EXPLANATORY MEMORANDUM TO

THE MEDICAL DEVICES (NORTHERN IRELAND PROTOCOL) REGULATIONS 2021

2021 No. 905

1. Introduction

1.1 This Explanatory Memorandum has been prepared by the Department of Health and Social Care (DHSC) and is laid before Parliament by Command of Her 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) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices[1], (EU MDR), which as of 26th May 2021 fully applies in Northern Ireland. The instrument updates existing legislation, makes provision for fees and ensures that enforcement provisions can operate properly in Northern Ireland. The instrument also implements areas of national decision allowed for within the EU MDR which will allow the regulatory framework in Northern Ireland to align with that of the rest of the UK where possible.

3. Matters of special interest to Parliament

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

3.1 This instrument amends legislation made under section 2(2) of the European Communities Act 1972. The instrument will be made under the EU (Withdrawal) Act 2018 and the relevant explanations are set out in section 7 of this memorandum.

Matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business (English Votes for English Laws)

3.2 Not applicable.

4. Extent and Territorial Application

4.1 The territorial extent of this instrument varies between provisions. Parts 1, 4, 5, 7 and 8 extend to the entire United Kingdom. Parts 2, 3 and 6 extend to Northern Ireland only. Part 9 has the same extent as the legislation it amends. This means that regulation 43 extends to Northern Ireland only, and all other regulations in that Part extend to the entire United Kingdom.

4.2 The territorial application of this instrument varies between provisions. Details on the contents of each Part of the instrument can be seen under 3.2 to 3.5. Parts 1, 4, 5, and 7 apply to the entire United Kingdom. Parts 2, 3 and 6 apply to Northern Ireland only. In Part 8, regulation 31 applies to Great Britain only and all other regulations in that

[1] Full title: Regulation (EU) 2017/745 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.

Part apply to Northern Ireland only. In Part 9, regulation 43 applies to Northern Ireland only, and all other regulations in that Part apply to the entire United Kingdom.

5. European Convention on Human Rights

5.1 The Parliamentary Under Secretary of State at the Department of Health and Social Care, Lord Bethell, has made the following statement regarding Human Rights:

"In my view the provisions of The Medical Devices (Northern Ireland Protocol) Regulations 2021 are compatible with the Convention rights."

6. Legislative Context

6.1 The EU regulatory framework for general medical devices was previously set out in two Directives[2]: Directive 90/385/EEC on Active Implantable Medical Devices; and Directive 93/42/EEC on Medical Devices. In addition, there were various tertiary EU Regulations which supplement the framework. The two EU Directives have 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 European Communities Act 1972 (ECA).

6.2 On 5 April 2017, Regulation 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (EU MDR) was adopted by the EU and subsequently entered into force on 25 May 2017. The EU MDR amends Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No. 1223/2009 and repeals Council Directives 90/385/EEC and 93/42/EEC. The EU MDR fully applied in Northern Ireland – the term the EU uses for when a measure becomes generally operative – from 26 May 2021.

6.3 Under the terms of the Northern Ireland Protocol, the EU legislation that applies in Northern Ireland is listed in Annex 2 to the Protocol and includes the EU MDR. The EU MDR is directly applicable EU law, which by virtue of section 7A of the EU (Withdrawal) Act 2018 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. It is being made to:

a) make supplementary provision where the EU MDR allows Member States to make their own national provision;
b) implement the requirement in Article 7(3) of the Northern Ireland Protocol for the UK(NI) indication to be affixed to medical devices assessed by notified bodies established in the United Kingdom;
c) make provision for the enforcement of the EU MDR and the national provision made by the instrument. This is in part achieved through making amendments to the Consumer Rights Act 2015 and the Medicines and Medical Devices Act 2021;
d) set the fees for applications and inspections under the EU MDR;

[2] Directive 98/79 /EC is the third directive in Europe's medical devices framework, regulating in vitro Diagnostic Medical Devices but it is not relevant to this statutory instrument. That directive will not be repealed by the EU until 26 May 2022, the date on which Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices takes effect.

e) amend the requirements for the UK(NI) indication in the 2002 Regulations to enable the indication to be smaller than 5mm in height where it is the same height as the CE mark that it accompanies;

f) make consequential, savings and transitional provision within the 2002 Regulations;

g) make consequential amendments to other legislation so it reflects the application of the EU MDR in Northern Ireland, for example inserting references to the EU MDR as a relevant regulation when currently the 2002 Regulations are solely listed. The instrument amends: 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, the Medicines (Products for Human Use) (Fees) Regulations 2016, 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 primary aim of the EU MDR is to ensure a high standard of safety and quality for medical devices that are produced in, or supplied to, member states of the European Union. The changes the EU MDR introduces will affect medical device economic operators in Northern Ireland (which we estimate to be roughly 300 operators) and any prospective UK notified bodies. This instrument does not implement the EU MDR itself (which directly applies in Northern Ireland from 26 May 2021). Rather it updates the statute book to allow us to implement the EU MDR effectively and addresses areas of national decision within the EU MDR that enable the regulation of medical devices in Northern Ireland to continue to align with policy that applies in the rest of the UK . Specifically, these areas of national decision allow for:

- the continued practice of allowing the reprocessing of single-use devices if re-processors adhere to the requirements of an original manufacturer;
- maintaining the requirement to register custom-made devices;
- maintaining the MHRA's ability to authorise clinical investigations for all device risk classes before they can start and to continue requiring all clinical investigations for custom-made devices to be subject to MHRA assessment.

The instrument will also give the MHRA powers to serve enforcement notices for breaches of the EU MDR. The number of people affected by these enforcement measures is likely to be small due to the relatively small number of economic operators and historical data we have in relation to previous enforcement actions.

Explanations

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

7.2 Since May 26, the EU MDR has provided the EU (and Northern Ireland) regulatory system for general medical devices[3], after repealing EU Council Directive 93/42/EEC on general medical devices and Council Directive 90/385/EEC on Active Implantable

[3] This does not include *in vitro* diagnostic medical devices.

Devices. These previously mentioned Directives were implemented by the 2002 Regulations, which continue to regulate general medical devices in Great Britain.

Why is it being changed?

7.3 The EU MDR directly applies in Northern Ireland and fully applied from 26 May 2021. This instrument is being introduced so that the UK can effectively implement those areas of national decision permitted under the EU MDR in a way that enables Northern Ireland to continue to align with existing Great Britain policy, as well as transfer current fee structures and enforcement provisions.

What will it now do?

7.4 This SI will amend current legislation where required, introduce relevant enforcement provisions (including a criminal offence) and outline the fees structure for Northern Ireland. It will introduce provisions in areas of flexibility allowed for under the EU MDR, to allow Northern Ireland to continue to align with Great Britain policy where possible. In addition to the 2002 Regulations, the instrument also makes amendments to the following retained EU law:

a) the Blood Safety and Quality Regulations 2005 to include a reference to the EU MDR alongside the reference to the 2002 Regulations;
b) the Human Tissue (Quality and Safety for Human Application) Regulations 2007 to include a reference to the EU MDR in order to maintain the scope of these regulations;
c) the Medicines (Products for Human Use) (Fees) Regulations 2016 to provide that the fee for MHRA advice, includes advice in relation to obtaining a certificate referred to in the EU MDR for medical devices incorporating medicinal products.

8. European Union Withdrawal and Future Relationship

8.1 This instrument is not being made to address a deficiency in retained EU law but relates to the withdrawal of the United Kingdom from the European Union because it is being made under powers conferred by section 8C of, and paragraph 1(1)(ab) of Schedule 4, and paragraph 21 of Schedule 7 to, the European Union (Withdrawal) Act 2018. Relevant explanations are set out in section 7 of 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 the EU (Withdrawal) Act 2018 and there was no other requirement to consult as this instrument provides for a continuation of existing UK policy. Northern Ireland colleagues were engaged with during the instrument drafting process and other government departments were consulted about amendments to relevant primary legislation, such as BEIS in relation to the Consumer Rights Act 2015, and secondary legislation under Parts 7 and 9.

11. Guidance

11.1 Updated guidance is planned for publication when this instrument comes into force, to amend current guidance to reflect the content of the instrument. In addition, changes to gov.uk guidance will be required to direct the public and stakeholders towards relevant EU guidance for EU MDR compliance, and to highlight its application in Northern Ireland.

12. Impact

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

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

12.3 An Impact Assessment has not been prepared for this instrument because the cost of change is below the significant price and there will be minimal impact on the small number of businesses affected. A Regulatory Triage Assessment has been prepared.

12.4 In regard to public sector impact, the implementation of the increasingly rigorous requirements of the EU MDR affects the work required by 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 MDR have been kept on par with those charged in Great Britain, despite there being additional resource requirements to carry out the work under the EU MDR. The fees charged in Northern Ireland will therefore be below the cost recovery level.

12.5 Regarding clinical investigations, the Department estimates that there are four applications for authorisation to conduct clinical investigations in Northern Ireland per year, and the cost of implementing EU MDR requirements without fee adjustments is -£9,996 over two years. The new requirement to issue Single Registration Numbers for approximately 768 applications without charging a fee is estimated at -£76,800 across two years. Finally, if an organisation were to apply to MHRA for designation as a Notified Body (which MHRA compliance experts put at a 1% risk of occurring), there would be a cost impact of -£23,016 per initial application for designation (the only fee expected to apply within two years). Within the next two years we expect to revise the fee structures for both Great Britain and Northern Ireland as part of our work to introduce a new regulatory regime in Great Britain for medical devices after CE mark recognition ends in July 2023.

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 applications and inspections under the EU MDR. Where permitted under the EU MDR, the instrument also includes national provision to maintain the status quo with Great Britain so that economic operators may continue with current practices where possible, for example by allowing the re-processing of single use devices.

13.3 The basis for the final decision to maintain the current fee structure was engagement with the Northern Ireland Office and the creation of a Regulatory Triage Assessment to calculate reserve funding as an alternative measure to increasing fees. The wider

government strategy of alignment between Northern Ireland and Great Britain informed the policy decision to include provision to maintain the status quo in flexibility areas within this instrument.

14. Monitoring & review

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

15. Contact

15.1 Vicky Ferguson at the Devices Regulatory Policy Device Division, Email: Vicky.Ferguson@mhra.gov.uk, can be contacted with any queries regarding the instrument.

15.2 Camilla Fleetcroft at the Medicines & Healthcare products Regulatory Agency can confirm that this Explanatory Memorandum meets the required standard.

15.3 Lord Bethell 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 offences	Sub-paragraphs (3) and (7) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1) or	Set out the 'good reasons' for creating a criminal offence, and the penalty attached.

		23(1) or jointly exercising powers in Schedule 2 to create a criminal offence	
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.