EXPLANATORY MEMORANDUM TO

THE MEDICAL DEVICES (IN VITRO DIAGNOSTIC DEVICES ETC.) (AMENDMENT) REGULATIONS 2023

2023 No. [XXXX]

1. Introduction

1.1 This explanatory memorandum has been prepared by 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. Purpose of the instrument

2.1 This instrument relates to the implementation of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic regulations (EU IVDR) which since 26 May 2022 fully applied in Northern Ireland, under the terms of the Windsor Framework. The instrument updates existing legislation and makes supplementary provision, for example in relation to fees and enforcement, to ensure that the EU IVDR is fully implemented and can operate effectively in Northern Ireland.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 This instrument amends legislation including legislation made under section 2(2) of the European Communities Act 1972 (ECA) and the European Union (Withdrawal) Act 2018 (EUWA). The instrument will be made under section 8C of, and paragraph 1(1)(ab) of Schedule 4 and paragraph 21 of Schedule 7 to the EUWA. As this instrument is made under the EUWA it is not subject to the enhanced scrutiny requirements laid out in Schedule 8 to that Act.

4. Extent and Territorial Application

4.1 The territorial extent of this instrument varies between provisions. Unless otherwise stated, any amendment or revocation made by the instrument has the same extent as the provisions amended or revoked. Regulations 23, 33, 34 and 36 extend to Northern Ireland only.

4.2 The territorial application of this instrument varies between provisions. In Part 3, regulations 9, 11 and 13 apply in relation to Great Britain only. Regulations 10, 12, 14, 15, 18 and 19 apply in relation to Northern Ireland only.

5. European Convention on Human Rights

5.1 The Minister of State, Helen Whately MP, at the Department of Health and Social Care has made the following statement regarding Human Rights:

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

6. Legislative Context

6.1 The EU regulatory framework for *in vitro* diagnostic medical devices was previously set out in Directive 98/79/EC on *in vitro* diagnostic medical devices (IVDD). Additional tertiary EU legislation also supplemented the framework. The Directive has been transposed into UK law by the Medical Devices Regulations 2002 (SI 2002/618) (the 2002 Regulations) which were primarily made under section 2(2) of the ECA.

6.2 On 5 April 2017, the EU IVDR was adopted by the EU and subsequently entered into force on 25 May 2017. The EU IVDR repeals Directive 98/79/EC for EU regulation of *in vitro* diagnostic medical devices. The EU IVDR fully applied in Northern Ireland – the term the EU uses for when a measure becomes generally operative – from 26 May 2022.

6.3 Under the terms of the Windsor Framework, the EU legislation that applies in Northern Ireland is listed in Annex 2 to the Framework and includes the EU IVDR. The EU IVDR is directly applicable EU law, which by virtue of section 7A of EUWA applies in Northern Ireland and forms part of domestic law.

6.4 This instrument is being made under section 8C of, and paragraph 1(1)(ab) of Schedule 4 and paragraph 21 of Schedule 7 to the EU (Withdrawal) Act 2018 to:

a) make supplementary provision where the EU IVDR allows or requires Member States to make their own national provision. This is inserted into the Medical Devices (Northern Ireland Protocol) Regulations 2021;

b) implement the requirement in Article 7(2) of the Windsor Framework for the UK(NI) indication to be affixed to *in vitro* diagnostic medical devices assessed under the EU IVDR by notified bodies established in the United Kingdom;

c) make provision for the enforcement of the EU IVDR, including making it a criminal offence to breach certain Articles. Enforcement powers are provided by making amendments to the Consumer Rights Act 2015 and the Medicines and Medical Devices Act 2021;

d) provide for the fees for certificates of free sale and conformity assessment body designation and monitoring (the fees reflect current levels) and fee refunds and waivers under the EU IVDR;

e) make consequential, savings and transitional provision within the 2002 Regulations; this includes amending regulation 2A to enable medical devices that comply with the EU IVDR and are qualifying NI goods, to be placed on the Great Britain market as if they meet Great Britain requirements;

f) make consequential amendments to other legislation so it reflects the application of the EU IVDR in Northern Ireland, for example inserting references to the EU IVDR as a relevant regulation. In addition to the amendments noted above, the instrument amends: the Human Tissue Act 2004, the Blood Safety and Quality Regulations 2005, the Human Tissue (Quality and Safety for Human Application) Regulations 2007, the Legislative and Regulatory Reform (Regulatory Functions) Order 2007, Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012, the Waste Electrical and Electronic Equipment Regulations 2013, the Economic Growth (Regulatory Functions) Order 2017 and the Market Surveillance (Northern Ireland) Regulations 2021.

7. Policy background

What is being done and why?

7.1 The EU IVDR lays down rules concerning the placing on the market, making available on the market or putting into service of *in vitro* diagnostic medical devices for human use and accessories for such devices in the European Union. The EU IVDR also applies to performance studies concerning such *in vitro* diagnostic medical devices and accessories conducted in the European Union.

7.2 The EU IVDR aims to ensure the smooth functioning of the internal market for *in vitro* diagnostic medical devices, setting high standards of quality and safety for *in vitro* diagnostic medical devices to address common safety concerns for such products. The changes introduced by the EU IVDR will affect *in vitro* diagnostic medical device economic operators in Northern Ireland (we estimate there to be roughly 19 *in vitro* diagnostic businesses in Northern Ireland) and any prospective UK Notified Bodies.

7.3 This instrument does not implement the EU IVDR itself (which directly applied in Northern Ireland from 26 May 2022). Rather, it makes supplementary provision to ensure the EU IVDR can operate effectively in NI.

7.4 Specifically, this supplementary provision:

a) lays down effective, proportionate and dissuasive penalties (in the form of a criminal offence punishable by imprisonment, a fine or both), powers to impose enforcement notices and an amendment to extend the civil sanctions regime in Schedule 2 to the Medicines and Medical Devices Act 2021 (when that is brought into force) for the infringement of provisions in the EU IVDR;

b) appoints the Secretary of State as the authority responsible for Notified Bodies in relation to the EU IVDR;

c) requires certain documentation concerning *in vitro* diagnostic medical devices to be in English;

d) provides for fees for the designation and monitoring of Notified Bodies, and fees for certificates of free sale to continue (at the same level as existing fees) and for fee recovery, refund and waiver under EU IVDR;

e) creates an arbitration procedure for refused applications for performance studies;

f) requires performance study sponsors to apply to an ethics committee for an ethical review;

g) requires performance study sponsors to hold sufficient insurance (or equivalent finance resources) to meet any potential financial liability in the event of injury or death attributable to participation in the performance study;

h) provides for performance studies for *in vitro* diagnostic devices and clinical investigations for medical devices taking place in Northern Ireland and Great Britain, to allow for only a contact person to be established in Northern Ireland, supported by the legal representative established in Great Britain;

i) allows a Coronavirus test that complies with the EU common specification for such tests to be placed on the NI market without also obtaining a separate approval ("CTDA") from the MHRA;

j) provides for continued unfettered access by ensuring that *in vitro* diagnostic medical devices that meet the requirements of the EU IVDR and that are qualifying NI goods, can be placed on the Great Britain market with no additional barriers or burdens to NI traders; and

k) implements the requirement in Article 7(2) of the Windsor Framework for the UK(NI) indication to be affixed to *in vitro* diagnostic medical devices assessed under the EU IVDR by Notified Bodies established in the United Kingdom.

7.5 The number of people affected by the above enforcement measures is likely to be small due to the relatively small number of economic operators. Historical data we have in relation to previous free sale certificates and enforcement actions demonstrates that it is highly unlikely costs to businesses would exceed £5m.

Explanations

What did any law do before the changes to be made by this instrument?

7.6 Since 26 May 2022, the EU IVDR has provided the regulatory system for *in vitro* diagnostic medical devices in the EU (and Northern Ireland). The EU IVDR repealed Directive 98/79/EC. This Directive was implemented by the 2002 Regulations (in particular Part IV of those regulations), which continue to regulate *in vitro* diagnostic medical devices in Great Britain.

Why is it being changed?

7.7 The EU IVDR directly applies in Northern Ireland and fully applied from 26 May 2022. This instrument is being made primarily so that the EU IVDR operates properly in Northern Ireland and the UK can effectively implement areas of national decision permitted under the EU IVDR, for example in relation to fee structures and enforcement provisions. The instrument also makes consequential amendments to other pieces of domestic legislation, including secondary legislation made under section 2(2) of the ECA, to account for the EU IVDR now applying in Northern Ireland.

What will it now do?

7.8 This instrument will amend current legislation where required, introduce relevant enforcement provisions (including a criminal offence) and outline fees required for certificates for free sale and conformity assessment body designation and monitoring for *in vitro* diagnostic medical devices in Northern Ireland.

7.9 It will also make the supplementary provision outlined in paragraph 7.4.

7.10 The 2002 Regulations are amended to reflect that most of Part IV now only applies in Northern Ireland to those devices that are subject to transitional provision under the EU IVDR. The amendments will also ensure *in vitro* diagnostic medical devices that comply with the EU IVDR and are "qualifying NI goods", can be placed on the GB market without needing to meet additional requirements for that market. This ensures unfettered access for NI Qualifying Goods to the GB market. This instrument also removes the gloss applied to section 1 of the Human Tissue Act 2004, which has been made redundant by this instrument and removes the requirement to have a "UK responsible person" in Northern Ireland under regulation 44.

7.11 In addition to the 2002 Regulations, the instrument also makes consequential amendments to the following retained EU law:

a) the Blood Safety and Quality Regulations 2005 to maintain the scope of these regulations by including a reference to the EU IVDR alongside the reference to the 2002 Regulations;

b) the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012 to define "*in vitro* diagnostic medical device" with reference to the EU IVDR in Northern Ireland;

c) the Waste Electrical and Electronic Equipment Regulations 2013, to define "*in vitro* diagnostic medical devices" with reference to the EU IVDR in Northern Ireland;

d) the Human Tissue (Quality and Safety for Human Application) Regulations 2007 to include a reference to the EU IVDR in order to maintain the scope of these regulations;

e) the Consumer Rights Act 2015 to extend the inspection and enforcement powers for the purpose of ascertaining a breach of the EU IVDR.

8. European Union Withdrawal and Future Relationship

8.1 This instrument is being made under section 8C of, paragraph 1(1)(ab) of Schedule 4, and paragraph 21 of Schedule 7 in EUWA. In accordance with the requirements of that Act the Minister has made the relevant statements as detailed in Part 2 of the Annex to this Explanatory Memorandum.

9. Consolidation

9.1 No consolidation is being made to legislation as a result of this instrument.

10. Consultation outcome

10.1 No consultation has been undertaken for this instrument. There is no statutory duty to consult under EUWA and there was no other requirement to consult. Other government departments were consulted about amendments to relevant legislation, such as DEFRA in relation to the Waste Electrical and Electronic Equipment Regulation 2013 and the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012 and Department of Business and Trade in relation to the Consumer Rights Act 2015.

10.2 The NI Department of Health and Northern Ireland Office were consulted and have no objections.

11. Guidance

11.1 Guidance on gov.uk will be updated when the instrument comes into force to reflect its content.

12. Impact

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

12.2 There is no significant impact on the public sector.

12.3 A Regulatory Triage Assessment has been prepared for this instrument because the cost of change to business is below £5m a year and there will be minimal impact on the small number of businesses affected.

12.4 In regard to public sector impact, the implementation of the requirements of the EU IVDR affects the work required by the MHRA for monitoring, processing and enforcement. In order to retain alignment between Northern Ireland and Great Britain, the fees for services covered by the EU IVDR have been kept on par with those charged in Great Britain. The fees charged in Northern Ireland will therefore be at the cost recovery level. For the same reason, new activities undertaken by the MHRA under the EU IVDR, including issuing Single Registration Numbers and processing applications for performance studies, will also be free of charge.

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 regulatory burdens on small businesses (employing up to 50 people). However, to minimise the impact of the requirements the approach taken is to maintain the current fee structure so Northern Ireland operators do not need to pay increased amounts for equivalent activities under the EU IVDR.

13.3 The instrument maintains unfettered access to the GB market for devices that are qualifying NI goods and meet the requirements of the EU IVDR.

14. Monitoring & review

14.1 As this instrument is made under the European Union (Withdrawal) Act 2018, no review clause is required.

15. Contact

15.1 Joseph Burt, Head of Diagnostics at the Medicines and Healthcare products Regulatory Agency, email: Joseph.Burt@mhra.gov.uk can be contacted with any queries regarding the instrument.

15.2 Dr Laura Squire, Chief Healthcare Quality and Access Officer at the Medicines and Healthcare products Regulatory Agency can confirm that this Explanatory Memorandum meets the required standard.

15.3 Minister of State, Helen Whately MP, 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 include these statements alongside all EUWA SIs	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.
Criminal	Sub-paragraphs (3) and (7) of	Ministers of the Crown	Set out the 'good reasons' for creating a

offences	paragraph 28, Schedule 7	exercising sections 8(1) or 23(1) or jointly exercising powers in Schedule 2 to create a criminal offence	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 made under s. 2(2) ECA	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.

Part 2

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

1. Explanations

1.1 The explanations statement has been made in section 7 of the main body of this Explanatory Memorandum.