PROPOSED REPLACEMENT EU ACT
INITIAL ASSESSMENT OF IMPACT

DSC REF: DSC/05a/2026

Proposed Replacement EU Act

Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EU) 2017/745 (MDR) and (EU) 2017/746 (IVDR) as regards simplifying and reducing the burden of the rules on medical devices and in vitro diagnostic medical devices, and amending Regulation (EU) 2022/123 as regards the support of the European Medicines Agency for the expert panels on medical devices and Regulation (EU) 2024/1689 as regards the list of Union harmonisation legislation referred to in its Annex I [link]

This Regulation will amend Regulation (EU) 2017/745 [link] of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC: **Protocol Annex 2, Heading 21 on Medical Devices**. The regulation will also amend Regulation (EU) 2017/746 [link] of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU: **Protocol Annex 2, Heading 21 on Medical Devices**. The proposed Regulation also amends Regulation (EU) 2022/123 [link] of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices: **not listed in Protocol Annex 2**: **and** Regulation (EU) 2024/1689 [link] of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act): **not listed in Protocol Annex 2**.

Summary of the Act

Regulation (EU) 2017/745 (Medical Devices Regulation (MDR)) and Regulation (EU) 2017/746 (In Vitro Diagnostic Medical Devices Regulation (IVDR)) of the European Parliament and of the Council set a strengthened regulatory framework for medical devices and in vitro diagnostic medical devices (IVDs). Both these regulations apply in Northern Ireland (NI) under the Windsor Framework. The aim of the MDR and IVDR is to establish a robust, transparent, predictable and sustainable regulatory framework for medical devices and for in vitro diagnostic

medical devices, ensuring a high level of safety and health while supporting innovation.

This proposed EU Regulation aims to streamline and future-proof the MDR and IVDR regulatory frameworks. Its main objective is to simplify the applicable rules, reduce the administrative burden on manufacturers and enhance the predictability and cost-efficiency of the certification procedure by notified bodies; whilst also preserving a high level of public health protection and patient safety, helping achieve the initial objectives of the MDR and IVDR Regulations.

The European Parliament and Council are of the view that the lack of sufficiently predictable timelines for the certification process and diverging practices across the EU continue to undermine the efficiency of the process to obtain certified accreditation (CE marking). Further, they note several requirements under the MDR and IVDR Regulations are disproportionate to the actual risks posed by some devices, resulting in unnecessarily high costs and burdens. Overly onerous requirements may prompt manufacturers, especially SMEs, to discontinue supplying devices or to delay their launch, with potential negative consequences for patient care and public health. These requirements are also believed to negatively impact the competitiveness of the EU medical devices market, globally.

The general objective of this proposed regulation is to make MDR/IVDR more workable, predictable, innovation-friendly, and proportionate, while maintaining high public-health protection. This will address long-standing concerns from industry, notified bodies, and regulators. The proposal aims to deliver this via a series of measures to:

- Simplify and reduce administrative burdens.
- Increase proportionality and risk-appropriate regulation.
- Improve predictability and certification efficiency.
- Strengthen innovation pathways.
- Enhance EU coordination and digitalisation.
- Reduce costs and support SMEs; and
- Increase flexibility for devices manufactured “in House” by Health Institutions.

Department(s) Responsible

- **Department of Health (DoH, Lead) – Minister Mike Nesbitt**

Initial Assessment of Impact

Q: Does it appear likely that the application of the proposed replacement EU act would have a significant impact specific to everyday life of communities in Northern Ireland in a way that is liable to persist?

A: DoH's current understanding is that there will not be a significant impact specific to the everyday life of communities in a way that is liable to persist in relation to the proposed amendment to Regulations (EU) 2017/745 (MDR) and (EU) 2017/746 (IVDR). No practical impacts are anticipated for DoH.

Q: Does it appear likely that not applying the proposed replacement EU act would have a significant impact specific to everyday life of communities in Northern Ireland in a way that is liable to persist?

A: DoH's current understanding is that there **may** be impacts in relation to **non-application** of the proposed amendments, if a separate regulatory framework will have to be taken forward for NI. No practical impacts are anticipated for DoH**.**

UK Government Explanatory Memorandum

The relevant UK Government Explanatory Memorandum (EM) is not currently available.

Analysis by the European Commission on its Impact Assessment

The European Commission (EC) conducted a targeted evaluation of the MDR and IVDR Regulations. This regulatory proposal draws on the findings of their evaluation. Overall, the evaluation found that the benefits of the Regulations for patients and healthcare systems are materialising by strengthening device safety and performance and increasing transparency. However, these achievements come at high and often disproportionate compliance costs, caused also by high regulatory complexity.

The targeted evaluation showed that:

- certain requirements, especially in relation to conformity assessment procedures, are overly complex, burdensome, lengthy and costly.
- the application of legal requirements by national authorities and notified bodies is not sufficiently aligned.
- current coordination mechanisms are not sufficiently efficient and effective.
- there is no sufficient technical-regulatory advice available at EU level.
- adaptive pathways for breakthrough innovation and orphan or 'niche' devices do not exist.
- the Regulations have unintended negative impacts on innovation, competitiveness and patient care.
- there is a need for improved coherence with other EU law, such as the Clinical Trials Regulation.

The EC evaluation demonstrated there is potential to simplify and to reduce the burden relating to the implementation of both the MDR and IVDR Regulations, without undermining their main objectives.

The EC further engaged key stakeholders via a call for evidence on the targeted revision of the MDR and IVDR. Feedback indicated that respondents agreed with the EC identified hurdles stemming from the MDR and IVDR Regulations. Stakeholders referenced their disproportionate costs, high administrative burden and the overall regulatory complexity. This aligned with the findings of the targeted evaluation.

Stakeholders showed overall broad support for measures aimed at simplifying and making the regulatory framework more proportionate and efficient, reducing administrative burden, and allowing for more flexibility to support innovative devices to reach the market.

This proposal is to address the issues identified during the targeted evaluation. The proposed revision of the MDR and IVDR consists of targeted simplification measures, that seek to reduce burden and ensure greater predictability of the legislative framework. The EC view these proposed amendments as not intending to modify the objectives of the legislation, but as amendments to ensure the continued availability of safe and innovative devices and safeguarding a high level of patient safety, public health and healthcare.

In this context, an **impact assessment was not deemed necessary nor appropriate**, in terms of timing and efficiency by the Commission.

Departmental Engagement

DoH Officials have been liaising with colleagues from the Department for Economy (DfE), the Department of Health and Social Care (DHSC) and the Medicines and Healthcare products Regulatory Agency (MHRA). Medical device and In-Vitro medical device regulation is a reserved matter for which the MHRA remain the UK competent authority.

DoH will continue to liaise with relevant colleagues to understand all implications NI.