Biomedical Alliance in Europe

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 BioMed Alliance welcomes the publication of the European Commission's proposal (2025/0404 (COD) for a targeted revision of the Medical Devices Regulation (MDR) and In Vitro Diagnostics Regulation (IVDR). The 34 European Medical Societies that the Alliance represents believe that reform is 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 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.

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

[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/

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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 below), 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.

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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 given that 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 the CIRCABC platform 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 and useful for both healthcare professionals and patients. We recommend that this is a

[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

priority topic for the scientific co-ordination role envisaged for the European Medicines Agency and that engagement with the target audiences is undertaken.

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 and breakthrough 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.

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 the 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 that whether or not the validity of a certificate of 5 years should be retained or abolished, 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 serve as vital tool for patients, including for devices that have been on the market for a number of years.

→ With the removal of the 5-year validity of certificates it is essential to better monitor the safety of implantable high-risk devices long term, since safety issues may occur after several years. Implant cards for Well Established Technologies must also be retained as a vital tool for patients.

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.

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[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

→ 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, high-risk devices enter clinical practice, leading to increased adverse events and an erosion of public trust in the CE mark.

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. 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. For instance, during the COVID-19 pandemic, health institutions first developed their own tests before industry developed a CE-marked equivalent. Under the IVDR, it was difficult to transfer these essential diagnostics to other health institutions so that a broader patient group could benefit 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.

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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.