EXPLANATORY MEMORANDUM TO

THE MEDICAL DEVICES (AMENDMENT ETC.) (EU EXIT) REGULATIONS 2019

2019 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 Act.

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

2. Purpose of the instrument

2.1 This instrument amends the Medical Devices Regulations 2002 to ensure they are fit for purpose in a no deal EU Exit scenario. This instrument will also amend the 2002 Regulations so that the UK will have a regulatory system in place on 30th March 2019 which will mirror (insofar as that is possible) all the key elements contained in Regulations 2017/745 on medical devices (MDR) and 2017/746 on in vitro diagnostic medical devices (IVDR), in line with the transitional timetable being followed by the EU for the full application of those two Regulations in the EU.

Explanations

What did any relevant EU law do before exit day?

2.2 EU law provided for the EU regulatory system for medical devices and *in vitro* diagnostic devices (IVDs) of which the UK is a part before exit day. This includes the system of conformity assessment which is required for all medical devices and IVDs before these can be placed on the EU market. As explained further in section 6 below the current EU regime consists of three EU Directives and a number of pieces of EU tertiary legislation. The new MDR and IVDR have been applied directly in UK law since May 2017 and will be fully implemented in the EU from May 2020 and May 2022 respectively.

Why is it being changed?

2.3 In a no deal EU Exit scenario, the UK's current participation in the European regulatory network for medical devices would end, and the MHRA would take on the responsibilities for the UK market that are currently undertaken through the EU system to ensure the continued safety of patients.

What will it now do?

2.4 This instrument will strengthen the Medicines and Healthcare product Regulatory Agency's (MHRA) market surveillance and assurance role allowing it to take on roles formerly conducted by the wider EU regulatory system. Furthermore, the UK has also committed to implementing all key elements of the new MDR and IVDR in UK law even in a no deal scenario. These changes are set out in section 7.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 The instrument contains provisions which anticipate prospective changes to be made by the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019, which are laid in draft alongside this instrument, and by the Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 which will be laid in draft on 21st January 2019. Footnotes in the instrument indicate where this is the case. This instrument will be made at the same time as the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 and will not be made before the Genetically modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019.

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 includes Scotland and Northern Ireland.

3.3 The powers under which this instrument is made cover the entire United Kingdom (see section 8(1) of the European Union (Withdrawal) Act 2018) and the territorial application of this instrument is not limited either by the Act or by the instrument.

4. Extent and Territorial Application

4.1 The territorial extent of this instrument is all of the United Kingdom.

4.2 The territorial application of this instrument is all of the United Kingdom.

5. European Convention on Human Rights

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

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

6. Legislative Context

6.1 The regulation of medical devices is an area of shared competence between the EU and Member States under Article 4 the Treaty on the Functioning of the EU (TFEU); in light of the EU's comprehensive exercise of the competence, Member States are precluded from exercising the competence nationally.

6.2 The EU regulatory framework for medical devices 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 tertiary EU Regulations which supplement the framework.

6.3 The three EU Directives have been transposed into UK law by the Medical Devices Regulations 2002 SI 2002/618 (the 2002 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.

6.4 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).

6.5 These two new EU Regulations replace the three EU Directives but they will only fully apply from 26 May 2020 in the case of the MDR and 26 May 2022 in the case of the IVDR.

6.6 The EU (Withdrawal) Act 2018 (EUWA) provides at section 2 that domestic legislation made under section 2(2) ECA continues to have effect in domestic law on or after exit day notwithstanding that the ECA is repealed by virtue of section 1. "Exit day" is defined at section 20 to mean 11pm on 29 March 2019. By virtue of being saved under section 2 EUWA, the 2002 Regulations form part of "retained EU law" as defined in section 6(7) EUWA.

6.7 Section 3 EUWA provides that EU Regulations and tertiary Regulations that are in force and apply immediately before exit day also continue to form part of domestic law on or after exit day and form part of retained EU law. This means that the majority of the provisions of MDR and the IVDR do not automatically form part of domestic law after exit day by virtue of section 3 EUWA on the basis that they do not apply immediately before exit day. However, Article 120(5) MDR and Article 110(5) IVDR allow devices that are compliant with the new Regulations to be placed on the market prior to the Regulations' full application. This means that although most of the MDR and IVDR do not formally apply prior to exit day, the rights, powers, liabilities, obligations, restrictions, remedies and procedures contained in them may be relied on (and are recognised and available in domestic law by virtue of s. 2(1) of the European Communities Act 1972) prior to exit day for lawful placing on the market. This has created a need to ensure that the provisions of the MDR and IVDR can continue to be relied on after exit day even though they do not automatically form part of the UK's retained EU law but instead are retained by virtue of section 4.

6.8 Section 8 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.

6.9 These Regulations exercise the power in section 8 EUWA to amend the 2002 Regulations to ensure that all aspects of retained EU law in relation to medical devices operate effectively and are not deficient after exit day as a result of the UK's withdrawal from the EU. This includes inserting certain re-stated (see paragraph 21 of Schedule 7 to the EUWA) provisions of the MDR and IVDR into domestic law (the 2002 Regulations) in order that those provisions operate effectively and can continue to be relied on after exit day as they are now.

7. Policy background

What is being done and why?

7.1 The 2002 Regulations place obligations on manufacturers to ensure that medical devices and IVDs are safe and fit for their intended purpose.

7.2 The term 'medical device' is defined in the 2002 Regulations and includes, for example, bandages, hospital beds, surgical instruments and joint replacements.

7.3 The term 'in vitro diagnostic device' is also defined in the 2002 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 2002 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, is the Competent Authority for medical devices, including IVDs and active implantable medical devices, in the UK under the three EU Directives. 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 them on the market in the EU. 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 2002 Regulations, there is a UK requirement to register the lowest risk medical devices (Class I devices), custom-made devices and all IVDs with the MHRA if the manufacturer or authorised representative is legally established within the UK.

Alignment with the new Regulations

7.9 The 2002 Regulations will be amended to—

- fix any deficiencies in those regulations arising out of the UK's withdrawal from the EU;
- mirror (insofar as that is possible) all the key elements contained in the MDR and IVDR and which will be brought into force in line with the transitional timetable being followed by the EU for the full application of those two Regulations.

Conformity assessment for medical devices and IVDs

7.10 The UK has announced its intention to continue to recognise the CE Mark on medical devices and IVDs, which have demonstrated their conformity with EU regulatory requirements for a time-limited period. During this period, medical devices and IVDs would be accepted on the UK market if they meet all EU requirements, which for all but the lowest-risk devices would include certification by EU Notified Bodies.

7.11 In a no-deal scenario, UK-based Notified Bodies will no longer be recognised by the EU after 29 March 2019, meaning the devices they have certified will no longer be in conformity with the applicable EU Directive, if individual units were to be placed on the market after 29 March 2019. In order to support the continuity of supply of products to the UK market, there must be appropriate market surveillance and ongoing safety monitoring procedures in place. Therefore, UK law will give UK-based Notified Bodies an ongoing legal status and continue to recognise the validity of certificates that they issued prior to 29 March 2019, although they will not be able to issue certificates for new products. This will allow products covered by certificates issued by UK-based Notified Bodies before 29 March 2019 to continue to be placed on the UK market. The MHRA will continue to oversee the activities of these bodies. UK law will not require any changes to the labelling of affected products.

Expansion of registration requirements and creation of a UK Responsible Person

7.12 In a no-deal scenario, all medical devices, including active implantable medical devices, IVDs and custom-made devices will need to be registered with the MHRA prior to being placed on the UK market. This is to ensure that the UK, whilst no longer part of the EU devices regulatory network, can become an effective standalone regulator, by strengthening the market surveillance and assurance role of the MHRA. The person who registers devices with the MHRA must have a registered UK address.

7.13 Where a device manufacturer is not established in the UK, registration of a product with the MHRA must be undertaken by a 'UK Responsible Person' established in the UK and with a UK registered address who will take responsibility for the product in the UK. This person must be available as a contact for the MHRA to discuss any concerns around the conformity or safety of a product.

7.14 The MHRA will allow an appropriate transitional period for people placing medical devices and IVDs on the UK market to comply with these requirements. The transitional period will vary depending on the risk category of the devices placed on the UK market, with a requirement for higher risk devices to register after 4 months, medium risk after 8 months and low risk products after 12 months. The MHRA will not require manufacturers to place the name or address of the UK Responsible Person on the device label, or on the device itself.

Data exchange

7.15 In a no-deal scenario, the UK will no longer have access to EU data systems, including Eudamed, the European Databank on Medical Devices. These systems facilitate the exchange of information between Notified Bodies, national Competent Authorities and the European Commission. Under the new Regulations, Eudamed will be significantly overhauled to capture data, including on CE certificates, incidents, clinical investigations and market surveillance activities. Furthermore, access to Eudamed will be expanded to include those manufacturing and supplying devices. The MHRA is building an electronic system that expands on the current registrations

database, which will mirror, insofar as possible, the new Eudamed requirements. This will enable additional information and more complex data to be captured for market surveillance purposes.

7.16 The UK will continue to recognise existing clinical investigation approvals – both for regulatory and ethics approvals – and there will be no need to re-apply. UK clinical investigation applications will continue to be authorised by the MHRA and ethics committees as they are presently.

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

8.1 This instrument is being made using the power in section 8 of the European Union (Withdrawal) Act 2018 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.

9. Consolidation

9.1 This instrument will consolidate amendments to the Medical Devices Regulations (2002) in order to make the Regulations fit for purpose in a no-deal EU Exit scenario with amendments which will mirror (insofar as that is possible) all the key elements contained in the MDR and IVDR.

10. Consultation outcome

10.1 MHRA and DHSC conducted informal consultation with industry and the third sector over a series of deep dives to develop no deal proposals. Informal consultation at official level was also conducted with the devolved administrations. Secretaries of State in Scotland and Wales and the Permanent Secretary in Northern Ireland in the respective health departments were informed of the proposed positions ahead of formal consultation.

10.2 Some of the proposed changes to medical devices regulations were included in the formal written consultation alongside the proposals for medicines and clinical trials. This consultation lasted 4 weeks (4th October – 1st November 2018 inclusive). There were 168 responses through the online portal and 9 via email. Responses were received from a range of interests including medical devices companies (including SMEs), trade bodies, NHS trusts, universities, research organisations, charities, health-related professional bodies (including from the devolved administrations), law firms, and learned societies.

10.3 Respondents broadly accepted the proposed policy positions outlined in the consultation. Specific concerns were raised about the added regulatory burden that some economic operators may incur, and the timetable for transition and compliance. This feedback has been taken on board in reaching the conclusions above and further clarity will be provided in guidance ahead of EU Exit.

10.4 There were also requests for additional guidance and clarification on the final approach for many of the proposals. This feedback has been taken on board and further guidance will be provided ahead of EU exit. The Government's response to the consultation was published on 3rd January 2019 (https://www.gov.uk/government/publications/further-guidance-note-on-the-regulation-of-medicines-medical-devices-and-clinical-trials-if-theres-no-brexit-deal).

11. Guidance

11.1 Additional guidance will be provided in advance of EU Exit on the policy issues above.

12. Impact

12.1 The impact on business, charities or voluntary bodies is set out in the impact assessment published alongside this Explanatory Memorandum on the legislation.gov.uk website.

12.2 The impact on the public sector is set out in the impact assessment published alongside this Explanatory Memorandum on the legislation.gov.uk website

12.3 A full Impact Assessment is submitted with this memorandum and published alongside the Explanatory Memorandum on the legislation.gov.uk website.

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.

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 EU Withdrawal Act 2018, no review clause is required.

15. Contact

15.1 Ian King at the Medicines and Heath products Regulatory Agency Telephone: +44 7825 256 320 or email: ian.king@mhra.gov.uk can be contacted with any queries regarding the instrument..

15.2 Patrick Carey at the Medicines and Health products Regulatory Agency can confirm that this Explanatory Memorandum meets the required standard.

15.3 The Minister of State for Health, Stephen Hammond 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 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 2(2) ECA 1972	Paragraph 13, 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	Statement explaining the good reasons for modifying the instrument made under s. 2(2) ECA, identifying the relevant law before exit day, and explaining the instrument's effect on retained EU law.
Scrutiny statement where amending regulations under 2(2) ECA 1972	Paragraph 16, 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	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, Stephen Hammond has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In my view the Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 does no more than is appropriate".

1.2 This is the case because we are making amendments to domestic legislation and some direct EU legislation (as outlined in paragraphs 6.2 to 6.9). These amendments do no more than necessary to create a system based on unilateral recognition of CE marked medical devices. There are some concepts which are so closely related the EU, such as EU Notified Bodies (see paragraph 7.11), which also cannot retain the same legal status after exit day as they had before exit day and amendments have been necessary to take account of this fact but also to ensure that measures are in place to ensure patient safety standards are maintained.

2. Good reasons

2.1 The Minister of State for Health, Stephen Hammond 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 are that this instrument seeks to ensure that the regulatory provisions applying after exit day are, so far as possible, the same as they were before exit day. This provides legal certainty and a degree of continuity with regard to the requirements which businesses have to meet.

3. Equalities

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

"In relation to the draft instrument, I, Stephen Hammond, Minister of State for Health 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, Stephen Hammond 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 but including within the scope of those offences the matters which would have been within the scope of the new EU Regulations."

5.2 These regulations will bring within the scope of the criminal sanctions regime in s. 12 (breach of safety regulations) of the Consumer Protection Act some matters which would not clearly have been considered 'safety regulations' for the purposes of that Section. However, it is appropriate that the same level of sanction applies to those provisions as applies to breaches of the current medical devices regulations.

6. Legislative sub-delegation

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

"In my view it is appropriate to create a relevant sub-delegated power in the Medical Devices (Amendment etc.) (EU Exit) Regulations 2019."

6.2 It is appropriate for the Secretary of State to have a power to direct that devices or classes of device which meet standards which are equivalent to the requirements set out in the Regulations but which have not been through the EU regulatory system and do not bear a CE mark, may be placed on the UK market. This will provide the Secretary of State sufficient flexibility to meet any obligations arising out of the World Trade Organisation agreements in the event of no general free trade agreement being agreed with the EU.

6.3 It is also appropriate for the Secretary of State to determine by direction that certain requirements imposed on medical device manufacturers in relation to the reprocessing of single use devices should not apply to health institutions (or where health institutions arrange for reprocessing by an external reprocessor) where certain conditions provided for in the regulations are met. This power will enable the Secretary of State to make rapid decisions to enable hospitals and other health care providers to reprocess single use devices but only under appropriate and strict conditions.