**EXPLANATORY MEMORANDUM TO**

**THE MEDICAL DEVICES (AMENDMENT) (EU EXIT) REGULATIONS 2021**

**2021 No. 873**

## 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 Instrument.

## 2. Purpose of the instrument

2.1 This instrument is required to ensure that the United Kingdom (UK) has a functioning statute book following the end of the Implementation Period (IP) and to ensure that essential EU tertiary legislation can operate effectively within the UK regulatory system.

2.2 This instrument amends The Medical Devices Regulations 2002 (as they apply in Great Britain) in accordance with Schedule 1 of this instrument.

2.3 The following EU tertiary legislation concerning medical devices is amended in accordance with Schedule 2 of this instrument:

a) Commission Decision 2002/364/EC of 7th May 2002 on common technical specifications for *in vitro*-diagnostic medical devices;

b) Commission Regulation (EU) No 207/2012 of 9th March 2012 on electronic instructions for use of medical devices;

c) Commission Regulation (EU) No 722/2012 of 8th August 2012 concerning particular requirements as regards the requirements laid down in Council Directives 90/385/EEC and 93/42/EEC with respect to active implantable medical devices and medical devices manufactured utilising tissues of animal origin;

d) Commission Implementing Regulation (EU) No 920/2013 of 24th September 2013 on the designation and supervision of notified bodies under Council Directive 90/385/EEC on active implantable medical devices and Council Directive 93/42 on medical devices.

2.4 These amendments are being made to ensure that the regulatory landscape for medical devices is fit for purpose following the end of the IP. They will address failures of retained EU Law to operate effectively and correct other deficiencies.

***Explanations***

*What did any relevant EU law do before IP completion day?*

2.5 EU law provides for a harmonised EU regulatory system for medical devices - of which the UK was a part of until 31 December 2020. This includes the system of conformity assessment, which is required for all medical devices placed on the EU market. The EU regime consisted of Directive 90/385/EC on active implantable medical devices, Directive 93/42/EC on general medical devices and Directive

98/79/EC on *in vitro* Diagnostic Medical Devices, which were implemented into UK law by the Medical Devices Regulations 2002 ("the 2002 Regulations") and several pieces of directly applicable EU tertiary legislation.

2.6 This EU tertiary legislation deals with matters relating to:

a) the common specifications for certain types of in vitro diagnostic medical devices such as testing kits for HIV;

b) the circumstances in which electronic instructions for use of medical devices could be given;

c) the regulatory requirements for medical devices which contain tissues of animal origin; and

d) the detailed requirements for conformity assessment bodies to apply to become EU notified bodies.

2.7 From 1 January 2021 the Medicines and Healthcare products Regulatory Agency (MHRA) took on the responsibilities for regulating medical devices on the UK market to ensure the continued safety of patients. Changes are now required to ensure that the UK statute book reflects the correct policy positions following the end of the IP.

*What will these regulations do?*

2.8 Schedule 1 makes amendments to the 2002 Regulations (as they apply in Great Britain) to correct a number of deficiencies which were not made when those Regulations were amended by the Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 S.I. 2020/1478.

2.9 Schedule 1 makes a number of technical amendments to the 2002 Regulations, corrects some errors and makes a number of textual amendments. In particular, textual amendments are made to references to EU legislation or EU bodies so that those references are now to domestic legislation or to domestic UK based bodies. For example, the following terms have been changed from (EU) 'Notified Bodies' to (UK) 'Approved Bodies' and references to (EU) 'harmonised standards' to (GB) 'designated standards'. The Schedule also makes provision for manufacturers of small medical devices to be able put a small sized UKCA mark on their devices.

2.10 Schedule 2 makes amendments to a number of pieces of EU tertiary legislation, retained under the EU Withdrawal Act 2018, which relate to medical devices. This is to ensure that this tertiary legislation operates effectively in the context of UK medical devices regulation (as it applies in Great Britain).

2.11 In particular, Schedule 2 makes amendments to four pieces of EU tertiary legislation (listed above in paragraph 2.3) to remove processes and procedures which are not relevant to the operation of that legislation in a domestic context. Schedule 2 also makes textual amendments to references to EU legislation or EU bodies so that those are references to domestic legislation or to domestic UK based bodies.

## 3. Matters of special interest to Parliament

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

3.1 This instrument was laid for sifting on 2 July 2021 and considered by the European Statutory Instruments Committee and the Secondary Legislation Committee on 13 July 2021. The Sifting Committees agreed that the instrument should follow the negative resolution procedure.

***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 is the United Kingdom.

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

## 5. European Convention on Human Rights

5.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation no statement is required.

## 6. Legislative Context

6.1 Currently, devices are regulated under the 2002 Regulations. In addition, there are various pieces of EU tertiary legislation which supplement the framework.

6.2 The 2002 Regulations and the EU tertiary legislation therefore represent "retained EU law" on medical devices under sections 2 and 3 (respectively) of the European Union (Withdrawal) Act 2018 (EUWA).

6.3 The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020 No. 1478) substantially amended the 2002 Regulations to reflect the position at the end of 2020 under the Northern Ireland Protocol. It also made amendments to the Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 S.I. 2019/791 which in turn made amendments which applied only to Great Britain. Taken together these amendments reflected the different legal arrangements in Great Britain and Northern Ireland.

6.4 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.

6.5 The EU Withdrawal Agreement Act 2020 made amendments to EUWA to take account of the IP and to provide for the implementation of the Withdrawal Agreement.

6.6 This instrument exercises the powers in section 8 of EUWA to amend the 2002 Regulations to ensure that aspects of UK law in relation to medical devices operate effectively, comply with the relevant agreements and are not deficient.

## 7. Policy background

***What is being done and why?***

*Making corrections to the UK statute book*

7.1 This instrument corrects deficiencies in UK legislation resulting from the UK's withdrawal from the EU. These changes are being made to ensure that the UK has an accurate, fully functioning regulatory framework for medical devices.

*Updating terminology and providing clarity.*

7.2 Schedule 1 of this instrument amends the 2002 Regulations to provide clarity on issues relating to the terminology used in those Regulations so that it reflects the UK regulatory structure.

7.3 For example, Schedule 1 substitutes references to (EU) "Notified Bodies" with references to (UK) "Approved Bodies" and references to (EU) "harmonised standards" to (GB) "designated standards".

7.4 The Schedule also makes a technical amendment to ensure that small medical devices are correctly marked

*Clarifying size requirements for the UKCA marking*

7.5 Schedule 1 of this instrument amends the Medical Device Regulations 2002 to provide that minimum sizing requirements for the UKCA marking will not apply, where, having regard to the small size of the device, it is not possible for the device to bear a marking of that minimum size provided that the UKCA marking continues to meet relevant requirements as to visibility, legibility and indelibility.

*Amending references to EU institution and process in relevant EU tertiary legislation*

7.6 Schedule 2 of this instrument amends EU tertiary legislation concerning medical devices to change references and terminology used so that it reflects the structures and processes in domestic regulatory structures. In addition, references to "designating authorities" (EU bodies) are replaced with references to the Secretary of State.

7.7 The amendments to legislation remove the need for consultation and involvement of the EU Commission and Member States in the assessment of active implantable medical devices and medical devices manufactured utilising tissues of animal origin (Transmissible Spongiform Encephalopathy susceptible material) as well as the assessment during the designation of UK Approved Bodies.

7.8 Examples of the changes include references to "Notified Bodies" (EU term) amended to "Approved Bodies" (GB term), references to CE marking (EU term) amended to refer to the UKCA marking (GB term) and references to UK Responsible Persons are added.

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

8.1 This instrument is made using the powers in section 8 of EUWA in order to address failures of retained EU Law to operate effectively and to correct other deficiencies. Schedule 1 makes amendments to the 2002 Regulations (as they apply in Great Britain) to correct a number of deficiencies. Schedule 2 makes amendments to several pieces of EU tertiary legislation which relate to medical devices to ensure that legislation operates effectively in the context of the 2002 Regulations (as they apply in Great Britain).

8.2 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 Post-Implementation Period guidance for medical devices is available at: https://www.gov.uk/government/collections/new-guidance-and-information-for-industry-from-the-mhra#devices

## 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 produced for this instrument as no, or no significant, impact on private, public or voluntary sectors is foreseen.

## 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 impact of the legislation 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 supporting the continued safe supply of medical devices to the UK market.

## 14. Monitoring & review

14.1 As this instrument is made under the EUWA, no review clause is required.

## 15. Contact

15.1 Jason Eldridge at the Medicines and Heath products Regulatory Agency email: Jason.Eldridge@mhra.gov.uk can be contacted with any queries regarding the instrument.

15.2 Jack Turner 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, Edward Argar 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

# 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)e, 9 and 23(1) or jointly exercising powers in Schedule 2. | Explain what, if any, amendment, repeals or revocations are being made to the Equality Acts 2006 and 2010 and legislation made under them.<br><br>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<br>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 23(1) or jointly exercising powers in Schedule 2 to create | Set out the 'good reasons' for creating a criminal offence, and the penalty attached. |

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|---|---|---|---|
| | | 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 | Anyone 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:<br>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,<br>b) containing information about the relevant authority's response to—<br>(i) any recommendations made by a committee of either House of Parliament about the published draft instrument, and<br>(ii) any other representations made to the relevant authority about the published draft instrument, and<br>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. Sifting 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 2021 should be subject to annulment in pursuance of a resolution of either House of Parliament (i.e. the negative procedure)".

1.2 This is the case because the changes to be made within this instrument are minor technical amendments which are being made to address failures of retained EU Law to operate effectively and to correct other deficiencies. These are not expected to have any significant, impact on private, public or voluntary sectors.

### 2. Appropriateness statement

2.1 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 2021 does no more than is appropriate".

2.2 This is the case because this instrument is necessary to ensure that the statute book continues to function correctly following the end of the Implementation Period.

### 3. Good reasons

3.1 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".

3.2 These reasons are set out in section 7 of the explanatory memorandum.

### 4. Equalities

4.1 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.

4.2 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.".

## 5. Explanations

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