EXPLANATORY MEMORANDUM TO

THE MEDICAL DEVICES (AMENDMENT) (EU EXIT) REGULATIONS 2020

2020 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 Her Majesty.

2. Purpose of the instrument

2.1 This instrument is required to ensure that the United Kingdom ('UK') has a functioning statute book at the end of the implementation period ('IP') and makes a number of amendments to other instruments for that purpose. The instruments this instrument amends are:

- 1. Medical Devices (Amendment etc.) (EU Exit) Regulations 2019/791 ("the 2019 Regulations");
- 2. Schedule 2 to the Human Medicines and Medical Devices (Amendment)(EU Exit) Regulations 2019/1385 ("the Amendment Regulations"); and
- 3. Medical Devices Regulations 2002 S.I. 2002/791 ("the Principal Regulations").

These amendments are being made to ensure that the regulatory landscape is fit for purpose at the end of the IP. The amendments will also ensure the safety of UK patients through the continued supply of approved devices to the UK.

Explanations

What did any relevant EU law do before exit day?

2.2 EU law provides for a harmonised EU regulatory system for medical devices. The UK is a part of this regulatory system until 31 December 2020. This includes the system of conformity assessment which is required for all medical devices placed on the EU market. The current EU regime consists of three EU Directives and a number of pieces of EU tertiary legislation. In addition to these Directives, the EU Medical Devices Regulation (MDR) and EU *in vitro* Diagnostic Medical Devices Regulation (IVDR) have been in force since May 2017 and are due to fully apply from May 2021 and May 2022 respectively. This is explained further in section 6 of this explanatory memorandum.

Why is it being changed?

2.3 From 1 January 2021 the Medicines and Healthcare products Regulatory Agency (MHRA) will take on the responsibilities for regulating medical devices on the UK market (that are currently undertaken by the MHRA as part of the EU system) to ensure the continued safety of patients. Changes are required to ensure the UK statute book reflects the correct policy positions on completion of the IP, in light of the Withdrawal Agreement and the Northern Ireland Protocol.

What will it now do?

2.4 Schedule 1 of instrument amends the Principal Regulations to clarify how devices will be regulated in Northern Ireland as of the end of the IP, under the terms of the Northern Ireland Protocol. In particular that Schedule amends the Principal Regulations to ensure that devices placed on the Northern Ireland market are required to meet EU legislation which will apply in Northern Ireland under the Northern Ireland Protocol. For example, it makes provision for the addition of the UK(NI) marking to be placed on devices along with the Conformité Européene (CE) marking where that device has been certified for the NI market by a UK notified body.

2.5 Schedule 1 also makes provision for the registration of devices being placed on the market in Northern Ireland by persons located in Northern Ireland and also makes provision for the appointment of a UK responsible person where the manufacturer of the device does not have any other relevant presence in the UK.

2.6 Schedule 2 of the instrument amends the 2019 Regulations, so that the changes brought about by those regulations will only apply in Great Britain.

2.7 Schedule 2 then also amends the 2019 Regulations:-

a) To introduce a new Great Britain regulatory route to market for devices at the end of the Implementation Period. It provides for a UK mark consisting of the letters UKCA (UK Conformity Assessed), a new UK product marking that will be used for manufactured goods being placed on the market in Great Britain.

b) To provide for the conversion of UK Notified Bodies, which will no longer be recognised by the EU, to UK Approved Bodies and enables them to conduct conformity assessments for the purposes of devices that will be awarded the UK mark.

c) To set out a time-limited period for the recognition of CE-marked devices on the market from the end of the IP to ensure an uninterrupted supply of medical devices for UK patients.

d) To make provision for the period after the end of that time-limited has expired for qualifying Northern Ireland goods to continue to be placed on the market in Great Britain even though they will remain subject to the requirements of EU law.

e) To change the dates in the 2019 Regulations so that those run from IP completion day rather than 'exit day'. This includes, for example, the transition to the requirements regarding UK Responsible Persons and expanded registration requirements with the Medicines and Healthcare products Regulatory Agency (MHRA), which will start at the end of the IP in order to ensure sufficient oversight of devices placed on the market.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None.

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 The territorial application of this instrument varies between provisions.

3.3 The powers under which this instrument is made cover the entire United Kingdom.

4. Extent and Territorial Application

4.1 The territorial extent of this instrument is England, Scotland, Northern Ireland and Wales.

4.2 The territorial application of this instrument is England, Scotland, Northern Ireland and Wales.

5. European Convention on Human Rights

5.1 The Minister of State for Health, Edward Argar, has made the following statement regarding Human Rights:

"In my view the provisions of The Medical Devices (Amendment) (EU Exit) Regulations 2020 are compatible with the Convention rights."

6. Legislative Context

6.1 The current EU regulatory framework that applies to medical devices in the UK is set out in three Directives:

- Directive 90/385/EEC on Active Implantable Medical Devices;
- Directive 93/42/EEC on Medical Devices; and
- Directive 98/79/EC on *in vitro* Diagnostic Medical Devices.

In addition, there are various pieces of EU tertiary legislation which supplement the framework.

6.2 The three EU Directives have been transposed into UK law by the Principal Regulations which are mostly made under section 2(2) of the European Communities Act 1972 (ECA). The EU tertiary legislation, made under the three EU Directives, takes direct effect in the UK by virtue of section 2(1) ECA.

6.3 On 5 April 2017, two new EU Regulations on medical devices were adopted and they subsequently entered into force on 25 May 2017:

- Regulation (EU) 2017/745 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 (the MDR); and
- Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (the IVDR).

6.4 These two new EU Regulations were due to fully replace the three EU Directives over a transitional period. The 2019 Regulations inserted new Parts into the Principal Regulations so that the effect of the changes being made to EU law were reflected in post exit day UK law. This instrument removes now those provisions from the 2019 Regulations as they would apply after the end of the IP.

6.5 The European Union (Withdrawal) Act 2018 (EUWA) provides at section 2 that domestic legislation made under section 2(2) ECA continues to have effect in domestic law notwithstanding that the ECA is repealed by virtue of section 1. By virtue of being saved under section 2 of EUWA, the 2002 Regulations form part of "retained EU law" as defined in section 6(7) of EUWA.

6.6 Section 8 of EUWA provides that a Minister of the Crown may by regulations make such provision as the Minister considers appropriate to prevent, remedy or mitigate (a)

any failure of retained EU law to operate effectively; or (b) any other deficiency in retained EU law arising from the withdrawal of the UK from the EU.

6.7 The EU Withdrawal Agreement Act 2020 made amendments to EUWA to take account of the transition period and to provide for the implementation of the Withdrawal Agreement. In particular, EUWA was amended to provide powers in s. 8C to give effect to the Northern Ireland Protocol.

6.8 This instrument exercises the powers in sections 8 and 8C of EUWA to amend the 2002 Regulations and 2019 Regulations to ensure that all aspects of post IP completion day UK law in relation to medical devices operate effectively, comply with the Withdrawal Agreement and are not deficient.

7. Policy background

What is being done and why?

Regulation of medical devices prior to the end of the IP

7.1 The Principal Regulations place obligations on manufacturers to ensure that medical devices and *in vitro* diagnostic medical devices (IVD)s are safe and fit for their intended purpose.

7.2 The term 'medical device' is defined in the Principal Regulations and includes, for example, bandages, hospital beds, surgical instruments and joint replacements.

7.3 The term '*in vitro* diagnostic medical device' is also defined in the Principal Regulations and includes, for example, blood glucose monitors, HIV blood diagnostic tests and pregnancy self-test kits.

7.4 The term 'active implantable medical device' is defined in the Principal Regulations and includes, for example, implantable hearing aids, cardiac pacemaker systems, and implantable infusion pumps.

7.5 The Secretary of State, acting through the MHRA, has remained the Competent Authority for medical devices, including IVDs and active implantable medical devices, in the UK under the three EU Directives during the implementation period and the rules for assessing and placing devices on the market have remained unchanged during that period. Notified Bodies are independent conformity assessment bodies. Within the current system, the Competent Authority in each EU Member State is responsible for certain activities, including:

- carrying out market surveillance, including compliance and enforcement activities;
- assessing, designating and monitoring Notified Bodies, which is undertaken by regular audit of their activities;
- operating a vigilance system to oversee manufacturers' responses to safety incidents.

7.6 In general, a device cannot be placed on the EU market (to be read as including the EEA) without carrying the CE marking of conformity, which is an indication by a manufacturer that it has met certain requirements following a conformity assessment procedure. For all but the lowest risk devices, the manufacturer must undergo a conformity assessment involving an EU Notified Body. Following an appropriate assessment, the Notified Body will issue relevant certification. This allows

manufacturers to place their devices on the EU market. Once a medical device or IVD has been placed on the EU market, the manufacturer must continue to monitor the product and report certain adverse incidents to their Competent Authority.

7.7 Under the current EU regulatory framework, manufacturers based outside of the EU who place a medical device or IVD on the EU market must have an authorised representative that is legally established within the EU. The authorised representative holds legal responsibility for ensuring the compliance of the devices produced by those manufacturers and serves as their contact person established in the Union (EEA).

7.8 Under the Principal Regulations, there is an EU requirement to register the lowest risk medical devices (Class I devices), custom-made devices and general IVDs with the Competent Authority in which the manufacturer or its authorised representative is legally established. The Principle Regulations also require that all other IVDs are registered with the MHRA if the manufacturer or authorised representative is legally established within the UK.

7.9 The MHRA will take on the responsibilities for the UK medical devices market that are currently undertaken through the EU system at the end of the Implementation Period. The following legislative fixes are made to reflect this change and ensure that the regulatory landscape for both GB and NI are fit for purpose.

GB Route to Market

7.10 Schedule 2 of this instrument (which only extends to Great Britain) amends The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 to provide a GB regulatory route to market on the end of the IP.

7.11 The Secretary of State will be able to designate UK Approved Bodies to conduct assessments against the relevant requirements for the purpose of awarding certificates enabling devices to bear the UKCA mark.

7.12 Existing UK Notified Bodies with designations under the MDD, IVDD or AIMDD will have their designations rolled over, without having to undergo a new designation process.

7.13 UK Approved Bodies will be able to conduct conformity assessments, in relation to the UKCA mark, for medical devices, active implantable medical devices and *in vitro* diagnostic medical devices under Parts II, III, and IV of the Principal Regulations (in the form in which they will exist on 1 January 2021).

7.14 Medical devices being placed on the GB market will be able to make use of the UK conformity assessment route. Medical devices certified by a UK Approved Body will be able to show the UKCA (UK Conformity Assessed) mark.

7.15 Manufacturers of Class I medical devices and general in vitro diagnostic medical devices will be able to self-declare their conformity against Part II of the 2002 Regulations and Part IV of the 2002 regulations respectively (as amended by this instrument), before affixing a UKCA mark and placing the device on the market.

7.16 Any devices that are in conformity with EU legislation (MDD, AIMDD, IVDD, MDR, IVDR) can continue to be placed on the market in the GB until 30 June 2023. This is to provide manufacturers with time to adjust to future GB regulations that will be consulted on and published at a later date.

7.17 Any devices that are in conformity with EU legislation (MDD, AIMDD, IVDD, MDR, IVDR) can be placed on the NI market with a valid CE marking.

7.18 UK approved bodies (even when based in GB), and known for this purpose as notified bodies, will be able to undertake third party conformity assessment for devices placed on the NI-only market that are affixed with the CE UK(NI) marking and not intended for the EU market.

Implementation of EU Medical Device Regulation (MDR) and in vitro Medical Device Regulation (IVDR)

7.19 This instrument revokes the MDR and IVDR provisions for Great Britain, that would have been implemented through The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019. The MDR had been due to fully apply in 2020, during the IP. However, this was extended by the EU Commission a further 12 months during the IP until May 2021.

UK Responsible Person and MHRA registration requirements

7.20 This instrument changes the dates for the transitional application of the requirement to appoint a UK Responsible Person (UKRP) and MHRA registration provisions that are set out in the 2019 Regulations so that those transitional provisions start to run from IP completion day. These requirements specify that any device placed on the GB market requires registration with the MHRA. Where a manufacturer is not based in the UK, registration of a product must be undertaken by a UKRP that has a UK registered address. This person, who will take responsibility for the device, must be available as a contact for the MHRA to discuss any concerns around conformity or safety. This is to ensure that the MHRA has a strengthened market surveillance role as a standalone regulator on the IP competition date.

The regulation of medical devices in Northern Ireland

7.21 Under the terms of the Northern Ireland Protocol, which was annexed to the 2019 UK/EU Withdrawal Agreement, Northern Ireland will remain part of the UK's single customs territory and will have access to the EU single market. Under the terms of the Protocol, which comes into effect on 1 January 2021, Northern Ireland will continue to align with certain EU legislation, including that relating to the regulation of medical devices.

7.22 The Principal Regulations will be amended to clarify how medical devices will be regulated in Northern Ireland at the end of the IP, taking account of the Northern Ireland Protocol.

7.23 The MHRA will continue to conduct market surveillance activity on behalf of NI and will need to ensure that relevant EU law is applied in NI. Where incidents occur in NI, these will need to be reported to the MHRA. Most non-UK manufacturers will be required to appoint a UK Responsible Person to take responsibility for the device and to act as a regulatory point of contact in the UK and to register the device with the MHRA.

7.24 Where a device manufacturer is based within GB and wishes to place a device on the Northern Ireland market, an Authorised Representative will need to be designated. The Authorised Representative will need to be based within the European Union or Northern Ireland. Where that Authorised Representative is based in Northern Ireland, it will be responsible for registering the device with the MHRA. Where the Authorised

Representative is based in the European Union, the Great Britain-based manufacturer will be responsible for registering the device with the MHRA.

7.25 The 2002 Regulations are also amended to extend the MHRA registration requirements (so that they are similar to those which will apply in GB) to other classes of device in accordance with a transitional timetable. Prior to the end of the Implementation Period only lower risk Class I, general IVDs and custom-made devices required registration under the EU Directives, though all other IVDs were also required to be registered with the MHRA under the Principle Regulations. The provisions to extend the registration requirements to all classes of device are to ensure that MHRA has sufficient regulatory oversight of devices in NI and can fulfil its legal obligations as the regulator for NI.

8. European Union (Withdrawal) Act 2018/Withdrawal of the United Kingdom from the European Union

8.1 The provisions in Schedule 2 of this instrument are being made using the powers in sections 8 and 23 of EUWA and section 41 of the European Union Withdrawal Agreement Act 2020 in order to address failures of retained EU law to operate effectively or other deficiencies arising from the withdrawal of the United Kingdom from the European Union and to make provision which arises as a consequence of the Withdrawal Agreement. Schedule 2 also, in reliance on section 8C of EUWA, makes amendments which facilitate access to the market in Great Britain of qualifying Northern Ireland goods. Schedule 1 of this instrument is made using section 8 and section 8C of EUWA and section 41 of the European Union Withdrawal Agreement Act 2020 in respect of provisions which give effect to the requirement of the Northern Ireland Protocol. In accordance with the requirements of EUWA the Minister has made the relevant statements as detailed in Part 2 of the Annex to this Explanatory Memorandum.

9. Consolidation

9.1 There are no plans to consolidate the legislation amended by this instrument.

10. Consultation Outcome

10.1 No formal consultation took place. An informal consultation conducted by the MHRA took place on The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019.

10.2 The devolved administrations have been engaged on these changes.

11. Guidance

11.1 End of transition period guidance for medical devices is available at: https://www.gov.uk/guidance/regulating-medical-devices-from-1-january-2021.

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. Following a Regulatory Triage Assessment, it was determined that this instrument has a low level of impact on businesses.

13. Regulating small business

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

13.2 The MHRA will seek to minimise the legislation's impact by providing guidance to relevant stakeholders. Grace periods are also provided for appointing UK Responsible Persons and registering devices with the MHRA.

13.3 The basis for the final decision on what action to take to assist small businesses is to maintain patient safety whilst allowing continued access to the UK market.

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 Donna McInnes at the Medicines and Heath products Regulatory Agency Telephone: +44 203 080 6449 or email: donna.mcinnes@mhra.gov.uk can be contacted with any queries regarding the instrument.

15.2 Jonathan Lepper at the Medicines and Health products Regulatory Agency can confirm that this explanatory memorandum meets the required standard.

15.3 Edward Argar, Minister of State for Health 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

Part 1

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), 9 and 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), 9 and 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), 9 and 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), 9 and 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), 9 and 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 2018 SIs.	Explain the instrument, identify the relevant law before exit 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), 9, and	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 sections 10(1), 12 and 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 4 or 14, Schedule 7.	Statement of the reasons for the Minister's opinion that the SI is urgent.
Explanations where amending regulations under s. 2(2) ECA 1972	Paragraph 14, Schedule 8	Anybody making an SI after exit day under powers outside the European Union (Withdrawal) Act 2018 which modifies subordinate legislation made under s. 2(2) ECA 1972.	Statement explaining the good reasons for modifying the instrument made under s. 2(2) ECA 1972, identifying the relevant law before exit day, and explaining the instrument's effect on retained EU law.
Scrutiny statement where amending regulations under s. 2(2) ECA 1972	Paragraph 15, Schedule 8	Anybody making an SI after exit day under powers outside the European Union (Withdrawal) Act 2018 which modifies subordinate legislation made under s. 2(2) ECA 1972.	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.

Part 2

Statements required when using enabling powers under the European Union (Withdrawal) 2018 Act

1. Appropriateness statement

1.1 The Minister of State for Health, Edward Argar MP, has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In my view The Medical Devices (Amendment) (EU Exit) Regulations 2020 does no more than is appropriate".

1.2 This is the case because this instrument is necessary to ensure that the statute book functions correctly at the end of the Implementation Period.

2. Good reasons

2.1 The Minister of State for Health, Edward Argar, has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In my view there are good reasons for the provisions in this instrument, and I have concluded they are a reasonable course of action".

2.2 These reasons are set out in paragraph 7 of this explanatory memorandum.

3. Equalities

3.1 The Minister of State for Health, Edward Argar, has made the following statement:

"The draft instrument does not amend, repeal or revoke a provision or provisions in the Equality Act 2006 or the Equality Act 2010 or subordinate legislation made under those Acts.

3.2 The Minister of State for Health, Edward Argar, has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In relation to the draft instrument, I, Minister of State for Health, Edward Argar, have had due regard to the need to eliminate discrimination, harassment, victimisation and any other conduct that is prohibited by or under the Equality Act 2010.".

4. Explanations

4.1 The explanations statement has been made in section 2 of the main body of this explanatory memorandum.

5. Criminal offences

5.1 The Minister of State for Health, Edward Argar, has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In my view there are good reasons for maintaining the existing criminal offences (and penalties for those offences) which apply to medical device regulations under the Consumer Protection Act 1987."

5.2 These Regulations will bring within the scope of the criminal sanctions regime in section 12 (breach of safety regulations) of the Consumer Protection Act 1987 the use

of the UKCA and UK(NI) indication which would not clearly have been considered 'safety regulations' for the purposes of that Section.

5.3 These Regulations will also keep the use of the CE marking within the scope of the criminal sanctions regime in section 12 (breach of safety regulations) of the Consumer Protection Act 1987 until 30 June 2023. However, it is appropriate that the same level of sanction applies to those provisions as applies to breaches of the current medical devices regulations.