Biomedical Alliance in Europe

June 2026

Medical societies' position on the MDR/IVDR Revision Proposal

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BioMed Alliance position on revision of the Regulations on Medical Devices and IVD Devices

Safeguarding quality of patient care in the pursuit of simplification

The 34 European Medical Societies that the BioMed Alliance represents believe that reform of the regulatory system necessary, as some of the unintended consequences of the implementation of MDR and IVDR have led to high costs and a reduced availability of essential devices and diagnostics[1]. Nonetheless, healthcare professionals believe that simplification in the Commission's proposal (2025/0404 (COD) for a targeted revision of the Medical Devices Regulation (MDR) and In Vitro Diagnostics Regulation (IVDR) must not come at the expense of robust safety standards and transparency of clinical evidence, which are essential to maintain a high level of patient safety and care. This document provides an overview of the BioMed Alliance position, a series of suggested amendments, and examples of devices approved on the basis of equivalence.

Summary of our position:

- Simplification of regulations should not imperil the **safety** of medical devices.
- Proposed changes to MDR and IVDR article 5.5 on **in-house devices**, should reduce the administrative burden for health institutions, while facilitating innovation and the safe sharing of devices and diagnostics between health institutions, thereby improving patient access to state-of-the-art personalised care.
- The **amendment to the AI Act** must not lead to reduced requirements for AI-medical devices, and Chapter III requirements in the act must be upheld.
- **Transparency of clinical evidence** for patients and healthcare professionals must be improved including by making information on clinical evidence and SS(C)Ps available, in an easily accessible and readable format.
- The expanded role for the Expert Panels for Medical Devices and IVDs and the EMA has the potential to improve **scientific coordination and support** in the system.
- Pathways for **Orphan & Breakthrough devices and diagnostics** may facilitate their approval and ensure better availability in the EU, thereby enhancing patient access. A new pathway for **Paediatric devices** is needed for niche devices which fall outside the Orphan definition.
- The expanded use of **equivalence** for the approval of high-risk medical devices under MDR will lead to more safety concerns, this provision must either be removed from the proposal or the pathway must be subject to specific controls.
- The safe **reprocessing** and repurposing of devices can facilitate healthcare and reduce waste, but any reprocessing must adhere to strong safety standards.
- Considering the removal of the **5-year validity of certificates** under MDR, it is essential to better monitor the safety of implantable high-risk devices long term, since safety issues may occur after several years.

[1] For more information see e.g.: https://www.biomedeurope.org/news/press-release-biomed-alliance-calls-for-the-establishment-of-a-new-coordinating-mechanism-within-the-european-medicines-agency-to-tackle-deficiencies-at-the-heart-of-mdr-and-ivdr/

- **Implant cards** for Well Established Technologies must also be retained as a vital tool for patients in MDR.

General

While the sectors for medical devices and in vitro diagnostics differ from each other and each have their own needs, there are certain overarching issues in the regulatory system that should be addressed for both sectors together.

In-House devices

We welcome proposed changes to article 5.5 of MDR and IVDR that facilitate the transfer of in-house devices between health institutions (when this is in the interest of patients' health) and that reduce administrative requirements. In-house devices, including software applications and diagnostics, that are developed within one institution can be of great value to patients in other health institutions (see more below).

→ We support the deletion of the provision that requirements to provide a justification that patient needs cannot be met by an alternative CE-marked device in IVDR (more information on page 8 and 13), and believe a similar approach should be maintained under MDR article 5.5c, particularly for software or applications.

→ We propose that Article 5.5. of MDR, which states that in-house devices must be 'manufactured and used' within a health institution be amended to allow a device manufactured in a hospital to be used outside the hospital by a patient (for example an orthotic or moulded cup for patients with disability), which is currently not possible when a literal interpretation of MDR is applied.

Artificial intelligence

We welcome efforts to streamline the regulatory frameworks for Artificial Intelligence, MDR and IVDR, including the possibility of a single application under both frameworks, provided that sufficiently strong safeguards continue to apply.

Article 4 of the revision proposal states that the Artificial Intelligence Act (EU) 2024/1689) is to be amended, and that MDR and IVDR should be moved from Annex I section A (List of Union harmonisation legislation based on the New Legislative Framework) to Annex I section B (List of other Union harmonisation legislation). This would mean that MDR and IVDR will be the main legislative frameworks that apply, and in the AI Act only certain provisions such as Article 6(1), Articles 102 to 109 and Article 112 apply (see AI Act article 2.2), while excluding other requirements that generally apply to high-risk systems in chapter III such as literacy and human oversight. While the new MDR Article 5.9 states that the Commission must take into account the requirements of chapter III of the AI act when adopting implementing acts, delegated acts or common specifications, it may take time to develop these.

→ The amendment to the AI Act must not lead to reduced requirements for AI-medical devices, it is essential that implementing acts, delegated acts or common specifications based on AI act chapter III requirements for high-risk AI systems are prepared and adopted without delay (see amendment 7 on page 17).

Transparency

Transparency of the clinical evidence submitted and accepted by a regulator is a fundamental pillar of regulatory accountability in other EU health product regulatory frameworks that seek to deliver a high level of health protection. It is essential to recognise that all clinical evidence is generated by patients who voluntarily accept risk by enrolling in clinical studies in order to enhance medical knowledge. As a result, there is no clear legal, ethical or regulatory justification to maintain clinical evaluation reports as 'commercially confidential' under the current framework. Claims that clinical evaluation reports contain proprietary or intellectual property do not stand up to scrutiny; the clinical data accepted by regulators to verify safety and performance should be a matter of public record. Furthermore, improved transparency of clinical evidence is a support to new product developers, who would be able to understand the clinical development strategies that have been accepted for similar devices.

The revision proposal seeks to limit the requirement for manufacturers to prepare Summaries of Safety and Clinical Performance (SSCPs) only to implantable and Class III devices under MDR, and it also proposes to remove SSCPs for patients. While this may appear to be a small change, it is evidence of a broader movement that deprioritises transparency for users of devices. Allowing clinicians access to these reports is vital, when we consider that the publicly available information concerning innovative and high-risk devices evaluated by the EMA Expert Panels demonstrates that the majority of devices have serious deficiencies in the clinical evidence submitted, yet all devices are CE-marked and available[2].

The transparency requirements for clinical investigation reports have been poorly operationalised. Despite rules being in effect since 2021, and while there are over 1,300 unique applications for clinical investigations submitted to national regulators annually[3], there are still only 4 clinical investigation reports published on CIRCABC (used in the absence of EUDAMED).

We agree with the finding of the European Commission that public summaries "should be drawn up in a way that is clear for the intended user of the device." Nonetheless, the current policy for SS(C)P generation requires that manufacturers copy exact text from clinical evaluation reports[4], which limits the utility of these documents for those not familiar with the language of regulatory affairs.

→ The use of SS(C)Ps must be expanded instead of reduced, and guidance needs to be developed to ensure that they are offered in a format that is easy to understand, findable and useful for both healthcare professionals and patients (amendment 3 on page 12). We recommend that this is a priority topic for the scientific co-ordination role envisaged for the EMA and that engagement with the target audiences is undertaken.

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[2] See: European Commission. List of opinions provided under the CECP [Internet]. Brussels: European Commission; [cited 2026 Feb 4]. Available from: https://health.ec.europa.eu/medical-devices-expert-panels/experts/list-opinions-provided-under-cecp_en

[3] Geraghty M, Malandrini F, Callea G, McDonnell A, Martelli N, Tangila Kayembe O, et al. Regulatory readiness for innovation: a mixed-methods study of national competent authority professional and organizational capacities in the context of pre-market clinical investigations and early feasibility studies. Expert Rev Med Devices. 2026 Jan;23(1):87-97. doi: 10.1080/17434440.2025.2594460

[4] Medical Device Coordination Group. MDCG 2019-9 Rev. 1: Summary of safety and clinical performance. A guide for manufacturers and notified bodies. Brussels: European Commission; 2022 Mar. Available from: https://health.ec.europa.eu/document/download/5f082b2f-8d51-495c-9ab9-985a9f39ece4_en

Coordination and support

We support the expanded role of the **European Medicines Agency (EMA)** to provide scientific, technical and administrative support for both medical devices and IVDs (MDR Article 106b). Lack of scientific coordination has been a major gap in the current system, with fragmented oversight, and with different actors such as notified bodies, competent authorities and expert panels acting in silos. The EMA is in the right position to play such a coordinating role with its extensive experience in regulating the pharmaceutical sector and its current role in managing the Expert Panels. We also support the establishment of regulatory sandboxes under MDR (Articles 59b–59c) and IVDR (Articles 54b–54c), to facilitate innovation and the testing of emerging technologies under strict oversight.

The use of **Expert Panels for Medical Devices** and IVDs to support the regulatory system is another positive development (MDR article 106), as their specialist knowledge and clinical experience allows them to contribute further to the evaluation of, for example, orphan devices. We welcome the inclusion of more diverse profiles, including those with expertise in the regulatory field, but it is important that the panels continue to have sufficient clinical involvement to retain their independent function inside the system. This requires a balanced conflict of interest policy, that allows for the right profiles to be included, while also managing competing interests. Clarification is necessary on the practical application of the new provision that expert panels shall take into account information provided by stakeholders including patient' organisations and healthcare professional organisations.

→ We support the expanded role of the EMA to provide scientific, technical and administrative coordination. We also support greater involvement of the expert panels, and a broader inclusion of different profiles, while maintaining their unique and independent role in the system.

Orphan, breakthrough devices and paediatric devices

The new pathways for orphan devices and breakthrough technologies are key to ensure an easier and more affordable route to certification to improve their access to the EU Market. In the past years, clinicians in our network have noticed that a number of orphan devices, and particularly paediatric devices, have disappeared from the EU market. From our exchanges with manufacturers it has become clear that high costs of certification, long timelines, and uncertainty around certification procedures have led to manufacturers deciding not to pursue conformity assessment under MDR and IVDR. This has led to a reduced availability of orphan devices, thereby negatively impacting patient care.

The BioMed Alliance therefore welcomes the support (including through early dialogue), the proposed new pathways (MDR article 52a and IVDR article 48a) and the reduced notified body fees for orphan devices and SMEs (MDR article 50.2). However, we reiterate that special support will also be required for the (on- and off-label) use of essential paediatric devices, particularly those that will not fall within the orphan devices definition. In addition, more clarification is necessary on how the reduced fees will be covered, as this may lead to a higher fee for other devices.

MDR article 52a paragraph 7 on the provision of certificates with conditions can provide an important pathway to put orphan and breakthrough devices on the market while there is limited clinical data available (due to small patient populations or novel technologies). The wording of

the article should be amended to include stronger post-market clinical follow-up requirements, to compensate for the limited level of clinical evidence that was initially available and to identify potential issues that can only be identified once more patients have been treated.

→ New pathways for orphan and breakthrough devices and diagnostics will provide assistance to manufacturers aiming to certify those products for the EU market, thereby improving their availability to healthcare professionals and patients. Similar types of support should be provided for paediatric devices, as they may fall outside the scope of orphan and breakthrough devices, but are still in need of support to enhance their availability on the EU market (see amendment 10, 11 and 12 starting on page 20).

Medical devices

An appropriate balance must be found in the regulatory system for medical devices, reducing the administrative burden where this does not affect high safety standards. Measures such as the new IT Tool for reporting the interruption of supply under MDR article 10a(4) and increased options for structured dialogue before and after submission may provide practical support. On the other hand, the impact of several of the proposed simplification measures should be carefully evaluated.

For instance, the removal of the 5-year validity of certificates (MDR Article 56) must not lead to increased safety risks for devices. For many types of high-risk implantable devices, such as coronary stents, heart valves, and joint replacements, significant differences between devices may become apparent only after more than 5 years. These are very commonly used devices, so any late failures would have major implications for public health. We propose to retain the 5 year validity of certificates for class 2b implantable and class 3 devices. Alternatively, the decision whether the validity of a certificate of 5 years should be retained or abolished for a certain device type, should depend on expert advice about the particular class or type of device. Such an opinion could be obtained from the relevant Expert Panel.

In addition, we do not agree with the proposed change to MDR article 18.3, stating that well established technologies are exempt from the requirements to provide an implant card, as they are a vital tool for patients, including for devices that have been available for multiple years.

→ It is essential to monitor the safety of implantable high-risk devices long term, since safety issues may occur after several years (see amendment 13 on page 25). Implant cards for Well Established Technologies must also be retained as a vital tool for patients (see amendment 4 on page 13).

Equivalence

The proposal aims to relax the requirements for establishing equivalence for implantable and Class III devices and seeks to make regulatory rules ‘more flexible’ (see MDR Article 61.5). The new provision allows manufacturers of high-risk implants to claim equivalence to another device in their conformity assessment application, permitting them to rely on clinical data for that specific alternative device, and removing the requirement to perform a clinical investigation. This will be achieved by removing the requirement for a contract between manufacturers, and by reducing the evidence threshold for demonstrating equivalence, by allowing devices with ‘similar’ rather than the same clinical and biological characteristics. As a

result of this, new high-risk implantable devices may be marketed without any form of pre-market clinical investigation.

This represents a fundamental reversal of policy developed under the MDR to improve the evidence base for the highest risk medical devices, and a step backwards for the EU regulatory framework. It also disregards the European Commission's own conclusion in 2012 which noted that "'*equivalence' with another implantable or class III device is not a sufficient justification to omit clinical investigations*." [5] The revision proposal justifies this change because similar device data is 'available', however no further justification has been provided for this fundamental change to clinical evidence requirements for high-risk implants.

There are many examples of devices approved on the basis of claims of equivalence under the previous EU medical device directives, with serious complications occurring after their approval. In some cases, their use led to the deaths of patients, and in other cases to the need for urgent re-operation with removal of the faulty device and its replacement by a safer alternative. In these cases, equivalence had been accepted by the notified body but was inappropriate because of a change or difference in design or manufacture. For instance, examples include heart valves that caused numerous complications including thrombus formation or embolisms, metal-on-metal hip implants with high revision rates, and transvaginal meshes that can cause infection, pain, and other complications (more details and references to the scientific publications are given in the Appendix). Since the Medical Device Regulation came into force there have been significantly less similar incidents, most likely due to its stricter conditions for claiming equivalence.

Facilitating the reliance on data for equivalent devices is not a technical 'simplification', but a demonstrated safety risk. Standards of clinical evidence are already often insufficient, the EU funded Co-ordination of Research and Evidence for high-risk Medical Devices (CORE-MD) Project found that the clinical evidence was insufficient for high-risk medical devices used in cardiology, orthopaedics and diabetic medicine[6]. The patient impact of this can be seen today, where devices such as continuous glucose monitors with unproven clinical performance create challenges for EU patients. The consensus recommendations from the CORE-MD project[7] also stated clearly that manufacturers of a new high-risk device entering an existing market must be able to state with confidence that their device is at least as good as those that have already been approved, which will require pre-market clinical investigations. A claim of equivalence without robust pre-market clinical investigations for high-risk implants is unacceptable on ethical and evidentiary grounds.

→ The equivalence pathway must not be reinstated for high-risk devices as it institutionalises a "race to the bottom" for clinical evidence. Rather than fostering innovation of new technologies, lowering the evidence threshold for claimed "me-too" products threatens to return the European market to a state where clinically unproven,

[5] See: COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT ON THE REVISION OF THE REGULATORY FRAMEWORK FOR MEDICAL DEVICES /* SWD/2012/0273 final */
Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52012SC0273
[6] See: page 32 of https://www.biomedeurope.org/wp-content/uploads/2025/07/BioMed-Recommendations-MDR-IVDR-2025.pdf
[7] See: Fraser et al, Lancet Regional Health Europe, 2025, https://www.thelancet.com/journals/lanepe/article/PIIS2666-7762(25)00252-2/fulltext

high-risk devices enter clinical practice, leading to increased adverse events and an erosion of public trust in the CE mark (see amendment 1 and 2 starting on page 10).

Reprocessing of medical devices

For certain types of devices that are intended for single use, safe reprocessing and reuse is possible and can reduce waste and costs in the healthcare system. In the current situation member states decide at national level if they allow reprocessing of single use devices, leading to a fragmented approach across the EU. Under the revision proposal this discretion is removed, and there is an additional responsibility that is put on the manufacturer to justify why a device is single use. In practice, this provision could lead to a more careful evaluation of which devices can be safely repurposed, but a clear implementation plan and understanding of how it will be applied in practice are necessary.

→ The safe repurposing of devices can facilitate healthcare and reduce waste, but any reprocessing must of course adhere to strong safety standards (see amendment 9 on page 19). Common specifications detailing how devices can be safely reprocessed and refurbished, and how manufacturers can justify that a device is single use, must be developed without delay.

In vitro diagnostic devices

In-house devices play an essential role in the health sector and are widely used for diagnosis and evaluation of response to treatment. Many laboratories develop or modify diagnostics in house, to meet specific patient needs and to provide personalised care, particularly when there is no suitable alternative on the market. A case study[8] at a large university hospital laboratory in Belgium showed that 47% of tests part of the portfolio of hospital laboratories are in house devices and there is currently no alternative available for 72% of those. In specialized laboratories, this number can increase to 80-90%[9]. These are often complex tests for rare diseases, specialised tests and/or tests that are performed rarely. At the same time, in house devices might be developed for their interoperability with existing systems, for quality reasons, or to get access to the latest innovation through using a Research Use Only device that is not available on the market as a CE-marked device.

In house device play a key role in the diagnostic pathway and care for patients with rare diseases, who otherwise may not have access to essential diagnostics. In addition, during the COVID-19 pandemic, health institutions first developed their own tests and shared them with other laboratories, before industry developed a CE marked equivalent. Facilitating the development and sharing of in-house devices is therefore essential for preparedness and rapid responses to health threats. Since the implementation of IVDR, it was difficult to transfer these essential diagnostics to other health institutions so that a broader patient group could benefit

[8] Pieter Vermeersch*, Tobias Van Aelst and Elisabeth M.C. Dequeker: The new IVD Regulation 2017/746: a case study at a large university hospital laboratory in Belgium demonstrates the need for clarification on the degrees of freedom laboratories have to use lab developed tests to improve patient care. Clin Chem Lab Med. 2020;59(1):101-6.

[9] Bart R. Lubbers, Anke Schilhabel, Christa M. Cobbaert et al.: The new EU Regulation on in vitro diagnostic medical devices: implications and preparatory actions for diagnostic laboratories. Hemasphere. 2021;5(5):e568.

from them. In addition, laboratories faced a high administrative burden disincentivising the development of innovative IVDs.

BioMed Alliance therefore welcomes the proposed amendments to IVDR Article 5.5 to encourage innovation, reduce the administrative burden that laboratories face, and to facilitate the transfer of in-house IVDs from one health institution to another. The changed wording of article 5.5a will allow for a transferability in the interest of patients' health, allowing innovative tests to provide access to a broader group of patients and likely lowering costs for the healthcare system. We also believe the deletion of article 5.5d will encourage innovation and reduce administrative requirements for diagnostic laboratories, as they will no longer be required to survey the market and prove that their in-house test performs better than a reputed CE-marked equivalent. We agree that quality in the diagnostic sector is preserved and the safe use of in-house devices can continue, as diagnostic laboratories already regularly demonstrate adherence to strong safety standards through (e.g. ISO15189 or equivalent) accreditation and participation in internal and External Quality Assessment systems (EQA).

→ Changes to article 5.5 as described in the revision proposal must be maintained in the upcoming legislative negotiations, as they would reduce costs for diagnostic laboratories and facilitate the availability of personalised diagnostics. (see amendment 5 on page 13)

Biomedical Alliance in Europe

Medical societies' suggested draft Amendments to MDR/IVDR Revision Proposal

Introduction

The BioMed Alliance, representing 34 European medical and research societies, has prepared 14 suggested amendments to the MDR/IVDR revision proposal published by the European Commission (2025/0404 (COD). Whereas the proposal takes important steps to simplify the regulatory framework, there are also aspects that will lower safety standards. The suggested draft amendments below have been prepared with healthcare professionals for the consideration of the co-legislators. The suggestions deliver simplification without reducing safety standards and transparency of clinical evidence, which are essential to maintain a high level of patient safety and care. For more information, including a list of cases demonstrating issues with claiming equivalence, also see our position paper from 16 March here.

Priority amendments

Addressing equivalence

Amendment 1	
Article 1 – paragraph 52 - Revision Proposal **Article 61- paragraph 5 – MDR** **Clinical evaluation (claims of equivalence for Class III and implantable devices)**	
Text proposed by the Commission	**Proposed Amendment**
5. A manufacturer of a device demonstrated to be equivalent to an already marketed device not manufactured by it, may also rely on paragraph 4 in order not to perform a clinical investigation provided that the original clinical evaluation has been performed in compliance with the requirements of this Regulation and the manufacturer provides clear evidence thereof to the notified body.';	***5. A manufacturer of a device demonstrated to be equivalent to an already marketed device not manufactured by it, may also rely on paragraph 4 in order not to perform a clinical investigation provided that the following conditions are fulfilled in addition to what is required in that paragraph:*** ***— the two manufacturers have a contract in place that explicitly allows the manufacturer of the second device full access to the technical documentation on an ongoing basis, and*** ***— the original clinical evaluation has been performed in compliance with the requirements of this Regulation, and the manufacturer of the second device provides clear evidence thereof to the notified body.***
Justification	
We propose to retain the wording that was provided in the original MDR Article 61.5. The proposed text by the Commission would permit a new high-risk therapeutic implant to be marketed without a clinical investigation, when there is a technology approved under MDR	

which is used for a 'similar' clinical condition, with 'similar' materials. There is a risk that there are slight changes in design or manufacturing that would adversely affect the health of patients.

In the past, the use of such equivalence pathways led to multiple serious public health concerns in which patients died or were seriously harmed, which we have summarised.[10] *It also disregards the European Commission's own conclusion in 2012 which noted that "'equivalence' with another implantable or class III device is not a sufficient justification to omit clinical investigations.*[11]*"*

We therefore recommend that the current text of MDR be retained allowing the use of equivalence for lower risk devices while requiring a contract for Class IIb implantable or Class III devices. For Class III or implantable devices which may safely be marketed without any clinical investigation, the use of equivalence could be permitted under strict conditions in the proposed text for 'well-established technologies' or by means of common specifications.

Amendment 2	
Annex XIV - Part A - Section 3 - MDR Criteria for claims of equivalence	
Text proposed by the Commission	**Proposed Amendment**
'Biological: the device uses the same or similar materials or substances in contact with the same human tissues or body fluids for a similar kind and duration of contact and similar release characteristics of substances, including degradation products and leachables; Clinical: the device is used for the same or similar clinical condition or purpose, including similar severity and stage of disease, at the same site in the body, in a similar population, including as regards age, anatomy and physiology; has the same kind of user; has similar relevant critical performance in view of the expected clinical effect for a specific intended purpose.';	'Biological: the device uses the same ~~or similar~~ materials or substances in contact with the same human tissues or body fluids for a similar kind and duration of contact and similar release characteristics of substances, including degradation products and leachables; Clinical: the device is used for the same ~~or similar~~ clinical condition or purpose, including similar severity and stage of disease, at the same site in the body, in a similar population, including as regards age, anatomy and physiology; has the same kind of user; has similar relevant critical performance in view of the expected clinical effect for a specific intended purpose.';
Justification	

[10] See Biomedical Alliance in Europe. (2026, March 16). BioMed Alliance position MDR IVDR Revision. https://www.biomedeurope.org/wp-content/uploads/2026/03/BioMed-Alliance-position-MDR-IVDR-Revision.pdf

[11] See: COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT ON THE REVISION OF THE REGULATORY FRAMEWORK FOR MEDICAL DEVICES /* SWD/2012/0273 final */
Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52012SC027

Changing the clinical and biological criteria from "same" to "similar" for high-risk and implantable medical devices poses a significant threat to patient safety. The BioMed Alliance has explicitly warned that the expanded use of equivalence for the approval of high-risk medical devices under the MDR revision will inevitably lead to more safety concerns.

Promotion of transparency

Amendment 3	
Article 1 – paragraph 24 - Revision Proposal **Article 32 – paragraph 1 - MDR** **Summary of safety and clinical performance (health care professional and patient access to the clinical evidence for high-risk devices)**	
Text proposed by the Commission	**Proposed Amendment**
1. 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 shall be made available to the public via Eudamed. The draft of the summary of safety and clinical performance shall be part of the documentation to be submitted to the notified body involved in the conformity assessment pursuant to Article 52. The manufacturer shall ensure that the summary of safety and clinical performance is available in Eudamed as part of the information on the device to be provided pursuant to Article 29(1) and mention on the label or instructions for use where that summary is available.'	1. 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. The draft of the summary of safety and clinical performance shall be part of the documentation to be submitted to the notified body involved in the conformity assessment pursuant to Article 52. The manufacturer shall ensure that the summary of safety and clinical performance is available in Eudamed as part of the information on the device to be provided pursuant to Article 29(1) and ~~mention~~ ***provide a direct link or QR code*** on the label or instructions for use ***to*** where that summary is available.'
Justification	
Transparency of the clinical evidence is a fundamental pillar of both regulatory accountability and evidence-based medicine.[1] Well-established technologies should be subject to the same requirements for transparency of clinical evidence as other implantable and Class III devices. In order to enhance transparency, and provide adequate access to information to patients, the SSCP should be provided to both healthcare professionals and patients. Including a link or QR code to the SSCP on the label or instructions for use might also improve access to this	

essential document, as some users may find it difficult to navigate the different modules of EUDAMED.

Amendment 4	
Article 1- paragraph 16 - Revision Proposal **Article 18 – paragraph 3 - MDR** **Implant card and information to be supplied to the patient with an implanted device**	
Text proposed by the Commission	**Proposed Amendment**
3. Implants that are well-established technology devices shall be exempted from the obligations laid down in this Article	~~3. Implants that are well-established technology devices shall be exempted from the obligations laid down in this Article~~
Justification	
Implant cards are necessary, for instance to protect patients who may be implanted with devices which are 'MRI unsafe', to ensure that prophylactic antibiotics or peri-operative care can be delivered effectively, and to allow the patient to identify the exact type of device that they have been implanted with. There is no clinical reason for removing the requirement to provide an implant card for 'well-established technologies'.	

In house diagnostics

Amendment 5	
Article 2 paragraph 5 - Revision Proposal **Article 5 – paragraph 5 - IVDR** **Placing on the market and putting into service (In House Devices)**	
Text proposed by the Commission	**Proposed Amendment**
5. With the exception of the relevant general safety and performance requirements set out in Annex I, the requirements of this Regulation shall not apply to devices manufactured and used only within health institutions established in the Union, provided that all of the following conditions are met: (a) the devices are not transferred to another legal entity, except to another health institution in the duly justified interest of public health, patient safety or patient health, or to prepare or respond to a public health emergency;'; (b) manufacture and use of the devices occur under appropriate quality management systems;	5. With the exception of the relevant general safety and performance requirements set out in Annex I, the requirements of this Regulation shall not apply to devices manufactured and used only within health institutions established in the Union, provided that all of the following conditions are met: (a) the devices are not transferred to another legal entity, except to another health institution in the duly justified interest of public health, patient safety or patient health, or to prepare or respond to a public health emergency; (b) manufacture and use of the devices occur under appropriate quality management systems;

(c) the laboratory of the health institution is compliant with standard EN ISO 15189 or, where applicable, national provisions for quality and competence in medical laboratories, including national provisions regarding accreditation; (e) upon request by a competent authority, the health institution provides information on the use of such devices to its competent authority, which shall include the justification referred to in point (a); (f) the health institution draws up a declaration which it shall make publicly available, including: (i) the name and address of the manufacturing health institution, (ii) the details necessary to identify the devices (iii) a declaration either that the health institution is accredited to the standard referred to in point (c) or that the devices meet the relevant general safety and performance requirements set out in Annex I and, where applicable, information on which requirements are not fully met with a reasoned justification therefor; (g) as regards class D devices in accordance with the rules set out in Annex VIII, where the health institution is not accredited to the standard referred to in point (c), the health institution draws up documentation sufficiently detailed to enable the competent authority to ascertain that the relevant general safety and performance requirements set out in Annex I are met; (i) the health institution reviews experience gained from clinical use of the devices and takes all necessary corrective actions. Member States shall retain the right to restrict the manufacture and use of any specific type of such devices and shall be permitted access to inspect the activities of the health institutions.	(c) the laboratory of the health institution is compliant with standard EN ISO 15189 or, where applicable, national provisions for quality and competence in medical laboratories, including national provisions regarding accreditation; (e) upon request by a competent authority, the health institution provides information on the use of such devices ***and if and how they are shared with other health institutions,*** to its competent authority, which shall include the justification referred to in point (a); (f) the health institution draws up a declaration which it shall make publicly available, including: (i) the name and address of the manufacturing health institution, (ii) the details necessary to identify the devices (iii) a declaration either that the health institution is accredited to the standard referred to in point (c) or that the devices meet the relevant general safety and performance requirements set out in Annex I and, where applicable, information on which requirements are not fully met with a reasoned justification therefor***. The declaration requirements shall be implemented in a harmonised manner throughout the Union in order to ensure their consistent application by the Member States, while avoiding unnecessary duplication of conformity assessment or quality review procedures.*** (g) as regards class D devices in accordance with the rules set out in Annex VIII, where the health institution is not accredited to the standard referred to in point (c), the health institution draws up documentation sufficiently detailed to enable the competent authority to ascertain that the relevant general safety and performance requirements set out in Annex I are met;

This paragraph shall not apply to devices that are manufactured on an industrial scale. For the purposes of the first subparagraph, point (a), in the case of a transfer of the device to another health institution, the transferring and receiving health institutions shall ensure traceability of the device. For the purposes of the first subparagraph, point (i), where the device is transferred in accordance with the first subparagraph, point (a), the receiving health institution shall report any incident related to the device to the transferring health institution. This paragraph shall also apply to devices manufactured and used within a laboratory that is established in the Union and provides consistent, state of the art testing services for clinical research, provided those devices are intended exclusively for use in the framework of a clinical trial subject to Regulation (EU) No 536/2014 of the European Parliament and of the Council*. Where, in this paragraph, reference is made to a health institution, such reference shall also be understood as reference to a laboratory referred to in the first sentence of this subparagraph.	(i) the health institution reviews experience gained from clinical use of the devices and takes all necessary corrective actions. Member States shall retain the right to restrict the manufacture and use of any specific type of such devices and shall be permitted access to inspect the activities of the health institutions. This paragraph shall not apply to devices that are manufactured on a~~n large~~ ***commercial*** scale**.** For the purposes of the first subparagraph, point (a), in the case of a transfer of the device to another health institution, the transferring and receiving health institutions shall ensure traceability of the device. For the purposes of the first subparagraph, point (i), where the device is transferred in accordance with the first subparagraph, point (a), the receiving health institution shall report any incident related to the device to the transferring health institution. This paragraph shall also apply to devices manufactured and used within a laboratory that is established in the Union and provides consistent, state of the art testing services for clinical research, provided those devices are intended exclusively for use in the framework of a clinical trial subject to Regulation (EU) No 536/2014 of the European Parliament and of the Council*. Where, in this paragraph, reference is made to a health institution, such reference shall also be understood as reference to a laboratory referred to in the first sentence of this subparagraph.
Justification	
BioMed Alliance welcomes the Commission's proposed amendments to IVDR Article 5.5. In-house devices play an essential role in the health sector and are widely used for diagnosis and evaluation of response to treatment, to meet an unmet diagnostic need[12]*. In the interest*	

[12] For more information and examples of in house tests, see: 'EFLM's Positions statement on the proposed 2025/0404(COD) IVDR Amendment of Article 5.5:

of patient care and safety, laboratories may need to develop their own diagnostic tests for a variety of reasons, including effectiveness, interoperability with existing equipment, better clinical performance, faster adaptation to evolving scientific knowledge etcetera. Mitigating administrative burdens for in-house devices is essential to meet patient needs, including for patients with rare diseases and for personalised care.

The proposed changes would restore and further encourage innovation, reduce the administrative burden faced by laboratories, and facilitate the transfer of in-house IVDs from one health institution to another, when this is duly justified and documented. This can also be key for a rapid response to health emergencies, for instance during COVID-19, when the first tests were developed as in-house assays.

The proposed removal of Article 5(5)(d) does not affect the safety of the devices, but addresses the, often difficult, requirement to demonstrate non-equivalence results It also alleviates the need to conduct comparative studies which are sometimes very challenging to carry out without the purchase of new equipment and CE-IVD kits. In practice, this requirement in the current text of IVDR led to a significant administrative burden and legal uncertainty for diagnostic laboratories. The removal of paragraph D will have a direct impact on patient care by freeing up resources (time and financial means), as well as by avoiding monopolies that do not benefit patients.

Historically, many of today's diagnostic gold standards originated in laboratories, which translated emerging scientific knowledge into clinically validated assays long before commercial products became available. Requiring laboratories to demonstrate that no equivalent CE-marked device can meet patient needs establishes commercial products as the default benchmark and creates a substantial disincentive to develop superior assays. This is especially problematic in advanced molecular and genomic diagnostics, where the concept of "equivalence" is often scientifically inappropriate because assays may differ fundamentally in target design, analytical sensitivity, breadth of coverage, turnaround time, bioinformatic interpretation, and clinical utility.

Our proposed modifications to the revision proposal would allow competent authorities to identify potential misuse of the provisions, while alleviating concerns that a parallel market would be created, which is not the intention of this article. Appropriate safeguards remain in place, including quality management systems such as ISO 15189 with also the requirement to illustrate the state of art, traceability, documentation, and oversight by competent authorities and an appropriately restructured IVD expert panel. Removing Article 5.5(d) would therefore support continuity of care, preserve access to specialised and low-volume diagnostics, and enable laboratories to respond more rapidly and effectively to unmet medical needs and healthcare emergencies

Other amendments

Expanded definition clinical data

Amendment 6
Article 1- paragraph 2 - Revision Proposal **Article 2 – paragraph 48 - MDR**

https://www.researchgate.net/publication/404548019_EFLM_position_statement_on_the_proposed_20250404COD_IVDR_Amendment_of_Article_55

Definitions (clinical data)	
Text proposed by the Commission	**Proposed Amendment**
(48) 'clinical data' means information concerning safety or performance that is generated from the use of a device and is sourced from any of the following: – clinical investigations of the device concerned or of a device for which equivalence to the device concerned can be demonstrated; – other studies published in scientific literature on the device concerned or of a device for which equivalence to the device concerned can be demonstrated; – other clinical experience published in peer-reviewed scientific literature with the device concerned or a device for which equivalence to the device concerned can be demonstrated; – clinically relevant information coming from post-market surveillance, in particular the post-market clinical follow-up;';	(48) 'clinical data' means information concerning safety or performance that is generated from the use of a device and is sourced from any of the following: – clinical investigations of the device concerned or of a device for which equivalence to the device concerned can be demonstrated; – other studies published in scientific literature on the device concerned or of a device for which equivalence to the device concerned can be demonstrated; – other clinical experience published in peer-reviewed scientific literature with the device concerned or a device for which equivalence to the device concerned can be demonstrated; – clinically relevant information coming from post-market surveillance, in particular the post-market clinical follow-up***, databanks and registries****;';*
Justification	
Registries are valuable resources for many medical devices, which can provide high-quality post-market data. Article 108 of the MDR provides for 'measures to encourage the establishment of registers and databanks'. The inclusion of registries in the definition of clinical data will encourage that registries are utilised when relevant. *We also caution against the use of non-clinical information such as computer simulation and modelling in the definition of clinical data as these models cannot replicate a clinical investigation.*	

Interaction with the AI Act

Amendment 7	
Article 1 – paragraph 5 Revision Proposal **Article 5 – paragraph 8 - MDR** **Placing on the market and putting into service (AI medical devices)**	
Text proposed by the Commission	**Proposed Amendment**
8. When adopting implementing acts pursuant to paragraph 6 of this Article, delegated acts pursuant to paragraph 7 of	~~8. When adopting~~ ***The Commission shall adopt*** implementing acts pursuant to paragraph 6 of this Article, delegated acts

this Article or Common Specifications pursuant to Article 9 of this Regulation concerning devices that are high-risk AI systems as referred to in Article 6(1) of Regulation (EU) 2024/1689 of the European Parliament and of the Council***, or that use high-risk AI systems as safety components, the Commission shall take into account the requirements set out in Chapter III, Section 2, of that Regulation.	pursuant to paragraph 7 of this Article or Common Specifications pursuant to Article 9 of this Regulation concerning devices that are high-risk AI systems as referred to in Article 6(1) of Regulation (EU) 2024/1689 of the European Parliament and of the Council***, or that use high-risk AI systems as safety components, ***and*** the Commission shall ~~take into account~~ ***ensure that*** the requirements set out in Chapter III, Section 2, of that Regulation ***are fully integrated into and complied with under this regulation***.
Justification	
The use of AI in healthcare is associated with numerous benefits, but the potential risks are also higher than in other sectors due to the potential impact on patient health. The proposed move of the MDR/IVDR from AI Act annex Ia to annex Ib, must not lead to any lowering of standards, and it is therefore essential that Chapter III requirements for high-risk AI systems are integrated into the regulatory framework for medical devices and IVDs without delay.	

Addressing shortages

Amendment 8	
Article 1- paragraph 10 - Revision Proposal **Article 10a – paragraph 4 - MDR** **Obligations in case of interruption or discontinuation of supply of certain devices**	
Text proposed by the Commission	**Proposed Amendment**
4. The Commission, where needed in cooperation with the EMA, shall set up, maintain, and manage an IT system to facilitate the reporting and information exchange regarding cases of interruption or discontinuation of the supply of devices in accordance with paragraphs 1, 2 and 3. That IT system shall be integrated in or interoperable with the European database on medical devices referred to in Article 33. It shall also enable health institutions and healthcare professionals to inform competent authorities about the unavailability or the immediate risk of unavailability of devices needed for the exercise of their professional activity. 5. The EMA, in collaboration with the Executive Steering Group on Shortages of Medical Devices (MDSSG) established by Article 21 of Regulation (EU) 2022/123, shall develop a methodology to identify the	4. The Commission, where needed in cooperation with the EMA, shall set up, maintain, and manage an IT system to facilitate the reporting and information exchange regarding cases of interruption or discontinuation of the supply of devices in accordance with paragraphs 1, 2 and 3. That IT system shall be integrated in or interoperable with the European database on medical devices referred to in Article 33***, and information on interruptions and discontinuations shall be accessible for patients and healthcare professionals***. It shall also enable health institutions and healthcare professionals to inform competent authorities about the unavailability or the immediate risk of unavailability of devices needed for the exercise of their professional activity. 5. The EMA, in collaboration with the Executive Steering Group on Shortages of

devices, or categories of devices, for which it is reasonably foreseeable that an interruption or discontinuation of supply could result in serious harm or a risk of serious harm to patients or public health as referred to in paragraph 1. Based on that methodology, the EMA, in collaboration with the MDSSG and in agreement with the Commission, shall draw up, publish and keep up to date a list of devices, or categories of devices, to which paragraphs 1, 2 and 3 shall apply. For the purpose of this paragraph, the MDCG, representatives of manufacturers, other relevant actors in the supply chain for the medical device sector and representatives of healthcare professionals, of patients and of consumers may be consulted as necessary.	Medical Devices (MDSSG) established by Article 21 of Regulation (EU) 2022/123, shall develop a methodology to identify the devices, or categories of devices, for which it is reasonably foreseeable that an interruption or discontinuation of supply could result in serious harm or a risk of serious harm to patients or public health as referred to in paragraph 1. Based on that methodology, the EMA, in collaboration with the MDSSG, ***healthcare professionals, patients and the expert panels,*** and in agreement with the Commission, shall draw up, publish and keep up to date a list of devices, or categories of devices, to which paragraphs 1, 2 and 3 shall apply. For the purpose of this paragraph, the MDCG, representatives of manufacturers, other relevant actors in the supply chain for the medical device sector and representatives of healthcare professionals, of patients and of consumers may be consulted as necessary.
Justification	
It is essential that healthcare professionals and patients are informed in a timely manner on any potential disruptions of supply or discontinuations, to make sure that they can make the necessary preparations and identify potential alternatives. Considering the clinical expertise of the expert panels, they must also be involved in establishing a list of devices for which supply will be disrupted and identifying potential alternatives, to ensure the list corresponds with reality in a clinical setting.	

Reprocessing of devices

Amendment 9	
Article 1 – paragraph 15 - Revision Proposal **Article 17 MDR** **Single-use devices and reprocessing of devices that are not for single use**	
Text proposed by the Commission	**Proposed Amendment**
1. A device shall only be intended for single-use where the manufacturer, in light of the design, construction, material, chemical, physical and biological properties of the device, cannot ensure that the device continues to meet the relevant safety and performance requirements when reused in accordance with its intended purpose after appropriate reprocessing. The manufacturer's justification of an indication	1. A device shall only be intended for single-use where the manufacturer, in light of the design, construction, material, chemical, physical and biological properties of the device, cannot ensure that the device continues to meet the relevant safety and performance requirements when reused in accordance with its intended purpose after appropriate reprocessing. The manufacturer's justification of an indication

of single use shall be part of the technical documentation referred to in Annex II. 2. If the device is not intended for single-use, the manufacturer shall provide information about the appropriate reprocessing process for allowing reuse in the instructions for use in accordance with Annex I, Section 23.4, point (n). 3. Single-use devices and devices that cannot be further reprocessed may be subject to full refurbishing within the meaning of Article 2(31). The natural or legal person that carries out the full refurbishing shall be considered as the manufacturer of the fully refurbished device. 4. The Commission may adopt, in accordance with Article 9(1), CS on general requirements regarding reprocessing of devices or fully refurbishing of single use devices.';	of single use shall be part of the technical documentation referred to in Annex II 2. If the device is not intended for single-use, the manufacturer shall provide information about the appropriate reprocessing process for allowing reuse in the instructions for use in accordance with Annex I, Section 23.4, point (n). ***3. By way of derogation from paragraph 1, Member States may decide to allow reprocessing within a health institution of devices marked as single-use by a manufacturer, provided that they ensure that the safety and performance of the reprocessed device is equivalent to that of the original device.*** ~~3~~**4**. Single-use devices and devices that cannot be further reprocessed may be subject to full refurbishing within the meaning of Article 2(31). The natural or legal person that carries out the full refurbishing shall be considered as the manufacturer of the fully refurbished device. ~~4~~**5**. The Commission ~~may~~ ***shall*** adopt, in accordance with Article 9(1) ***and with the input of the expert panels***, CS on general requirements regarding reprocessing of devices or fully refurbishing of single use devices.';
Justification	
The reprocessing of single use medical devices is often safely possible, and quality and safety are assured through the cleaning, disinfection, sterilisation and related procedures, as well as testing and restoring the technical and functional safety of the used device. Reprocessing enhances sustainability in the healthcare system, reduces waste and is practiced throughout the healthcare system.	

Support for paediatric devices

Amendment 10	
Article 1 – paragraph 40 - Revision Proposal **Article 50 – paragraph 2 - MDR** **Access to notified bodies and fees**	
Text proposed by the Commission	**Proposed Amendment**

2. Notified bodies shall apply at least a 50 % fee reduction for manufacturers that are micro enterprises within the meaning of Recommendation 2003/361/EC and at least a 25 % fee reduction for small enterprises within the meaning of that Recommendation. They shall apply at least a 50 % fee reduction for manufacturers that apply for conformity assessment of an orphan device referred to in Article 52a(3). Notified bodies shall provide manufacturers that are micro or small enterprises within the meaning of Recommendation 2003/361/EC the possibility to defer the payment of fees until the relevant conformity assessment activity is finalised.	2. Notified bodies shall apply at least a 50 % fee reduction for manufacturers that are micro enterprises within the meaning of Recommendation 2003/361/EC and at least a 25 % fee reduction for small enterprises within the meaning of that Recommendation. They shall apply at least a 50 % fee reduction for manufacturers that apply for conformity assessment of an orphan device referred to in Article 52a(3) ***or a paediatric device referred to in Article 52a(4)***. Notified bodies shall provide manufacturers that are micro or small enterprises within the meaning of Recommendation 2003/361/EC the possibility to defer the payment of fees until the relevant conformity assessment activity is finalised.
Justification	
Healthcare professionals have noted that certain paediatric devices have disappeared from the market (see more details below in the justification for amendment 12). Paediatric devices often cater to small patient groups, therefore offering limited potential return on investment for manufacturers when compared to the high certification costs. A fee reduction may therefore enhance the availability of these essential devices on the EU market.	

Amendment 11	
Article 1 – paragraph 43 – point g - Revision Proposal **Article 52 – paragraph 14 – point d - MDR** **Conformity assessment procedures**	
Text proposed by the Commission	**Proposed Amendment**
(d) the modalities of the conformity assessment procedures regarding breakthrough devices and orphan devices set out in Article 52a;’;	(d) the modalities of the conformity assessment procedures regarding breakthrough devices, ~~and~~ orphan devices**,** ***and paediatric devices*** set out in Article 52a;’;
Justification	
See the justification for amendment 12 below.	

Amendment 12	
Article 1 – paragraph 44 - Revision Proposal **Article 52 – paragraph a - MDR** **Conformity assessment of breakthrough devices, of paediatric devices and of orphan devices**	
Text proposed by the Commission	**Proposed Amendment**

Conformity assessment of breakthrough devices and of orphan devices 1. For the conformity assessment of breakthrough devices and orphan devices, for which a notified body is involved in the conformity assessment, the procedures laid down in Article 52 shall apply subject to the specific arrangements set out in this Article. 2. A device shall be considered a breakthrough device if it meets the following criteria: (a) it is expected to introduce in the Union a high degree of novelty with respect to the device technology, related clinical procedure or the application of the device in clinical practice; (b) it is expected to provide a significant positive clinical impact on patients or public health, for a life-threatening or irreversibly debilitating disease or condition, by either of the following: (i) offering a significant positive clinical or health impact compared to available alternatives and the state of the art; (ii) fulfilling an unmet medical need where there is an absence or insufficiency of available alternative options for that purpose. 3. A device shall be considered an orphan device if it meets the following criteria: (a) it is intended for the treatment, diagnosis, or prevention of a disease or condition that presents in not more than 12 000 individuals in the Union per year; (b) at least one of the following criteria is met: (i) there are insufficient available alternatives; (ii) the device is expected to provide a clinical benefit compared to available alternatives or the state of the art, taking into account both device-specific factors and patient population-specific factors. 4. Upon a duly substantiated request by a manufacturer or a notified body, an expert panel referred to in Article 106 shall provide an opinion as to whether the criteria set out	Conformity assessment of breakthrough devices***, of paediatric devices*** and of orphan devices 1. For the conformity assessment of breakthrough devices***, paediatric devices*** and orphan devices, for which a notified body is involved in the conformity assessment, the procedures laid down in Article 52 shall apply subject to the specific arrangements set out in this Article. 2. A device shall be considered a breakthrough device if it meets the following criteria: (a) it is expected to introduce in the Union a high degree of novelty with respect to the device technology, related clinical procedure or the application of the device in clinical practice; (b) it is expected to provide a significant positive clinical impact on patients or public health, for a life-threatening or irreversibly debilitating disease or condition, by either of the following: (i) offering a significant positive clinical or health impact compared to available alternatives and the state of the art; (ii) fulfilling an unmet medical need where there is an absence or insufficiency of available alternative options for that purpose. 3. A device shall be considered an orphan device if it meets the following criteria: (a) it is intended for the treatment, diagnosis, or prevention of a disease or condition that presents in not more than 12 000 individuals in the Union per year; (b) at least one of the following criteria is met: (i) there are insufficient available alternatives; (ii) the device is expected to provide a clinical benefit compared to available alternatives or the state of the art, taking into account both device-specific factors and patient population-specific factors.

in paragraph 2 or 3 of this Article, as applicable, are fulfilled. That opinion shall be published on a dedicated website without disclosing any confidential information as referred to in Article 109 and shall be duly taken into consideration by the manufacturer and the notified body. 5. Where the opinion of the expert panel confirms the fulfilment of the criteria set out in paragraph 2 or 3 of this Article, the manufacturer of a breakthrough device or of an orphan device, as applicable, may request advice from the expert panels referred to in Article 106 regarding its clinical development strategy and appropriate preclinical or clinical data for the clinical evaluation of the device. 6. For a confirmed breakthrough device or an orphan device, as applicable, the notified body involved in the conformity assessment procedure set out in Article 52 shall prioritise the conformity assessment of that device and apply, where appropriate, a rolling review with a view to reduce assessment timelines. The notified body shall give due consideration to an opinion or advice provided by the expert panels in accordance with paragraph 4 or 5 and, where it does not follow such opinion or advice, it shall provide duly justified reasons. The notified body may ask the expert panel to clarify the opinion it has provided. 7. The notified body shall issue a certificate pursuant to Article 56 where the premarket clinical evidence, even if based on limited clinical data, is deemed adequate, provided that either of the following conditions is fulfilled: (a) the benefit of the immediate availability on the market of the device outweighs the risk associated with the fact that additional clinical data are still required; (b) the benefit-risk-ratio of the device is favourable and the manufacturer commits to providing additional data from post-market clinical follow-up activities.	***4. A device shall be considered a paediatric device if it meets the following criteria:*** ***(a) it is intended for the treatment, diagnosis, or prevention of a disease or condition in children under 18;*** ***(b) at least one of the following criteria is met:*** ***(i) there are insufficient available alternatives;*** ***(ii) the device is expected to provide a clinical benefit compared to available alternatives or the state of the art, taking into account both device-specific factors and patient population-specific factors.*** ~~4~~***5***. Upon a duly substantiated request by a manufacturer or a notified body, an expert panel referred to in Article 106 shall provide an opinion as to whether the criteria set out in paragraph 2, 3 ***and 4*** of this Article, as applicable, are fulfilled. That opinion shall be published on a dedicated website without disclosing any confidential information as referred to in Article 109 and shall be duly taken into consideration by the manufacturer and the notified body. ~~5~~***6***. Where the opinion of the expert panel confirms the fulfilment of the criteria set out in paragraph 2, 3 ***and 4*** of this Article, the manufacturer of a breakthrough device**,** ***paediatric device*** or of an orphan device, as applicable, may request advice from the expert panels referred to in Article 106 regarding its clinical development strategy and appropriate preclinical or clinical data for the clinical evaluation of the device. ~~6~~***7***. For a confirmed breakthrough device**,** ***paediatric device*** or an orphan device, as applicable, the notified body involved in the conformity assessment procedure set out in Article 52 shall prioritise the conformity assessment of that device and apply, where appropriate, a rolling review with a view to reduce assessment timelines.

Where appropriate, the notified body shall limit the validity of the certificate and specify any conditions for or limitations to the certificate's validity in accordance with Article 56, such as a requirement for the manufacturer to conduct specific post-market clinical follow-up activities within a specified period of time. 8. The Commission is empowered to adopt delegated acts in accordance with Article 115 in order to amend this Article to adapt to technical or scientific progress or to take into account developments regarding conformity assessment of breakthrough devices or orphan devices at international level. 9. The Commission may, by means of implementing acts, lay down further details of the procedure for the conformity assessment of breakthrough devices or orphan devices set out in this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).	The notified body shall give due consideration to an opinion or advice provided by the expert panels in accordance with paragraph 4 or 5 and, where it does not follow such opinion or advice, it shall provide duly justified reasons. The notified body may ask the expert panel to clarify the opinion it has provided. ~~7~~***8***. The notified body shall issue a certificate pursuant to Article 56 where the premarket clinical evidence, even if based on limited clinical data, is deemed adequate, provided that either of the following conditions is fulfilled: (a) the benefit of the immediate availability on the market of the device outweighs the risk associated with the fact that additional clinical data are still required; (b) the benefit-risk-ratio of the device is favourable and the manufacturer commits to providing additional data from post-market clinical follow-up activities. Where appropriate, the notified body shall limit the validity of the certificate and specify any conditions for or limitations to the certificate's validity in accordance with Article 56, such as a requirement for the manufacturer to conduct specific post-market clinical follow-up activities within a specified period of time. ~~8~~***9***. The Commission is empowered to adopt delegated acts in accordance with Article 115 in order to amend this Article to adapt to technical or scientific progress or to take into account developments regarding conformity assessment of breakthrough devices**,** ***paediatric devices*** or orphan devices at international level. ~~9~~***10***. The Commission may, by means of implementing acts, lay down further details of the procedure for the conformity assessment of breakthrough devices**,** ***paediatric devices*** or orphan devices set out in this Article. Those implementing acts shall be adopted in accordance with the

	examination procedure referred to in Article 114(3). ***11. The Commission may, by means of implementing acts, lay down requirements for the preparation of a paediatric development plan, for categories or groups of devices which are marketed for adults, but may have clinical benefit for paediatrics or the treatment of rare diseases. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).***
Justification	
Healthcare professionals have raised concerns regarding such devices disappearing from the market, one of the main barriers include limited options for early dialogue and high costs of certification. The newly proposed article 52a will improve the availability of essential orphan and breakthrough devices. *Nonetheless, there is a risk that certain paediatric devices will fall outside the definition of orphan devices, but the cost of certification compared to low potential return on investment due to small patient groups may still be a barrier for manufacturers that consider applying for CE marking. We therefore propose to specifically include a definition of paediatric devices, based on the definition of orphan devices, providing similar access to support. Unlike the pharmaceutical legislation, MDR does not include provisions on paediatric devices and this amendment would provide children with better access to essential medical devices. The newly established paediatrics and rare diseases expert panel could support its implementation.* *Sub-section 11 has been added to prompt manufacturers of general adult medical devices to consider preparation of sizes that may be used in paediatrics or rare diseases. These requirements could be applied by the European Commission for particular device types which have potential for significant clinical benefit in these populations.*	

Validity of certificates

Amendment 13	
Article 1 – paragraph 47 - Revision Proposal **Article 56 – paragraph 2 and 2a - MDR** **Certificates of conformity (validity of certificates)**	
Text proposed by the Commission	**Proposed Amendment**
2. The validity of certificates shall not be limited in time, unless in exceptional cases where the notified body considers it necessary to limit the period of validity based on duly justified grounds. In those cases, the notified body shall indicate the period of	2. The validity of certificates shall not be limited in time***, except for class IIb implantable and class III devices for which certificates shall be valid for the period they indicate, which shall not exceed five years. On application by the manufacturer,***

validity on the certificate. If the period of validity of the certificate is limited, on application by the manufacturer, the notified body may, following an assessment performed in accordance with Annex VII, Section 4.11, extend the validity of the certificate. Any supplement to a certificate shall remain valid as long as the certificate which it supplements is valid.' 2a. During the validity of the certificate, the notified body shall carry out appropriate surveillance activities, including periodic reviews taking into consideration developments of the state of the art. Those reviews shall be proportionate to the risk class of the device.	***the validity of the certificate may be extended for further periods, each not exceeding five years, based on a re-assessment in accordance with the applicable conformity assessment procedures. Any supplement to a certificate shall remain valid as long as the certificate which it supplements is valid.*** ***For other class I and class II devices, the duration of certificates may be limited*** ~~unless~~ in exceptional cases where the notified body considers it necessary to limit the period of validity based on duly justified grounds. In those cases, the notified body shall indicate the period of validity on the certificate. If the period of validity of the certificate is limited, on application by the manufacturer, the notified body may, following an assessment performed in accordance with Annex VII, Section 4.11, extend the validity of the certificate. Any supplement to a certificate shall remain valid as long as the certificate which it supplements is valid.' 2a. During the validity of the certificate, the notified body shall carry out appropriate surveillance activities, including periodic reviews taking into consideration developments of the state of the art, ***Post-Market Surveillance and vigilance data, and relevant data from clinical registries and other real-world evidence sources***. Those reviews shall be ***documented and*** proportionate to the risk class of the device.
Justification	
For many types of high-risk implantable devices, such as coronary stents, heart valves, and joint replacements, significant differences between devices may become apparent only after more than 5 years. These are very commonly used devices, so any late failures would have major implications for public health. We propose to maintain the 5 year validity for class IIb implantable and class III devices, due to the potential risk for patients.	

Amendment 14
Article 2 paragraph 33 - point a - Revision Proposal **Article 51 – paragraph 2 - IVDR** **Certificates of conformity (validity of certificates)**

Text proposed by the Commission	Proposed Amendment
2. The validity of certificates shall not be limited in time, unless in exceptional cases where the notified body considers it necessary to limit the period of validity based on duly justified grounds. In those cases, the notified body shall indicate the period of validity on the certificate. If the period of validity of the certificate is limited, on application by the manufacturer, the notified body may, following an assessment performed in accordance with Annex VII, Section 4.11, extend the validity of the certificate. Any supplement to a certificate shall remain valid as long as the certificate which it supplements is valid.’;	2. The validity of certificates shall not be limited in time***, except for class C and D or innovative devices for which certificates shall be valid for the period they indicate, which shall not exceed five years. On application by the manufacturer, the validity of the certificate may be extended for further periods, each not exceeding five years, based on a re-assessment in accordance with the applicable conformity assessment procedures. Any supplement to a certificate shall remain valid as long as the certificate which it supplements is valid.*** ***For other class C and class D or innovative devices, the duration of certificates may be limited*** ~~unless~~ in exceptional cases where the notified body considers it necessary to limit the period of validity based on duly justified grounds. In those cases, the notified body shall indicate the period of validity on the certificate. If the period of validity of the certificate is limited, on application by the manufacturer, the notified body may, following an assessment performed in accordance with Annex VII, Section 4.11, extend the validity of the certificate. Any supplement to a certificate shall remain valid as long as the certificate which it supplements is valid.’;
Justification	
Class C and D IVDs test for conditions where false positives or false negatives may have significant consequences for individual patients and public health. Class C devices include genetic testing for cancer or inherited disorders and are often highly innovative. The administrative burden of a five-year reassessment is directly proportional to the systemic risk of allowing these devices to remain on the market indefinitely without a periodic re-evaluation.	

In House Medical Devices

Amendment 15	
Article 5 – paragraph 5 - MDR **Placing on the market and putting into service (In House Devices)**	
MDR text	**Proposed Amendment**

5. With the exception of the relevant general safety and performance requirements set out in Annex I, the requirements of this Regulation shall not apply to devices, manufactured and used only within health institutions established in the Union, provided that all of the following conditions are met:	5. With the exception of the relevant general safety and performance requirements set out in Annex I, the requirements of this Regulation shall not apply to devices, manufactured ~~and used only~~ within health institutions established in the Union, provided that all of the following conditions are met:
Justification	
Some in-house medical devices, for example a splint, are taken home by the patient. By requiring the device to be 'manufactured and used' within the health institution, this creates uncertainty or non-compliance for these necessary products.	

Annex: examples of devices approved on the basis of equivalence

These are some examples of high-risk medical devices where the scientific literature suggests that they were approved on the basis of equivalence and/or without definitive clinical trials (although within the EU system, the basis for issuing a certificate of conformity is not disclosed publicly). In each case, implantation of the device led in some patients to serious adverse effects requiring re-intervention or causing death:

Medtronic Parallel heart valve

This valve was manufactured in the USA but marketed only outside the USA, including in Europe. There had been insufficient pre-clinical modelling or evaluation of flow patterns through the valve. After problems occurred, studies revealed that there was a region of stasis within the hinge pocket of the valve, that resulted in thrombus formation and embolism.

- Gross JM, Shu MC, Dai FF, Ellis J, Yoganathan AP. A microstructural flow analysis within a bileaflet mechanical heart valve hinge. J Heart Valve Dis 1996;5:581–590.
- Ellis JT, Healy TM, Fontaine AA, Saxena R, Yoganathan AP. Velocity measurements and flow patterns within the hinge region of a Medtronic Parallel bileaflet mechanical valve with clear housing. J Heart Valve Dis 1996;5:591–599.

St Jude Silzone Heart Valve

The Silzone valve was a modification of the standard St Jude mechanical bileaflet heart valve, with its sewing ring impregnated with silver on the hypothesis that it would have an antibacterial effect. The valve was approved on the basis of equivalence, but subsequent experimental studies demonstrated that the silver prevented tissue ingrowth and normal endothelialisation of the ring. Patients developed loosely adherent thrombus, and paraprosthetic regurgitation. The valve was taken off the market after patients had died.

- Schaff HV, Carrel TP, Jamieson WR, Jones KW, Rufilanchas JJ, Cooley DA, Hetzer R, Stumpe F, Duveau D, Moseley P, van Boven WJ, Grunkemeier GL, Kennard ED, Holubkov R. Artificial Valve Endocarditis Reduction Trial. Paravalvular leak and other events in silzone-coated mechanical heart valves: a report from AVERT. Ann Thorac Surg 2002;73:785–792.
- Ionescu A, Payne N, Fraser AG, Giddings J, Grunkemeier GL, Butchart EG. Incidence of embolism and paravalvar leak after St Jude Silzone valve implantation: experience from the Cardiff Embolic Risk Factor Study. Heart 2003;89:1055–1061.

Large-head metal-on-metal hip replacements

The DePuy ASR ASR XL Acetabular metal-on-metal hip replacement system was approved on the basis of equivalence in the EU, and by the 510(k) pathway, meaning it has never been clinically tested in patients before it was approved and sold. In 2008, the Australian Orthopaedic Association National Joint Replacement Registry reported a high rate of complications, with a revision rate at 5 years of about 13%. The device was taken off the market. It had been approved on claims related to long-discontinued prostheses, and to predicates that had different combinations of characteristics.

- Ardaugh BM, Graves SE, Redberg RF. The 510(k) ancestry of a metal-on-metal hip implant. New Engl J Med. 2013;368:97–100.

Modular-neck stems in total hip replacement

Stryker introduced the Rejuvenate and ABG II modular-neck stems to the European market between 2008 and 2009, positioning them as advanced, customizable orthopedic solutions for hip replacement surgery. The devices were marketed as offering improved flexibility, stability, and personalized fit for patients through their innovative modular design, which allowed for multiple neck and stem combinations. Both devices were approved on basis of equivalence in the EU market, meaning none of the devices have been clinically tested in patients before they were sold and implanted in patients. Due to high rates of complications and adverse event reports, Stryker issued a global, voluntary recall of the Rejuvenate and ABG II modular-neck stems in July 2012.

- Molloy DO, Munir S, Jack CM, Cross MB, Walter WL, Walter WK. Fretting and corrosion in modular-neck total hip arthroplasty femoral stems. J Bone Joint Surg Am 2014, 19; 96(6): 488-93. doi: 0.2106/JBJS.L.01625
- Seppänen M, Laaksonen I, Pulkkinen P, Eskelinen A, Puhto A-P, Kettunen J, Leskinen J, Manninen M, Mäkelä K. High Revision Rate for Large-head Metal-on-metal THA at a Mean of 7.1 Years: A Registry Study. Clin Orthop Relat Res 2018; 476(6): 1223-1230. doi: 10.1007/s11999.0000000000000159

Transvaginal meshes

There have been many reports of severe complications arising from the implantation of surgical and transvaginal meshes, using devices that had been approved on the basis of equivalence.

Since the clinical evidence submitted to a notified body is not publicly disclosed, it is impossible to undertake a comprehensive analysis of clinical studies within the EU.

A review of 9 meshes was conducted by the National Institute for Public Health and the Environment (RIVM) in the Netherlands. They had all been CE-marked under the medical device directives and were in use in the Netherlands in 2018. The investigators found major shortcomings in the documentation (and by implication, the evidence before approval) of all the meshes. In the majority of cases when equivalence was claimed, “adequate substantiation was lacking”. Details are provided in the report about later restrictions placed on the use of some devices, and about the withdrawal of others from the market (see page 18).

Another investigation was reported, that used details accessible through the FDA database. The authors found no evidence from clinical trials for 61 devices at the time of their approval. Analysis of 119 FDA ‘522 orders’ revealed that in 79 (66%) the manufacturer had ceased market distribution of the predicate device, and in 26 (22%) the manufacturer had changed the indication of the device to which equivalence was claimed.

- Roszek B, van Drongelen AW, Geertsma RE, van Baal JW. Mesh implants intended to treat patients with pelvic organ prolapse. Market survey and quality of technical documentation. RIVM letter report 2020-0154. National Institute for Public Health and the Environment (RIVM), the Netherlands, 2022.
- Heneghan CJ, Goldacre B, Onakpoya I, Aronson JK, Jefferson T, Pluddemann A, Mahtani KR. Trials of transvaginal mesh devices for pelvic organ prolapse: a systematic database review of the US FDA approval process. BMJ Open. 2017;7(12):e017125.