B devices must be reinstated. Placing near-patient testing devices solely under a QMS certificate, combined with even lower sampling of technical documentation would substantially reduce the level of NB scrutiny. Retaining the existing sampling approach is therefore essential. A minimum and consistent level of NB oversight for near-patient tests is critical to ensuring patient safety. As an alternative, the verification of the technical documentation for all near-patient testing devices could be maintained, with the review focused specifically on risk management, labelling and usability aspects.
50	115	2	40	b	Commission proposal:	High-risk procedure could be explained as follows:

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					"*Where the conduct of the study involves additional invasive procedures, including high-risk procedures for collection of specimens, or other risks for the subjects of the studies"* A definition of what procedures should be considered high risk in this context should be provided. Manufacturers should clearly define in their clinical performance study plans what procedures are high risk and what aren't. Furthermore, the requirements for informed consent for the use of leftover or archived specimens should also be considered. Requirements for informed consent related to the use of leftover or archived specimens are determined by local legislation, ethics committee expectations, and the risk assessment for participating patients. For investigations involving genetic information, national regulations often impose more stringent or specific protective measures, including detailed provisions on informed consent.	The classification of a procedure as high risk depends on the specific design of the clinical investigation. Key factors include: • **Population characteristics:** for example, newborns, pregnant women, children, elderly individuals. • **Clinical condition of enrolled subjects:** such as immunocompromised patients, individuals with specific cancer grades or types, or those with cardiovascular or respiratory diseases. • **Impact of erroneous results:** situations where false-negative or false-positive outcomes could significantly influence patient management (e.g., companion diagnostics). • **Nature of specimen collection:** including the **volume** (e.g., cerebrospinal fluid) and **type** of procedure (e.g., invasive procedures such as gastroscopy or surgery). The manufacturer must provide a clear justification of the clinical investigation risk, taking all relevant elements into account. In addition, the manufacturer should explicitly state: • whether approval from an ethics committee has been obtained, and • whether signed informed consent forms are available for the specimens used.
51	118	2	53	a	Commission proposal: "*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*	Manufacturers of class D devices, as well as class C devices intended for self-testing, near patient testing, companion diagnostics, or novel/orphan/breakthrough applications, 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.

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					acceptability of erroneous results. That PSUR shall be part of the technical documentation specified in Annex III." Annual PSURs enable early detection of trends in adverse events, erroneous results, and performance degradation. Extending the interval to two years increases the likelihood that emerging safety signals remain undetected for longer, delaying necessary corrective actions. Class D devices present the highest individual and public health risk (e.g., blood screening, transmissible agents), and annual updates are essential to ensure timely identification of safety concerns. The same approach should be maintained for class C devices for self-testing, near-patient testing and CDx. Class C devices for professional use that are not novel/orphan/breakthrough devices may retain a reduced frequency for administrative relief but still require updates following major changes. This approach preserves alignment with IVDR principles of proportionality and risk-based oversight.	Manufacturers of all other class C devices shall update the PSUR in the first year after the certificate is issued and every two years thereafter, or earlier if there is a significant change in the benefit–risk determination, in the acceptability of erroneous results, or when the NB has raised concerns and it has been agreed that these will be addressed through increased PSUR scrutiny. Each PSUR shall form part of the technical documentation as specified in Annex III.
52	118	2	53	b	Commission proposal: "*For class D devices, the notified body shall review the PSUR during the surveillance assessment. The manufacturer and notified body shall make such PSURs and the evaluation by the notified body available to the competent authorities through the electronic system referred to in Art 87"*	Team NB proposed text: "*For Class C devices intended for self-testing, near-patient testing, and companion diagnostics 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 Art 87."*

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					Self-testing and near-patient testing (NPT) devices are used by laypersons or in decentralized settings. Errors in performance or usability can lead to misdiagnosis, delayed treatment, or unnecessary interventions. Companion diagnostics directly influence drug selection and dosing for critical therapies (e.g., oncology). Incorrect results can cause serious harm or treatment failure. Without NB review, PSURs remain internal to manufacturers. This creates a risk that emerging safety signals or performance issues are not independently validated. NB oversight ensures objective evaluation of benefit-risk balance and acceptability of erroneous results, which is crucial for devices guiding high-stakes decisions. Self-testing and NPT devices often face real-world usability challenges. NB review of PSURs helps identify patterns of user errors or design flaws that manufacturers might overlook.	
53	11, 35	MDR: Ann I IVDR: Ann II	5	MDR: z IVDR: y	The proposal for removing the conventional maximum validity period of certificates issued by NBs (Art 56 and Ann VII 4.8 and 4.11) and replacing it by a continuous monitoring system can be considered. However, it should be considered and expected that there will be more interim escalations (e.g. suspensions) during the annual surveillance respectively the review period. The proposed new Ann VII, 4.11 Periodic reviews and the NB internal extension considerations of a certificate's validity period bears the risk of a very non-harmonized implementation.	Team NB proposed text: "*4.11. Periodic reviews and extension of a certificate's period of validity'* *The notified body shall have documented procedures in place relating to periodic reviews* ***latest every three years*** *after the* ***approval of*** *quality management systems or EU technical documentation assessment certificates or EU type-examination certificates. Those procedures shall require the manufacturer in question to submit at predefined intervals a summary of changes and of relevant data gathered by the manufacturer's post-market surveillance system,* ***including the consideration of evolving medical, scientific and technical knowledge or changes in regulatory requirements****. The notified body shall assess such information and shall pay*

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					It is strongly recommended to specify the details, for example the harmonization with common international ISO 13485-based regulatory schemes, and their uniform 3-year cycle. The proposed periodic reviews focus primarily on changes, PMS data and clinical data from PMS/PMCF activities. There is no explicit requirement to consider evolving medical, scientific and technical knowledge or changes in regulatory requirements, which could negatively impact patient safety." The NBs should have the possibility to actively reconfirm the continuous validity of the certificate after conducting positively the periodic review in the EUDAMED's Notified Bodies and Certificates module. Final note: The effectiveness of periodic review must be assessed in conjunction with other proposed reductions in systematic notified body oversight, including surveillance audits, technical documentation sampling and PSUR review.	*particular attention to clinical data from post-market surveillance and PMCF/PMPF activities undertaken since the previous certification or periodic review, including appropriate updates to manufacturers' clinical evaluation reports, without repeating assessments already conducted.* *The notified body shall have documented procedures in place relating to the extension of the period of validity of a certificate in cases where it has exceptionally limited the period of validity. Those procedures shall require the manufacturer to submit prior to the expiry of the certificate the data or documentation specified by the notified body to enable it to decide about the extension of the period of validity of the certificate.';* ***After the periodic review, the Notified Body shall reflect the outcome in the EUDAMED's Notified Bodies and Certificates module for the specific certificate."***
53a	11, 35	MDR: Ann I IVDR: Ann II	5	MDR: z IVDR: y	Section 3.3 of this document outlines a fundamental concern with the proposed replacement of re-certification by periodic review: **efficiency gains must not be achieved by uniformly lowering regulatory scrutiny**, but rather by **better targeting oversight based on demonstrated performance and lifecycle risk**. Experience from notified bodies shows that device-related risks are **not constant over time**:	Team NB proposed text: Annex VII, point 4.11 (additional paragraph) "Periodic review shall be applied in a manner that compensates for any reduction in systematic audits, technical documentation sampling or other reviews. Any adjustment in the level or intensity of notified body oversight shall be performance-based, justified, documented and reversible where emerging risks or lifecycle-related concerns are identified."

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					• Safety and performance issues most frequently occur **shortly after market entry**, when real-world use starts challenging design assumptions and clinical expectations. • After a period of stable, compliant performance, regulatory effort can be applied more proportionately without reducing patient safety. • Conversely, risks tend to **increase again at later lifecycle stages**, due to outdated standards, evolving clinical practice, accumulated changes, or unnoticed design or cybersecurity drift. The current formulation of Annex VII, point 4.11 focuses mainly on review of changes and post-market data, but does not sufficiently: • distinguish between these different lifecycle phases, or • link regulatory intensity to **demonstrated compliance quality over time**. Without such differentiation, the periodic review model risks becoming either: • **too light** in early and late lifecycle phases, or • **administratively repetitive** without safety benefit for well-performing devices. A performance-based periodic review framework is therefore essential to preserve the **preventive character of the MDR/IVDR**, while allowing proportionate regulatory relief where objectively justified.	
54	12	Ann I	6	c,d	Commission proposal: Rule 6, 2nd indent: *"– are reusable surgical instruments regardless of the body part with which they come into contact, in which case they are classified as class I;"*	Delete the proposed text in (c) and (d). Reinstate the existing wording for Rules 6 and 7.

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					Rule 7, adding 7th indent: *"- are reusable surgical instruments regardless of the body part with which they come into contact, in which case they are classified as class I;"* It is our opinion that the proposed changes, including reclassification of former Class III devices that inherently do show any of the above-mentioned risks to Class Ir devices, do not appropriately take into account the intended purpose and inherent risk of these devices and are therefore not congruent with the clear intent of MDR definitions as cited in the preamble. From a NB and expert position we cannot agree with this change for the following reasons: • Concerns related to device safety and performance In general, the classification rules of medical devices in the EU are based on the vulnerability of the human body. Potential risks related to design and manufacturing of devices should be considered. (Directive 2007/47/EC, 2007-09-05). The MDR, Chapter V, Classification and Conformity Assessment, Section 1, Classification, Art 51 Classification of Devices, requires that devices shall be divided into classes I, IIa, IIb and III, taking into account the intended purpose of the devices and their inherent risks. Classification shall be carried out in accordance with Annex VIII. Furthermore, the preamble to the MDR contains the following recital for Class I devices: *"(60) The conformity assessment procedure for class I devices should be carried out, as a general rule, under the sole responsibility of manufacturers in view of the low level of*	

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					vulnerability associated with such devices. For class IIa, class IIb and class III devices, an appropriate level of involvement of a notified body should be compulsory." Note to vulnerability of the human body: The current classification of surgically invasive instruments for use on the CNS and CCS in class III is based on the high vulnerability of the regions mentioned and the associated correspondingly high-risk potential and potential damage, but not on the technical complexity of the instruments. Interventions on the structures of the CNS and CCS carry the highest risk on the part of the patient. For example, in the CNS even the slightest errors, contamination or material defects can lead to permanent neurological deficits, paralysis, cognitive damage and death. Typical CNS-related risks include the following: • Contamination/infection (e.g., meningitis, CJD/BSE): Even minimal bacterial or particulate contamination can cause severe neurological damage. • Mechanical injuries caused by surgery on the brain or spinal cord have the potential for irreversible damage. • Products that transport or manipulate cerebrospinal fluid can alter pressure conditions, which must be considered potentially life-threatening. • In the CNS, materials must be evaluated particularly strictly, as degradation products can damage the nerve tissue (material toxicity). Typical CCS-related risks include the following: • Even minimal bacterial or particulate contamination can cause severe, even systemic	

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					damage (e.g. endocarditis, sternum infections, sepsis). Embolisms can also be the result. • Mechanical injuries to large vessels or the heart can lead to life-threatening blood loss. • Death. If products with highest risk, in this case based on the vulnerability of the human body, will be classified in the lowest device risk category, systematic monitoring of production and design is not guaranteed due to the requirements of Art 52. This is to be regarded as critical, as most instrument-related notifications from the market (e.g. national databases on medical device risks (e.g. BfArM)) originate in production and quality system issues. The relatively low number of reportable/reported vigilance cases for class III instruments is very likely due to the currently very well-functioning monitoring of product design and manufacturing by NBs. A significant down-classification of reusable surgically invasive instruments with direct contact to the CNS and CCS from class III to class I in combination of the removal of the NB involvement (Art 52(7c)) will therefore have a negative impact on the safety of the products and patients. A possible economic impact, possibly due to higher costs related to injured patients (and their relatives), needs to be considered. Note: While the Rules 6 and 7 have been amended for the above stated changes, but as the Ann VIII, Chapter II, implementing rules 3.5 remain the same, which presents a source for very different interpretation on the application of the implanting rules, and rule indents. To very great likelihood, this will create major issues for a harmonized	

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					interpretation across stakeholders and is prone to a great inefficiency in the implementation and application.	

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55	13, 35	MDR: Ann IVDR: Ann III	MDR: 7 IVDR: 6	TD assessment sampling **Initial certification**	TD assessment sampling – initial **MDR** The proposal suggests installing a sampling mechanism for initial certification which will fall back to the level prior to the MDR and IVDR, and/or even below the former Directives. Comparison: • Proposal: Class III WET devices – initial TD sampling on representative basis (here as understood as EMDN L4 – when leaning on MDCG 2019-13). • Initial certification assessment level is below AIMDD/MDD and current MDR • Proposal Class IIb implantable WET devices: – TD sampling on representative basis (here as understood as EMDN L4 – when leaning on MDCG 2019-13) • Initial certification assessment level is below current MDR • Proposal Class IIb non-implantable WET devices: – TD sampling on representative basis (here as understood as MDA/MDN code level – when leaning on MDCG 2019-13) • Initial certification assessment level is below MDD and current MDR Generally, the coverage of the product scope for an initial certification procedure shall not be reduced, as the safety of products and well-being of patients, and users outweighs the	**MDR** • The terms of "generic device group" and "category of device" should be clearly defined. • To enable the selection of appropriate samples, device categories as set out in Implementing Regulation (EU) 2017/2185 should be reviewed and refined. Several codes are a recurring source of heterogeneous application (as observed during Joint Assessments) and are either too narrow (e.g. MDN 1207) or too broad (e.g. MDA0312, MDN1202). • Irrespective of device classification, differentiated expectations regarding the depth of scrutiny for well-established technology (WET) devices may be considered only where there is either: o an unambiguous legal definition of WET devices, or o an unambiguous restrictive list of device types qualifying as WET devices, or a combination of both • For class III devices a clear distinction is required between o Class III WET devices benefiting from the relief provided for in Article 61(6), while still remaining subject to technical documentation (TD) assessment for every device; and o class III WET devices that both benefit from Article 61(6) and qualify for a sampling approach, i.e. conformity assessment in accordance with Chapters I and III of Annex IX, including assessment of the technical documentation of one representative device per generic device group.

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					claimed potential. The way the proposal combines this measure with others lowers significantly the detection mechanism of non-compliant products and reduces significantly the mechanism of a systematic corrective and preventive mechanism for safeguarding EUs patient health. It is unclear why "from at least one representative device" a limit has been introduced to a rigid "one" sample only. By the nature of how the EMDN code levels and the MDA/MDN codes are structured – inhomogeneous – there is no scientific and technical justification why for an inhomogeneous group of devices only one device can be representative to cover the entire range to grant the certification. Especially, as the codes for generic device groups and device categories are not necessarily covering devices with comparable design features, same special characteristics (MDS) and technologies (MDT). Therefore, it is not clear how on that basis a NB can be made liable for certification. Further unclarity regarding: • "one representative device" for initial sampling: o If understood correctly, this would mean that with a positive conclusion of conformity for 1 device a broad product scope certification will be granted across all device types*, at the same time.	• For all other classes: only device types that meet a restrictive and unambiguous definition of well-established technology, and/or are included in a closed and binding list of qualifying device types , may be considered WET devices. It is strongly recommended to maintain the current approach, while it is acknowledged that leaner methodology could be used for sampling. Team NB proposed text (Art 52(3)): "*By way of derogation from the first subparagraph, class III devices that are listed as well-established technology devices specifically qualifying for sampling of Technical Documentation, shall be subject to a conformity assessment as specified in Chapters I and III of Annex IX, including an assessment of the technical documentation of at least one representative device per generic device group."* Team NB proposed text (Art 52(4)): *"Manufacturers of class IIb devices, other than custom-made or investigational devices, shall be subject to a conformity assessment as specified in Chapters I and III of Annex IX, including an assessment of the technical documentation of one representative device per generic device group or, in the case of* ***non-implantable class IIb devices that are well-established technology devices, at least one representative device per each category of devices****."* Team NB proposed text (Art 52(6)):

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					○ with a negative conclusion of conformity no certificate for any devices is granted. *Real-life example, MDR class IIa: According to the new proposal the following products under class IIa, e.g. under the code MDA 0312 would not be distinguished, and only 1 product of this heterogenic group shall be selected by the NB, e.g. a sampled TD for a visual system/light source (Endoscopic system) shall also cover power-driven surgical drills and saws for orthopedic procedures. Clinically and technically these product types are not comparable and require different design, manufacturing and clinical competence. It is strongly recommended to maintain the current approach of initial sampling to cover appropriately the product range which shall be certified. It is acknowledged that a leaner methodology could be used for the sampling itself. Acknowledgement of already covered generic device groups" and "category of devices" for which the technical documentation assessment has already been conducted for every device (class III, implantable IIb non-exempted/non-WET) as specified in Section 4 of Annex IX. In case the manufacturer (independent of its size) underwent already a class III or class IIb implantable TD assessment(s) (acc. Art. 52(3) and (4)), for the specific MDA/MDN codes (class IIa), or EMDN code (L4) for class IIb, no additional TD sampling for	"*Manufacturers of class IIa devices, other than custom-made or investigational devices, shall be subject to a conformity assessment as specified in Chapters I and III of Annex IX, including an assessment of the technical documentation of **at least one** representative device for each category of devices."* *Alternatively, the manufacturer may choose to draw up the technical documentation set out in Annexes II and III coupled with a conformity assessment as specified in Section 10 or Section 18 of Annex XI. The assessment of the technical documentation shall apply for **at least one** representative device for each category of devices."* *This mechanism can be expanded towards: ○ The Commission may, by means of implementing acts, draw up lists of devices that are a or are not a well-established technology. ○ Those implementing acts shall be adopted in accordance with the examination procedure referred to in Art 114(3). • Further, for the implementation a real risk-based approach for the assessment of Technical Documentation product-specific Common Specifications or guidance documents shall be developed. It shall be considered that not with every sampled TD the entire Ann I, II, and III might be necessary to be assessed fully. The product-specific Common Specifications or guidance shall clearly indicate which aspects are to be prioritized during the surveillance sampling.

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					class IIa/IIb have to be conducted under the initial certification procedure. **IVDR** Commission proposal: "*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 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."*	MDCG 2019-13 improvements: • To reduce the volume of an individual TD assessment, the current definition of device according to MDCG 2019-13 "device = Basic UDI-DI" shall be streamlined to one representative device (e.g. Art / Catalogue number) within the Basic UDI-DI. • For the selection of appropriate worst-case devices for sampling, independent of classification, the product status of BTX or orphan devices shall be an indicator to qualify for a priority in the risk-based sampling. • For the selection of appropriate worst-case devices for sampling, independent of classification, the product status of WET shall be an indicator to qualify for reduced priority in the risk-based sampling. **IVDR** The current sampling mechanism should be maintained. However, it is acknowledged that the sampling ratio between class B and class C devices is not risk-based and may result in a higher number of class B devices being sampled than class C devices. **I**ntroduce a simplified NB coding system to reduce the number of IVR codes and, consequently, the number of device categories.

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					The current proposal foresees a sampling mechanism for initial certification that would reduce the level of scrutiny to that of the pre-MDR/IVDR era, and in some cases even below the standards of the former directives. **Final note:** Reducing initial technical documentation sampling without compensatory lifecycle-based controls increases the risk that non-conformities remain undetected until post-market signals occur.	
56	13	Ann I	7	a,e	TD assessment sampling - surveilance In general, the coverage of the product scope under a certification by an appropriate frequency and relevant sampling size shall not be reduced, as the safety of products and well-being of patients, and users shall outweigh the claimed potential. The way the proposal combines this measure with others lowers significantly the detection mechanism of non-compliant products and reduces significantly the mechanism of a systematic corrective and preventive mechanism for safeguarding EU's patients' health. It is unclear how "on-cause" shall be interpreted, e.g. if in the course of the validity of a QMS certificate, if there are further products added with different characteristics (more worst-case), does that qualify for an "on-cause" TD Assessment by the NB?	Keep the current approach but adopt a simplified NB code system for MDR.

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					It is strongly recommended to maintain a systematic sampling of Technical Documentation to appropriately cover the certified product range over a defined timeline. Anyhow, it is acknowledged that a leaner methodology can be used for the sampling and annual assessments itself. The fundamental rule of Annex IX, 2.3 in combination with 3.5 shall be maintained. Additionally, to the measures proposed for the initial sampling above • Definition of “generic device group” and “category of device” in the legal text • revision of Implementing regulation 2017/2185 • list of WET devices. • Product-specific Common Specifications or guidance MDCG 2019-13 improvements: • “device redefined e.g. Art / Catalogue number within a Basic UDI-DI • BTX or orphan devices as indicator for risk-based sampling (higher priority). • WET as indicator for risk-based sampling (less priority)) the following is proposed for MDR surveillance sampling for micro and small enterprises the mandatory TD sampling every year (Annex IX, 2.3 in combination with 3.5) shall be considered to be lifted for the periodic cycle in case • - the manufacturer has less than 5 devices	

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					• - there are no quality related issues, • - and/or there has already been a class III (no WET) TD assessment conducted for the same MDA/MDN code / EMDN (L4) • - and/or there has already been a Class IIB (no WET) TD assessment conducted for the same MDA/MDN code / EMDN (L4) • - as a general rule to justify the maintenance of a quality management system certificate, one TD assessment with a review period (3 years) shall be considered as the minimum. • This means for the micro and small enterprises: • No mandatory annual TD assessment anymore • After the initial certification, only those devices are sampled which have not undergone an assessment. • For those devices covered by a TD assessment, the NB concentrates on PMS only – during the audit by auditors (only on cause PRs shall be included into a further review) • If there are significant changes, the NB would be informed accordingly and a focused review of the affected Annex I, II aspects is conducted. **Final note:** Where reliance on for-cause assessments is introduced, sampling schemes shall still provide for periodic reassessment of representative devices, regardless of the absence of post-market safety signals.	

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57	14, 35, 36	MDR: Ann I IVDR: Ann II	MDR: 7 IVDR: 6	MDR: c IVDR: a,e	Surveillance audits **MDR** An absence of reported safety issues does not necessarily indicate adequate conformity with MDR/IVDR requirements. Most manufacturers hold additional QMS certification (e.g. ISO 13485 and/or MDSAP), meaning that NBs will continue to conduct annual audits under these schemes. As a result, this change appears to offer little practical benefit to manufacturers. The requirement that, under certain conditions, surveillance audits and assessments should only be carried out every 24 months instead of every 12 months creates legal uncertainty and will lead to very different interpretations, as there are no specific requirements. Furthermore, it is below state of the art of internationally recognized certification schemes (in particular MDSAP certification and EN ISO 13485 certification), which stipulate regular certification and annual monitoring. Therefore, mandatory surveillance audits shall continue to take place annually in the interests of uniform requirements, a reliable level of monitoring, and uniform competitive conditions. It is strongly suggested to integrate the MDCG 2019-6, IV.10. clarification for "surveillance audit due dates" for harmonisation. **IVDR** Commission proposal: "*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 surveillance data or other duly justified grounds."*	**MDR** Team NB proposed text (Sec 3.3): *"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* ***hybrid or*** *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 every 12 months.* ***The first surveillance audit should be scheduled 12 months after the certification decision date. This is the so called "due date" (e.g. December) which defines the target dates for all upcoming regular surveillance audits (e.g. each December). In order to take in consideration, the necessity for contingent scheduling adjustments, surveillance audits can be conducted within a limited window of +/- three months from the due date without particular concern. However, if the surveillance audits are conducted outside this time window (earlier or later) this should be exceptional and must be justified and documented in consideration of the possible impact on the certificate's validity. A cumulation of deviations over the years, e.g. changing the due date is not allowed."*** **IVDR** The current sampling mechanism should be maintained. However, it is acknowledged that the sampling ratio between class B and

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					The current proposal suggests introducing a surveillance sampling mechanism that would lower the level of assessment to that applied before the IVDR—and potentially even below the requirements of the former directive. Ongoing assessment of technical documentation during surveillance is essential, as it enables the early identification of significant issues. NB reviews frequently lead to important corrections, such as refining or reducing the intended purpose, removing specimen types, requiring additional studies, or implementing labelling changes to improve clarity for users, including professional users. Such reviews substantially reduce the likelihood of safety concerns and non-conformities. Please see a real-life example below that demonstrate the risks that are related to this change: During an audit of an IVD manufacturer (device placed on the market under the IVDD), the severity of an incorrect readout had been classified as low. In reality, incorrect values could cause serious harm to patients. This underestimation meant that the PMS system would not have triggered appropriate actions, potentially leading to dangerous situations had the issue remained undetected. **Final note:** The reduction of surveillance audits in MDR and IVDR shall not considered in isolation. Where combined with reduced technical documentation sampling, reduced PSUR review or reliance on for-cause assessments, the cumulative effect may significantly weaken preventive oversight.	class C devices is not risk-based and may result in a higher number of class B devices being sampled than class C devices. **Proposed solution:** introduce a simplified NB coding system to reduce the number of IVR codes and, consequently, the number of device categories.

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58	14, 37	MDR: Ann I IVDR: Ann II	7	d	Unannounced audits (at least once every five years) were introduced in 2013 with the Recommendation 2013/473/EU and later incorporated into the MDR and IVDR as a key tool to detect noncompliance and ensure that manufacturers continuously comply with their quality management systems. It is not in the interest of patient safety to reduce this not only corrective but preventive monitoring measure to such an extent that the requirements fall back to the level that existed before various legislative measures were introduced as a result of problems with manufacturers and products. We would like to understand better if the reduction of that measure is based on data only under MDR/IVDR certifications (manufacturers complying towards already tightened MDR/IVDR certifications – early adopters) or is it already taking into account all manufacturers and devices which, according to the proposal will not undergo any scrutiny by a third party? Unannounced audits should continue to be carried out regularly on a mandatory basis. Please see a real-life examples below that demonstrate the risks that are associated with this change: • The audit of a manufacturer of sterile products revealed that the manufacturer had not systematically validated all relevant processes. As a result, they could not demonstrate that their products were reliably sterile. During an unannounced audit, additional sterile products were found in storage that had been produced by the manufacturer, carried a CE mark, and were intended for sale — yet these products were not even part of the certified product scope. This situation represents a significant risk, as no evidence existed to confirm the effectiveness of the	Reinstate existing Annex IX(3.4). Clarify that unannounced audits serve as a compensatory safeguard where other oversight activities are reduced.

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					sterilization process for these noncertified products. • During unannounced audits and conducted pen-testing of software related devices, the NBs experienced that the majority of the devices lack appropriate measure for cybersecurity. While the majority of tested devices were found to have at least medium severity vulnerabilities, about 30% of vulnerabilities are found to have potentially critical or high impact on patient health - either directly or indirectly. Only a few vulnerabilities do not have impact on patient safety. Common vulnerabilities: Inadequate protection against unauthorized access, unencrypted PHI data, API vulnerabilities, data deletion risks These vulnerabilities were uncovered through basic testing techniques, suggesting that more thorough and in-depth assessments could reveal even more critical issues. Example: Testers were able to modify all hospital patients' medications using a guest account in the web application **Final note:** Unannounced audits are particularly important where other systematic controls (e.g. routine technical documentation sampling or standalone PSUR review) are reduced, as they provide an independent preventive detection mechanism.	
59	25	Ann II	1	b(ii)	Commission proposal: "*Labels may be provided in digital form to the extent, and only under the conditions, set out in implementing rules adopted pursuant to this Regulation.*"	Delete proposed text. **Or** Proposed Team NB text:

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					For labels that include warning symbols and information on the contents of the kit or bottle, relying solely on an electronic IFU would create an unsafe situation. While an electronic IFU may be appropriate for professional use, removing full physical labelling from the product itself would introduce avoidable risks.	"*Instructions for Use may be provided in digital form to the extent, and only under the conditions, set out in implementing rules adopted pursuant to this Regulation.*"
60	26	Ann II	1	d(vii)	Commission proposal: "*date of issue of the instructions for use or, if they have been revised, date of issue and identifier of the latest revision of the instructions for use;* *Removal of with a clear indication of the introduced modifications."* It is important for the end user to be able to detect what has changed. Not having a clear revision history might be a concern for the patient's safety if this results in a mistake in the use of the device.	Reinstate existing requirement that any modifications must be clearly identified in the instructions for use.
61	25	Ann II	1	v	Commission proposal: *"For devices that are used exclusively with a medicinal product in accordance with Art 19 of [Proposal for a Directive on the Union code relating to medicinal products for human use, and repealing Directive 2011/83/EC and Directive 2009/35/EC] and packaged together with a medicinal product, the instructions for use may be included, where needed, as part of the co-packaging of the medicinal product with the device. Moreover, the information on the label of the device may be limited to the particulars referred to in Section*	Delete this paragraph or clarify why this is being added.

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					20.2., points (a) and (c), where, following agreement of the competent authority responsible for the authorisation of the medicinal product, the following conditions are met: *i. the information necessary for safe use and correct functioning of the device is provided to the user with the summary of product characteristics and/or package leaflet of the medicinal product under the responsibility of the marketing authorisation holder set out in [Proposal for a Directive on the Union code relating to medicinal products for human use, and repealing Directive 2011/83/EC and Directive 2009/35/EC;* *ii. the traceability and identification of the device is ensured by the marketing authorisation holder."* It is unclear why this provision has been introduced. Medicinal products are generally not packaged together with an IVD even for companion diagnostics. The diagnostic test is performed before the medicinal product is prescribed, not co-packaged or co-supplied with it. Therefore, the rationale for linking the two in this context is not evident.	
62	27	Ann II	2	f	Commission proposal: "*Where the device incorporates as an integral part a medical device that has an action ancillary to that of the device, as referred to in Art 1(4) of this Regulation, the documentation shall include the results of the assessment of the conformity of the medical device part with the relevant general safety and performance requirements set out in Annex I to*	Provide a clarification on the mechanism of opinions among NBs.

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					Regulation (EU) 2017/745 contained in the manufacturer's EU declaration of conformity or the relevant certificate issued by a notified body allowing the manufacturer to affix a CE marking to the medical device. Where those results of the conformity assessment are not available and where for the conformity assessment of medical device, if used separately, the involvement of a notified body is required in accordance with Regulation (EU) 2017/745, an opinion on the conformity of the medical device part with the relevant general safety and performance requirements set out in Annex I to Regulation 2017/745 issued by a notified body designated in accordance with that Regulation for the type of device in question shall be included in the documentation." The meaning of this provision is unclear. The mechanism for issuing "opinions" is not defined, including whether NBs are expected to issue them, who would be responsible, how device-related issues and confidentiality would be managed, and what level of detail or documentation such opinions should contain.	
63	43	Ann II	10	b	It is essential to ensure traceability between the tasks and actions outlined in the Performance Evaluation Plan and their implementation in the Performance Evaluation Report; this is critical for demonstrating methodological consistency and regulatory compliance.	Team NB proposed text: *1.1 "Performance Evaluation Plan* *As a general rule, the performance evaluation plan shall include at least:* • *a specification of the intended purpose of the device a specification of the intended purpose of the device as referred to in Section 20.4.1, point (c), of Annex I, including a specification of the analyte or marker to be determined by the device;*

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						• *a specification of the characteristics of the device as described in Section 9 of Chapter II of Annex I and in point (c) of Section 20.4.1. of Chapter III of Annex I a specification of the characteristics of the device as described in Section 9 of Annex I;* *(…)* • *a specification of methods **and aims**, including **methods or methodology for identification of existing relevant information (e.g. literature)** and the appropriate statistical tools, **planned to be** used for the examination of the **scientific validity**, analytical and clinical performance of the device and of the limitations of the device and information provided by it **in dedicated sections for planning of SV, AP and CP*** *1.2.1. Demonstration of Scientific Validity* *The scientific validity of the analyte or marker shall be demonstrated and documented in a dedicated section of the performance evaluation report **in accordance to the outlined aims and methods for scientific validity demonstration in the PEP as referred to in Annex XIII, Part A 1.1.*** *1.2.2 Demonstration of the analytical performance* *Analytical performance shall be demonstrated and documented in a dedicated section of the performance evaluation report, **in accordance to the outlined aims and methods for analytical performance demonstration in the PEP as referred to in Annex XIII, Part A 1.1.***

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						1.2.3. Demonstration of clinical performance *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 PEP as referred to in Annex XIII, Part A 1.1."***
64	43	Ann II	10	b	It would be beneficial to clarify the type of devices for which computational modelling and in silico testing can be used to support performance data.	Team NB proposed text: "*1.2. Demonstration of the scientific validity and the analytical and clinical performance:* *As a general methodological principle the manufacturer shall:* *(…)* • *generate any new or additional data necessary to address outstanding issues; where appropriate* ***(e.g. for Breakthrough, Novel and Orphan devices)*** *this may be supported by computational modelling and in silico testing."*
65	43	Ann II	10	e	The IVDR does not provide a definition of equivalence. To support consistent interpretation and application of this concept, it is essential to include a clear and harmonized definition.	Team NB proposed text: Proposed definition of equivalence to be added to Art 2 (Definitions) of the IVDR or in Annex XIII "*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,*

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						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."*