EXPLANATORY MEMORANDUM TO

THE MEDICAL DEVICES (AMENDMENT) (GREAT BRITAIN) REGULATIONS 2023

2023 No. [XXXX]

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 ("DHSC") and is laid before Parliament by Command of His Majesty.

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

2. Purpose of the instrument

2.1 The main objective of this instrument is to provide the UK medical devices sector with additional time to transition to the post-EU exit UK Conformity Assessed (UKCA) marking regime for medical devices. To achieve this, the instrument extends the periods during which manufacturers and importers can place CE marked medical devices on the market in Great Britain (GB).

2.2 These measures are necessary to ensure continuity of supply and availability of medical devices so that patients have continued access to safe and high-quality medical devices in GB, thereby safeguarding health.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments.

3.1 This instrument is made under section 15(1) of the Medicines & Medical Devices Act 2021 ("the MMDA"). It amends the Medical Devices Regulations 2002 (S.I. 2002 No 618, as amended) ("the UK MDR"), 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 and is being made under powers conferred after 21 June 2017. The procedural and publication requirements of paragraphs 13 and 14 of Schedule 8 to the European Union (Withdrawal) Act 2018 therefore do not apply. The statement required by paragraph 15 of Schedule 8 to that Act is set out in the Annex to this memorandum. The required explanation of the effect of the amendment and the law relevant to it, is set out in paragraphs 6.1 to 6.8.

4. Extent and Territorial Application

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

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

5. European Convention on Human Rights

5.1 Will Quince MP, Minister of State for Health and Secondary Care, has made the following statement regarding Human Rights:

"In my view the provisions of the Medical Devices (Amendment) (Great Britain) Regulations 2023 are compatible with the Convention rights."

6. Legislative Context

6.1 This instrument amends the UK MDR, which regulate the placing of medical devices on the GB market. The UK MDR were made under section 2(2) of the European Communities Act 1972 (amongst other powers) and implemented Directives 90/385/EEC, 93/42/EEC, and 98/79/EC ("the three Directives").

6.2 The UK MDR were amended by the Medical Devices (Amendments etc.) (EU Exit) Regulations 2019. These regulations made a series of amendments to correct deficiencies in the UK MDR arising from EU exit, including for example replacing the requirement to bear a CE marking with a requirement to bear a UKCA marking. The 2019 Regulations also inserted regulations 1ZA, 19B, 19C, 30A, 44ZA and 44ZB into the UK MDR in order to allow certain devices that comply with EU legislation to continue to be placed on the GB market and to be made available for clinical investigations and performance evaluations. These regulations have enabled medical devices that bear the CE marking, instead of the UKCA marking, to continue to be placed on the GB market. Regulation 1ZA states that regulations 19B, 19C, 30A, 44ZA and 44ZB will cease to have effect at 23:59 on 30 June 2023.

6.3 This instrument amends regulation 1ZA to set out a series of dates for when those regulations will now cease to have effect. That date remains 23:59 on 30 June 2023 for provisions relating to custom-made devices that comply with Directive 93/42/EEC or 90/385/EEC under regulations 19B and 30A, and for devices made available for clinical investigations and performance evaluations.

6.4 Regulations 19B, 30A and 44ZA relate to devices that comply with the three Directives. Regulations 19B and 30A will cease to have effect at 23:59 on 30 June 2028 and regulation 44ZA will cease to have effect at 23:59 on 30 June 2030 for placing devices (except custom-made devices) that comply with the Directives on the GB market.

6.5 After the UK's exit from the European Union, Directives 90/385/EEC and 93/42/EEC were repealed by Regulation (EU) 2017/745 of 5 April 2017 on medical devices ("EU MDR") on 26 May 2021, with transitional and savings provisions set out in Articles 120 and 122 of that Regulation. Directive 98/79/EC was repealed by Regulation (EU) 2017/746 of 5 April 2017 on *in vitro* diagnostic medical devices ("EU IVDR") on 26 May 2022, with savings and transitional provisions set out in Articles 110 and 112 of that Regulation. This instrument amends regulations 19B, 30A and 44ZA to refer to the Directives before they were repealed and to make it clear that a valid certificate under the EU's transitional provisions is considered valid for placing the device on the GB market. It follows that once the certificate expires or is rendered void under the EU's transitional provisions, the device can no longer be placed on the GB market.

6.6 Provision is also inserted into regulations 19B and 44ZA to make it clear that those regulations do not apply to medical devices that it has not been possible to place on the EU market since the three Directives were repealed - those being devices that did not require the involvement of a notified body in the conformity assessment procedure

under the relevant directive and also do not require the involvement of a notified body in the conformity assessment procedure under the EU MDR or EU IVDR.

6.7 Regulations 19C and 44ZB relate to devices that comply with the EU MDR and EU IVDR respectively. The amendment to regulation 1ZA means that these regulations will cease to have effect at 23:59 on 30 June 2030 for placing devices that comply with the EU MDR and EU IVDR on the GB market.

6.8 This instrument also amends regulation 2 (interpretation) of the UK MDR to add definitions for the EU MDR and EU IVDR. This is the amendment made by the instrument that triggers the statement required by paragraph 15 of Schedule 8 to the European Union (Withdrawal) Act 2018.

6.9 The MHRA has carried out a public consultation on the future regulation of medical devices and intends to lay further instruments under the Medicines and Medical Devices Act 2021 to implement significant amendments to the UK MDR. The extended periods set out in regulation 1ZA are therefore also intended to act as transitional periods for a future transition to the reformed requirements under the UK MDR.

7. Policy background

What is being done and why?

7.1 The UKCA regime for medical devices has been operational since 1 January 2021. In tandem, there has been continued recognition of medical devices that meet EU requirements. Since 1 January 2021, to place medical devices on the GB market, manufacturers have had the option to either utilise the UKCA route to market or to continue to comply with EU legislation.

7.2 Currently, the UK MDR allows general medical devices and *in vitro* diagnostic medical devices (IVDs) that hold a valid certification and/or declaration of conformity under EU legislation to be placed on the GB market. These provisions will cease to apply from 23:59 on 30 June 2023. This would mean that without this instrument, from 1 July 2023, medical devices for the GB market would only be accepted if they conform with UK MDR requirements and, for most devices, including bearing the UKCA marking.

7.3 The ongoing acceptance of CE marked medical devices enabled by this instrument will be time limited. Steps are being taken to build approved body capacity to meet the demand for UKCA conformity assessments to help ensure that the UK medical devices sector is ready to transition to UKCA marking at the end of the relevant transition period for the type of device.

7.4 CE marked devices compliant with the EU MDR or EU IVDR will be accepted on the GB market until 30 June 2030. This will provide the necessary time for the UK medical devices sector as a whole to prepare for the future UK regulatory regime.

7.5 The changes made by this instrument will mean that general medical devices, including custom-made devices, and IVDs that hold a valid certification/declaration of conformity under the EU MDR or the EU IVDR can continue to be placed on the GB market until the sooner of either the expiry of the product's certificate or 23:59 on 30 June 2030. This will apply even if the certification or declaration of conformity is dated after this instrument takes effect.

7.6 It is intended that a caveat to the acceptance of CE certificates under the EU MDR and EU IVDR will be introduced once further amendments have been made to the UK MDR to reform the regime. This will mean that certificates renewed after the reformed regime is in place will not be accepted and the device will need to meet UK MDR requirements and, if applicable, bear the UKCA marking in order to be placed on the GB market.

7.7 General medical devices that have a valid certification and/or declaration of conformity under the EU Medical Devices Directive (EU MDD) or the EU Active Implantable Medical Device Directive (EU AIMDD) can be placed on the market until the sooner of the expiry of the conformity certificate for the product or until 23:59 on 30 June 2028. IVDs that have a valid certification and/or declaration of conformity under the EU *in vitro* Diagnostic Medical Devices Directive (EU IVDD) or the EU IVDR can be placed on the market until the sooner of the expiry of the conformity certificate for the product or until 23:59 on 30 June 2030.

7.8 If placing medical devices on the GB market under these transitional measures, manufacturers will not be able to rely on expired certificates (unless such certificates have been otherwise deemed valid by the EU).

7.9 As set out above, all these arrangements will be temporary, with a fixed time of application in place for each of them. On expiry of the transitionary window, all devices will need to comply with the UK MDR in full in order to be placed on the GB market.

7.10 The measures in this instrument will minimise the loss of products from the GB market due to the move from CE to UKCA marking. By extending recognition of CE marking, we can ensure that suppliers of CE marked medical devices will be able to continue to supply to the GB market. Without these extended transitional arrangements in place, we would risk placing continuity of supply of medical devices at risk as manufacturers would not have adequate time to ensure all their products, including existing product lines, meet all regulatory requirements immediately.

8. European Union Withdrawal and Future Relationship

8.1 This instrument is not being made under the European Union (Withdrawal) Act 2018 but it does amend regulations (the UK MDR), which were made under section 2(2) of the European Communities Act 1972. In accordance with the requirements of the European Union (Withdrawal) Act 2018 the Minister has made the relevant statement as detailed in Part 2 of the Annex to this Explanatory Memorandum. An explanation of the effect of the amendment and the law relevant to it is set out in paragraphs 6.1 to 6.8.

9. Consolidation

9.1 This instrument makes amendments to the UK MDR. There are no plans to consolidate the legislation this instrument amends.

10. Consultation outcome

10.1 The MMDA requires that, before making regulations under section 15, a public consultation must be carried out in accordance with section 45(1) of the MMDA. A public consultation was carried out from 16 September 2021 to 25 November 2021 and proposals relating to the acceptance of CE marked devices were included in

chapter 15. There were 891 consultation responses: 413 from individuals and 451 from organisations. Responders from organisations included manufacturers of medical devices, healthcare institutions, trade associations and small/medium enterprises.

10.2 The responses were generally supportive of the proposals to introduce transitional arrangements for CE marked devices. A summary of the consultation responses and the Government's response was published on 26 June 2022 and can be found here: Consultation on the future regulation of medical devices in the United Kingdom - GOV.UK (www.gov.uk)[1].

10.3 This instrument is being made on a UK-wide basis. The Devolved Governments have been consulted on the development of this instrument.

11. Guidance

11.1 Updates to guidance on device regulation and device registration will be published before 30 June 2023, as we recognise this will be critical for proper implementation and interpretation of this instrument. This guidance will be found on GOV.UK (https://www.gov.uk/guidance/regulating-medical-devices-in-the-uk).

12. Impact

12.1 There is no significant impact on business, charities or voluntary bodies.

12.2 There is no, or no significant, impact on the public sector.

12.3 A full Impact Assessment (IA) has not been prepared for this instrument because the quantifiable annual net costs are de-minimis (i.e., the impact is less than £5m per annum). Instead, a de-minimis assessment has been prepared.

12.4 We have identified that there would be some costs associated with familiarisation with the regulations. These costs would be mitigated by the MHRA providing clear guidance on the changes introduced by this instrument.

12.5 Direct benefit impacts that are non-monetised will include the benefit to manufacturers of deferred implementation costs for bringing their devices into compliance with the UK MDR.

12.6 In addition, this measure may generate indirect benefits associated with avoiding potential market disruption that could arise if it were not introduced. Without this instrument, medical devices that do not comply with the UK MDR requirements could not be placed on the market in GB after 30 June 2023. This could have wider impacts such as reduced product availability and choice, consequent negative impacts on health, and/or higher prices which could add to current cost of living and global supply chain challenges, and which this instrument seeks to mitigate.

13. Regulating small business

13.1 The legislation applies to activities that are undertaken by small businesses.

13.2 No specific action is proposed to minimise the impact of the requirements on small businesses (employing up to 50 people) as this instrument will not have a significant impact on small businesses.

[1] https://www.gov.uk/government/consultations/consultation-on-the-future-regulation-of-medical-devices-in-the-united-kingdom

13.3 The basis for the final decision on what action to take to assist small businesses is that, while any cost implications for this instrument may represent a bigger proportion of the overall revenue of small businesses, this instrument represents an extension of the status quo. The MHRA therefore does not expect a significant cost impact on small and/or micro businesses.

14. Monitoring & review

14.1 The approach to monitoring of this legislation is captured in the UK MDR, which this instrument amends. Regulation 67 states that the Secretary of State must carry out a review of the UK MDR and publish a report setting out the conclusions of that review before the end of 31 December 2025.

14.2 In addition, section 46 of the MMDA 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).

15. Contact

15.1 Celia Mortimer at the MHRA email: Celia.mortimer@mhra.gov.uk can be contacted with any queries regarding the instrument.

15.2 Penny Wilson, Deputy Director for Innovative Devices, at the MHRA can confirm that this Explanatory Memorandum meets the required standard.

15.3 Will Quince MP, Minister of State for Health and Secondary Care at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.

Annex

Statements under the European Union (Withdrawal) Act 2018 and the European Union (Future Relationship) Act 2020

Part 1A

Table of Statements under the 2018 Act

This table sets out the statements that may be required under the 2018 Act.

Statement	Where the requirement sits	To whom it applies	What it requires
Sifting	Paragraphs 3(3), 3(7) and 17(3) and 17(7) of Schedule 7	Ministers of the Crown exercising sections 8(1) or 23(1) to make a Negative SI	Explain why the instrument should be subject to the negative procedure and, if applicable, why they disagree with the recommendation(s) of the SLSC/Sifting Committees
Appropriate-ness	Sub-paragraph (2) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1) or 23(1) or jointly exercising powers in Schedule 2	A statement that the SI does no more than is appropriate.
Good Reasons	Sub-paragraph (3) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1) or 23(1) or jointly exercising powers in Schedule 2	Explain the good reasons for making the instrument and that what is being done is a reasonable course of action.
Equalities	Sub-paragraphs (4) and (5) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1) or 23(1) or jointly exercising powers in Schedule 2	Explain what, if any, amendment, repeals or revocations are being made to the Equalities Acts 2006 and 2010 and legislation made under them. State that the Minister has had due regard to the need to eliminate discrimination and other conduct prohibited under the Equality Act 2010.
Explanations	Sub-paragraph (6) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1) or 23(1) or jointly exercising powers in Schedule 2 In addition to the statutory obligation the Government has made a political commitment to	Explain the instrument, identify the relevant law before IP completion day, explain the instrument's effect on retained EU law and give information about the purpose of the instrument, e.g., whether minor or technical changes only are intended to the EU retained law.

		include these statements alongside all EUWA SIs	
Criminal offences	Sub-paragraphs (3) and (7) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1) or 23(1) or jointly exercising powers in Schedule 2 to create a criminal offence	Set out the 'good reasons' for creating a criminal offence, and the penalty attached.
Sub-delegation	Paragraph 30, Schedule 7	Ministers of the Crown exercising section 8 or part 1 of Schedule 4 to create a legislative power exercisable not by a Minister of the Crown or a Devolved Authority by Statutory Instrument.	State why it is appropriate to create such a sub-delegated power.
Urgency	Paragraph 34, Schedule 7	Ministers of the Crown using the urgent procedure in paragraphs 5 or 19, Schedule 7.	Statement of the reasons for the Minister's opinion that the SI is urgent.
Scrutiny statement where amending regulations under 2(2) ECA 1972	Paragraph 14, Schedule 8	Anybody making an SI after IP completion day under powers conferred before the start of the 2017-19 session of Parliament which modifies subordinate legislation made under s. 2(2) ECA	Statement setting out: a) the steps which the relevant authority has taken to make the draft instrument published in accordance with paragraph 16(2), Schedule 8 available to each House of Parliament, b) containing information about the relevant authority's response to— (i) any recommendations made by a committee of either House of Parliament about the published draft instrument, and (ii) any other representations made to the relevant authority about the published draft instrument, and, c) containing any other information that the relevant authority considers appropriate in relation to the scrutiny of the instrument or draft instrument which is to be laid.
Explanations where amending regulations under 2(2) ECA 1972	Paragraph 15, Schedule 8	Anybody making an SI after IP completion day under powers outside the European Union (Withdrawal) Act 2018 which modifies subordinate legislation	Statement explaining the good reasons for modifying the instrument made under s. 2(2) ECA, identifying the relevant law before IP completion day, and explaining the instrument's effect on retained EU law.

		made under s. 2(2) ECA	

Part 1B

Table of Statements under the 2020 Act

This table sets out the statements that may be required under the 2020 Act.

Statement	Where the requirement sits	To whom it applies	What it requires
Sifting	Paragraph 8 Schedule 5	Ministers of the Crown exercising section 31 to make a Negative SI	Explain why the instrument should be subject to the negative procedure and, if applicable, why they disagree with the recommendation(s) of the SLSC/Sifting Committees

Part 2

Statements required under the European Union (Withdrawal) 2018 Act or the European Union (Future Relationship) Act 2020

1. Explanations where amending or revoking regulations etc. made under section 2(2) of the European Communities Act 1972

1.1 Will Quince MP, Minister of State for Health and Secondary Care, has made the following statement regarding regulations made under the European Communities Act 1972:

"In my opinion there are good reasons for the Medical Devices (Amendment) (Great Britain) Regulations 2023 to amend the Medical Devices Regulations 2002 (SI 2002 No 618). This is because the measures introduced in this instrument will ease the transition to the post-EU exit UKCA regime, securing continuity of supply and availability of medical devices to the UK. This will ensure that patients in the UK will continue to have access to safe and high-quality medical devices."

1.2 An explanation of the effect of the amendment and the law relevant to it is set out in paragraphs 6.1 to 6.8.