EXPLANATORY MEMORANDUM TO

THE MEDICAL DEVICES (AMENDMENT) (GREAT BRITAIN) REGULATIONS 2025

2025 No. 591

1. Introduction

1.1 This explanatory memorandum has been prepared by the Medicines and Healthcare products Regulatory Agency ("MHRA"), an executive agency of the Department of Health and Social Care and is laid before Parliament by Command of His Majesty.

1.2 This memorandum contains information for the Joint Committee on Statutory Instruments.

2. Declaration

2.1 Baroness Merron, Parliamentary Under-Secretary of State for Patient Safety, Women's Health and Mental Health at the Department of Health and Social Care confirms that this Explanatory Memorandum meets the required standard.

2.2 Dr Rob Reid, Deputy Director for Innovative Devices at the Medicines and Healthcare products Regulatory Agency confirms that this Explanatory Memorandum meets the required standard.

3. Contact

3.1 Lindsey Cox at the Medicines and Healthcare products Regulatory Agency Telephone: 020 3080 6000 or email: info@mhra.gov.uk can be contacted with any queries regarding the instrument.

Part One: Explanation, and context, of the Instrument

4. Overview of the Instrument

What does the legislation do?

4.1 The objective of this instrument is to provide continuity in the regulation of medical devices by maintaining the regulatory status quo. The legislation amends the Medical Devices Regulations 2002 (S.I. 2002/618) ("the 2002 Regulations") to remove the revocation date of four pieces of assimilated EU law which, if they were to expire on 25 and 26 May 2025, would create a significant gap in the regulatory framework and risk to patient safety.

Where does the legislation extend to, and apply?

4.2 The extent of this instrument (that is, the jurisdiction(s) which the instrument forms part of the law of) is the United Kingdom.

4.3 The territorial application of this instrument (that is, where the instrument produces a practical effect) is Great Britain only.

4.4 To facilitate its dual access to both the UK internal market and EU single market, since 26 May 2021, the EU Medical Devices Regulation (Regulation 2017/745) has applied in Northern Ireland. Since 26 May 2022, the EU In Vitro

Diagnostic Medical Devices Regulation (Regulation 2017/746) has applied in Northern Ireland.

5. Policy Context

What is being done and why?

5.1 Medical devices and in vitro diagnostic devices on the Great Britain market are regulated under the 2002 Regulations, which transposed three EU Directives (the Medical Devices Directive (93/42/EEC), Active Implantable Medical Devices Directive (90/385/EEC) and In Vitro Diagnostic Medical Devices Directive (98/79/EC)) into national law. As such, the 2002 Regulations contain references to a number of other pieces of assimilated EU law, which form part of the regulatory framework for Great Britain.

5.2 Four of those pieces of assimilated law will sunset on 25 and 26 May 2025. They are referred to at regulations 4H, 4J, 4K and 4L of the 2002 Regulations, and can be summarised as follows:

- Commission Decision 2002/364 on the common technical specifications for in vitro diagnostic medical devices sets out technical requirements that certain in vitro diagnostic medical devices must meet to demonstrate compliance with essential requirements when they are placed on the market or put into service.
- Commission Regulation (EU) No 207/2012 on electronic instructions for use of medical devices establishes the conditions under which the instructions for use of medical devices may be provided in electronic form instead of in paper form and sets out certain requirements concerning instructions for use in electronic form which are provided in addition to complete instructions for use in paper form.
- Regulation (EU) No 722/2012 concerning particular requirements for medical devices manufactured utilising tissues of animal origin lays down requirements in relation to the placing on the market and putting into service of medical devices, including active implantable medical devices, manufactured utilising animal tissue which is rendered non-viable or non-viable products derived from animal tissue. The Regulation applies to animal tissues, as well as their derivatives, originating from bovine, ovine and caprine species, deer, elk, mink and cats.
- Regulation (EU) No 920/2013 on the designation and the supervision of approved bodies sets out further requirements on the designation of approved bodies (organisations that assess medium and high-risk medical devices for conformity with the regulations) and a list of elements to be included in the interpretation of the relevant Directive annexes on minimum criteria to be met for the designation of bodies.

5.3 The expiration of this assimilated EU law on 25 and 26 May 2025 could impact the smooth operation of the 2002 Regulations, which would have significant patient safety impacts, as it currently provides for the: safety of certain in vitro diagnostic devices; safety of devices containing tissues of animal origin; provision of instructions for use of devices; and designation of approved bodies.

5.4 The government does not intend for this assimilated EU law to be kept in place indefinitely. This instrument serves as a temporary measure to maintain the status quo

until more permanent measures are in place; the first of those is expected to come into force in 2026.

5.5 The government is committed to ensuring that the regulations for medical devices continue to prioritise patient safety and give patients access to the medical devices they need. The MHRA is therefore currently developing legislation that will amend the 2002 Regulations more broadly to improve patient safety by introducing additional, risk-proportionate measures that must be taken before a product can be put on the market.

What was the previous policy, how is this different?

5.6 This is a continuation of the existing policy. The four pieces of assimilated EU law will continue to form part of the regulatory framework for Great Britain.

6. Legislative and Legal Context

How has the law changed?

6.1 This instrument amends the Medical Devices Regulations 2002 (S.I. 2002/618) by removing the 25 and 26 May 2025 revocation date of the following pieces of assimilated EU law: Regulations 4H (Commission Decision 2002/364), 4J (Commission Regulation (EU) No 207/2012), 4K (Regulation (EU) No 722/2012) and 4L (Regulation (EU) No 920/2013). The 2002 Regulations were made under section 2(2) of the European Communities Act 1972 to implement Directives 90/385/EEC, 93/42/EEC and 98/79/EC.

6.2 This instrument exercises the powers conferred by section 15(1), 16(1)(a), (b), (c), (e), (g) and (i),17(1)(b) and (c) of the Medicines and Medical Devices Act 2021 ("the 2021 Act").

Why was this approach taken to change the law?

6.3 This is the only possible approach to make the necessary changes.

7. Consultation

Summary of consultation outcome and methodology

7.1 The 2021 Act requires that, before making regulations under section 15, a public consultation must be carried out in accordance with section 45(1) of that Act. A public consultation was carried out from 14 November 2024 to 5 January 2025, which included the proposal to remove the revocation date of these pieces of assimilated EU law. There were 287 consultation responses: 107 from individuals and 180 from organisations including manufacturers of medical devices, healthcare institutions, trade associations and small/medium enterprises.

7.2 The responses were generally supportive, with 83% of those who responded to the proposal expressing agreement, largely citing the importance of regulatory continuity for patient safety. A summary of the consultation responses and the Government's response was published on 26 February 2025[1].

7.3 The MHRA has engaged with officials in the Devolved Governments on the development of this instrument.

[1] Consultation on Medical Devices Regulations: Routes to market and in vitro diagnostic devices - GOV.UK https://www.gov.uk/government/consultations/consultation-on-medical-devices-regulations-routes-to-market-and-in-vitro-diagnostic-devices

8. Applicable Guidance

8.1 Guidance is not required. Stakeholders will be made aware of the legislation through appropriate communications and engagement.

Part Two: Impact and the Better Regulation Framework

9. Impact Assessment

9.1 A full impact assessment has not been prepared for this instrument because the legislative change is not expected to result in any direct cost to businesses. This instrument relates to maintenance of existing regulatory standards. A qualitative de minimis assessment has been completed on the potential impact of each of these regulations.

Impact on businesses, charities and voluntary bodies

9.2 The removal of the sunset dates will retain the current regulatory arrangements, implying minimal anticipated impact on businesses. This is because there will be no familiarisation costs, as businesses are already aware of the regulations, further enhanced by stakeholder engagement through the consultation. Businesses that adhere to these regulations will have already implemented compliance measures, resulting in business costs. Furthermore, for Commission Regulation (EU) No 207/2012, businesses that choose to use electronic instructions for use of medical devices will continue to benefit from cost savings associated with reduced paper usage and streamlined processes.

9.3 Given that minimal direct costs to businesses are expected as a result of this change in regulations, there will not be any disproportionate impact on small and medium-sized enterprises (SMEs). Maintaining regulatory stability is particularly important for SMEs, which may have limited resources to adapt to frequent regulatory changes. By preserving the current regulatory framework, the government can support the growth and competitiveness of the medical device industry in Great Britian.

9.4 Furthermore, evidence from the consultation indicates that out of the 31 SMEs (businesses with fewer than 50 employees) that responded, none opposed the proposal to remove the sunset clause. 77% of SMEs expressed their agreement with the proposal, while 23% had no opinion on the matter.

9.5 Retaining all four assimilated EU laws will enable continued operation of the 2002 Regulations and therefore maintain appropriate patient safety standards for medical devices. During the consultation, respondents emphasised the necessity of these regulations for ensuring patient safety. The technical specifications in Commission Decision 2002/364 prevent diagnostic errors, while Commission Regulation (EU) No 207/2012 ensures clear instructions for use, reducing misuse. Regulation (EU) No 722/2012 prevents disease transmission from animal tissues, and Regulation (EU) No 920/2013 maintains the quality and safety of medical devices through ongoing oversight.

10. Monitoring and review

What is the approach to monitoring and reviewing this legislation?

10.1 Section 46 of the 2021 Act requires the Secretary of State to lay a report before Parliament every two years on the operation of regulations made under section 15 (and other powers under the Act).

10.2 The instrument does not include a statutory review clause. However, the consultation that proposed this legislative change is part of a wider programme of work undertaken by the MHRA to consider and, where necessary, make updates to the regulatory framework for medical devices, including assimilated EU law. The impact of any future legislative changes will be assessed, monitored and reviewed in accordance with the Better Regulation Framework.

Part Three: Statements and Matters of Particular Interest to Parliament

11. Matters of special interest to Parliament

11.1 This instrument is made under section 15(1), 16(1)(a), (b), (c), (e), (g) and (i),17(1)(b) and (c) of the Medicines and Medical Devices Act 2021. It amends the Medical Devices Regulations 2002, which were made under section 2(2) of the European Communities Act 1972 (amongst other powers). This instrument is subject to the draft affirmative procedure. The procedural and publication requirements applicable to this instrument have been followed.

12. European Convention on Human Rights

12.1 Baroness Merron, Parliamentary Under-Secretary of State for Patient Safety, Women's Health and Mental Health has made the following statement regarding Human Rights:

"In my view the provisions of the Medical Devices (Amendment) (Great Britain) Regulations 2025 are compatible with the Convention rights."

13. The Relevant European Union Acts

13.1 This instrument is not made under the European Union (Withdrawal) Act 2018, the European Union (Future Relationship) Act 2020 or the Retained EU Law (Revocation and Reform) Act 2023 ("relevant European Union Acts").