This Statutory Instrument has been printed to correct errors in S.I. 2020/1478 (which amended S.I. 2019/791 which amended S.I. 2002/618) and is being issued free of charge to all known recipients of S.I. 2020/1478.

STATUTORY INSTRUMENTS

2021 No. 873

EXITING THE EUROPEAN UNION

CONSUMER PROTECTION

The Medical Devices (Amendment) (EU Exit) Regulations 2021

Sift requirements satisfied	*13th July 2021*
Made - - - -	*20th July 2021*
Laid before Parliament	*21st July 2021*
Coming into force - -	*11th August 2021*

The Secretary of State, in exercise of the powers conferred by section 8(1) of, and paragraph 21 of Schedule 7 to, the European Union (Withdrawal) Act 2018(**a**), makes the following Regulations.

The requirements of paragraph 3(2) of Schedule 7 to that Act (relating to the appropriate Parliamentary procedure for these Regulations) have been satisfied.

Citation, commencement and application

1.—(1) These Regulations may be cited as the Medical Devices (Amendment) (EU Exit) Regulations 2021 and come into force on the twenty-first day after the day on which they are laid before Parliament.

(2) Regulations 2 and 3 apply in relation to England, Wales and Scotland only.

Amendment of the Medical Devices Regulations 2002

2. The Medical Devices Regulations 2002(**b**) are amended in accordance with Schedule 1.

(**a**) 2018 c. 16. Section 8 was amended by section 27(2) to (6) of the European Union (Withdrawal Agreement) Act 2020 (c.1) ("the 2020 Act"). Paragraph 21 of Schedule 7 was amended by paragraph 53(2) of Schedule 5 to the 2020 Act.

(**b**) S.I.2002/618. Paragraph 2(d) of Schedule 2 to S.I. 2020/1478 amended S.I. 2019/791 so that, on the coming into force of 2019/791, S.I. 2002/618, in so far as it applied to Great Britain, contained an application provision (regulation 1(2A)) to the effect that it only applied to Great Britain. Immediately beforehand, by virtue of Schedule 1 to S.I. 2020/1478, amendments were made to S.I. 2002/618, but only in so far as it applied to Northern Ireland. Accordingly, as a consequence of amendments made to S.I. 2002/618 by S.I. 2019/791 (as amended by S.I. 2019/1385 and 2020/1478) and by S.I. 2020/1478, two substantially different versions of S.I. 2002/618 have been in force since 31st December 2020 at 11p.m., one that applies in Great Britain and the other in Northern Ireland. These Regulations only amend the version of S.I. 2002/618 that applies in Great Britain.

Amendment of EU tertiary legislation

3. The following EU tertiary legislation concerning medical devices is amended in accordance with Schedule 2—

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

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

(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(**c**);

(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(**d**).

Signed by authority of the Secretary of State for Health and Social Care

Nadine Dorries
Minister of State,
20th July 2021 Department of Health and Social Care

SCHEDULE 1

Regulation 2

Amendments to Medical Devices Regulations 2002

1. In regulation 2(1)(**e**) (interpretation)—

(a) at the beginning omit "Subject to Parts VIII and IX,";

(b) in the definition of "mutual recognition agreement", for "the that country" substitute "that country";

(c) in the definition of "Regulation (EU) No 207/2012", at the end insert "(as retained under section 3 of the European Union Withdrawal Act 2018 and modified under section 8 of that Act)";

(d) in the definition of "Regulation (EU) No 722/2012", at the end insert "(as retained under section 3 of the European Union Withdrawal Act 2018 and modified under section 8 of that Act)".

2. In regulation 4H(**f**) (revocation of Commission Decision 2002/364 on 26th May 2025 and its effect before that date)—

(a) in paragraph (1), omit "("the Decision") (insofar as it is retained EU law)";

(b) omit paragraph (2).

3. For regulation 4J(**g**) (revocation of Regulation (EU) No 207/12 on 26th May 2020 and its effect before that date), substitute—

(**a**) EUDN 2002/364.
(**b**) EUR 2012/207.
(**c**) EUR 2012/722.
(**d**) EUR 2013/920.
(**e**) Relevant amendments have been made by S.I. 2013/2327 and 2019/791.
(**f**) Inserted by S.I. 2019/971 (as amended by S.I. 2020/1478).
(**g**) Inserted by S.I. 2019/971 (as amended by S.I. 2020/1478).

"Revocation of Commission Regulation (EU) No 207/2012 on 26th May 2025

4J. Commission Regulation (EU) No 207/2012 is revoked on 25th May 2025.".

4. For regulation 4K(**a**) (revocation of Regulation (EU) No 722/2012 on 26th May 2025 and its effect before that date), substitute—

"Revocation of Regulation (EU) No 722/2012 on 26th May 2025

4K. Regulation (EU) No 722/2012 is revoked on 26th May 2025.".

5. In regulation 4L(**b**) (Revocation of Regulation (EU) No 920/2013 on 26th May 2025 and its effect before that date)—

(a) in paragraph (1), for "notified" substitute "approved";

(b) omit paragraphs (4) and (5).

6. Omit regulation 4N(**c**) (the classification criteria in Directives 2003/12 and 2005/50).

7. In regulation 4T(**d**) (references in other legislation to Directives 90/385, 93/42 and 98/79)—

(a) in paragraph (2)—

(i) omit sub-paragraph (b),

(ii) at the end of the paragraph insert—

"(c) the reference to the expression "Directive 93/42/EEC" is to be construed, to the extent necessary for the practical application of that expression, as a reference also or instead to Part II of the Medical Devices Regulations 2002;

(d) the references to "paragraph 4.3 of Annex II to Directive 93/42/EEC" and "paragraph 5 of Annex III to Directive 93/42/EEC" are to be construed, to the extent necessary for the practical application of those provisions, as references also or instead to those paragraphs and those Annexes as they applied immediately before IP completion day and as modified by Schedule 2A.";

(b) in paragraph (4)(a), omit "or in accordance with Schedule 9".

8. In regulation 6 (scope of Part II)—

(a) at the end of paragraph (a), insert "and";

(b) at the end of paragraph (b), omit "and";

(c) omit paragraph (c).

9. In regulation 9(**e**) (determining compliance of general medical devices with relevant essential requirements) in paragraph (4), for "national standard" substitute "designated standard".

10. In regulation 10(**f**) (UK marking of general medical devices), after paragraph (5), insert—

"(6) In this regulation, where a device is required to bear a UK marking which meets the requirements of Annex 2 of Regulation (EU) No 765/2008, the requirement as to the minimum size of the UK marking specified in section 3 of that Annex is to be understood—

(a) as not applying 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; and

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(**a**) Inserted by S.I. 2019/971 (as amended by S.I. 2020/1478).
(**b**) Inserted by S.I. 2019/971 (as amended by S.I. 2020/1478).
(**c**) Inserted by S.I 2019/971 (as amended by S.I. 2020/1478).
(**d**) Inserted by S.I. 2019/971 (as amended by S.I. 2020/1478).
(**e**) Amended by S.I. 2019/791 (as amended by S.I. 2020/1478).
(**f**) Amended by S.I. 2019/791 (as amended by S.I. 2020/1478).

(b) as allowing a device to bear a UK marking of a size less than that minimum size provided that mark continues to meet the requirements as to visibility, legibility and indelibility in paragraphs (1) and (2).".

11. In regulation 21(**a**) (scope of Part III)—

(a) in paragraph (1), omit from "except for devices" to the end;

(b) for paragraph (3), substitute—

"(3) Where an active implantable device is intended to administer a medicinal product, that device must be governed by this Part without prejudice to the provisions of the Human Medicines Regulations 2012.";

(c) omit paragraph (4).

12. In regulation 23(**b**) (determining compliance of active implantable medical devices with relevant essential requirements), in paragraph (4) for "national standard" substitute "designated standard".

13. In regulation 24(**c**) (UK marking of active implantable medical devices), after paragraph (5), insert—

"(6) In this regulation, where a device is required to bear a UK marking which meets the requirements of Annex 2 of Regulation (EU) No 765/2008, the requirement as to the minimum size of the UK marking specified in section 3 of that Annex is to be understood—

(a) as not applying 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; and

(b) as allowing a device to bear a UK marking of a size less than that minimum size provided that mark continues to meet the requirements as to visibility, legibility and indelibility in paragraphs (1) and (2).".

14. In regulation 30(**d**) (manufacture etc. and conformity assessment procedures for active implantable medical devices)—

(a) in paragraph (1), for "set out in Directive 90/385" substitute "in the Annexes referred to in regulation 27(a)";

(b) in paragraph (2)—

(i) after "conformity assessment procedure" insert "in the Annexes referred to in regulation 27(a)",

(ii) omit "in accordance with Directive 90/385".

15. In regulation 32(**e**) (interpretation of Part IV), for the definition of "common technical specification" substitute—

""common technical specification" means a technical specification set out in the Annex to Commission Decision 2002/364/EC (as retained under section 3 of the European Union Withdrawal Act 2018(**f**) and modified under section 8 of that Act) for a relevant device referred to in a list in Annex II;".

16. In regulation 33 (Scope of Part IV)—

(a) in paragraph (1)—

(i) at the end of sub-paragraph (a) omit "and",

(ii) omit sub-paragraph (b);

(**a**) Amended by S.I. 2008/2936 and 2019/791.
(**b**) Amended by S.I. 2019791.
(**c**) Amended by S.I. 2019/971 (as amended by S.I. 2020/1478).
(**d**) Amended by S.I. 2008/2936, 2019/791 (as amended by S.I. 2020/1478) and S.I. 2020/1478.
(**e**) Amended by S.I. 2003/1697 and 2011/1043.
(**f**) 2018 c.16.

(b) in paragraph (2)—

(i) at the end of sub-paragraph (a) omit "and",

(ii) omit sub-paragraph (b).

17. In regulation 36(**a**) (UK marking of in vitro diagnostic medical devices), after paragraph (5), insert—

"(6) In this regulation, where a device is required to bear a UK marking which meets the requirements of Annex 2 of Regulation (EU) No 765/2008, the requirement as to the minimum size of the UK marking specified in section 3 of that Annex is to be understood—

(a) as not applying 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; and

(b) as allowing a device to bear a UK marking of a size less than that minimum size provided that mark continues to meet the requirements as to visibility, legibility and indelibility in paragraphs (1) and (2).".

18. In regulation 41(**b**) (manufacture etc. and conformity assessment procedures for in vitro diagnostic medical devices), omit paragraph (5).

19. In regulation 54(**c**) (fees payable in connection with the designation of approved bodies), in paragraph (5), in the definition of "Regulation (EU) No 920/2013", at the end insert "(as retained under section 3 of the European Union Withdrawal Act 2018(**d**) and modified under section 8 of that Act)".

20. In regulation 59(**e**) (interpretation of Part VII) omit "or a device for the purposes of Part VIII or IX".

21. In Schedule 2A(**f**) (modification of Annexes to Directives 90/385, 93/42 and 98/79)—

(a) in paragraph 2, before sub-paragraph (a), insert—

"(za) in Section 2, for "the functions referred to in Article 1(2)(a)" substitute "the purposes referred to in the definition of a medical device in regulation 2(1) of the Regulations";

(b) in paragraph 2(c), after paragraph (ii), insert—

"(iii) for "a device within the meaning of Article 1(4a)" substitute "a stable derivatives device";

(c) in paragraph 3—

(i) in sub-paragraph (e)(iii), after ""CE marking"" insert ", in both places it occurs,",

(ii) in sub-paragraph (e), after paragraph (iii), insert—

"(iv) for "Article 12" substitute "regulation 24";",

(iii) for sub-paragraph (g), substitute—

"(g) in Section 3.2—

(i) in the first paragraph, omit "of this Directive";

(ii) in point (c), for "Article 5" substitute "regulation 3A of the Regulations";",

(iv) for sub-paragraph (h) substitute—

"(h) in Section 3.3—

(i) for the first sentence substitute—

(**a**) Amended by S.I. 2019/791 (as amended by S.I. 2020/1478).
(**b**) Amended by S.I. 2019/791 (as amended by S.I. 2020/1478).
(**c**) The relevant amending instrument is S.I. 2017/207.
(**d**) 2018 c.16.
(**e**) Amended by S.I. 2003/1697 and 2019/791.
(**f**) Inserted by S.I. 2019/791 (as amended by S.I. 2020/1478).

"The quality system shall be audited by an approved body to determine whether it meets the requirements referred to in Section 3.2."

(ii) in the second sentence for "harmonized" substitute "designated";";

(d) for paragraph 8, substitute—

"**8.** In Annex 7—

(a) in Section 1.1 for "harmonised" substitute "designated";

(b) in Section 2.3.5 for "all competent authorities of the Member States in which the clinical investigation is being performed" substitute "the Secretary of State";";

(e) in paragraph 9, after sub-paragraph (a), insert—

"(aa) in Section 1 for "authorized representative" substitute "UK responsible person";" ;

(f) in paragraph 13—

(i) after sub-paragraph (d) insert—

"(da) in Section 3.1—

(i) in the first sentence, for "a notified body" substitute "an approved body";

(ii) for "other notified body" substitute "other approved body";

(iii) for "the competent authorities" substitute "the Secretary of State";",;

(g) in paragraph 15—

(i) after sub-paragraph (i) insert—

"(zj)in Section 8.2 for "notified body" substitute "approved body";";

(ii) in sub-paragraph (j), after paragraph (i), insert—

"(ia) for "notified body" substitute "approved body";";

(h) in paragraph 17—

(i) in sub-paragraph (e), after paragraph (ii), insert—

"(iii) for "competent authorities" substitute "Secretary of State";";

(ii) after sub-paragraph (g), insert—

"(ga) in Section 4.4 for "Article 5" substitute "regulation 3A of the Regulations";";

(iii) after sub-paragraph (j), insert—

"(k) in Section 6.4 for "notified body" substitute "approved body".";

(i) in paragraph 22, in sub-paragraph (d), for "the Secretary of State" substitute "Secretary of State".

SCHEDULE 2

Regulation 3

Amendments to EU tertiary legislation

PART 1

Amendments to Commission Decision 2002/364/EC

1. In Article 1 (which relates to the adoption of common technical specifications), at the end, insert "as that Annex applied before IP completion day and as modified by Schedule 2A to the Medical Devices Regulations 2002.".

2. Omit Article 2 (which relates to the addressees of the Decision).

3. In the Annex (which contains common technical specifications for in vitro diagnostic medical devices)—

(a) in point 3.1.4—

(i) for "CE marking" substitute "UK or CE marking",

(ii) for "CE marked" substitute "UK or CE marked";

(b) in point 3.1.8.—

(i) for "CE marked" substitute "UK or CE marked,",

(ii) for "notified body" substitute "approved body";

(c) in point 3.4.1—

(i) for "CE marking" substitute "UK or CE making",

(ii) for "CE marked" substitute "UK or CE marked";

(d) in Table 1, in the row marked Diagnostic sensitivity, for "Notified Body" in each place substitute "Approved Body".

PART 2

Amendments to Commission Regulation (EU) No 207/2012

4. In Article 1 (which relates to the scope of the Regulation), before the first paragraph insert—

"In this Regulation a reference to an Annex to Directive 90/385/EEC or to an Annex to Directive 93/42/EEC is to be construed as a reference to those Annexes as they applied immediately before IP completion day and as modified by Schedule 2A to the Medical Devices Regulations 2002.".

5. In Article 3 (which relates to the provision of instructions for use in an electronic form)—

(a) in paragraph 1(a), for "Directive 90/385/EEC" substitute "Part 3 of the Medical Devices Regulations 2002";

(b) in paragraph 1(b), (c) and (e) for "Directive 93/42/EEC" substitute "Part 2 of the Medical Devices Regulations 2002";

(c) in paragraph 1(d), for "Directives 90/385/EEC and 93/42/EEC", substitute "Part 3 or Part 2 of the Medical Devices Regulations 2002".

6. In Article 7 (which relates to access to instructions for use through a website)—

(a) in paragraph 2(e), for "Directive 95/46/EC" substitute "the Data Protection Act 2018(**a**) and the UK GDPR".

(b) after paragraph 2 insert—

"**3.** In this Article "the UK GDPR" has the same meaning as in Parts 5 to 7 of the Data Protection Act 2018 (see section 3(10) and (14) of that Act).".

7. For Article 8 (which relates to review of obligations by a notified body) substitute—

"Except for medical devices of Class I, as defined in Annex IX to Directive 93/42, the fulfilment of the obligations laid down in Articles 4 to 7 of this Regulation must be reviewed by an approved body during the applicable conformity assessment procedure for the medical device in question, as set out in Part 2 or Part 3 of the Medical Devices Regulations 2002. The review must be based on a specific sampling method adapted to the class and the complexity of the product.".

(**a**) 2018 c. 12.

8. In Article 10 (which relates to the commencement and applicability of the Regulation) omit "This Regulation shall be binding in its entirety and directly applicable in all Member States.".

PART 3

Amendments to Commission Regulation (EU) No 722/2012

9. In Article 2 (which relates to interpretation), in the stem of the paragraph, for "Directive 90/385/EEC and Directive 93/42/EEC" substitute "the Medical Devices Regulations 2002".

10. In Article 3 (which relates to risk analysis and risk management), for paragraph 1, substitute—

"1**.** Before lodging an application for a conformity assessment for the purpose of complying with regulation 13 or regulation 27 of the Medical Devices Regulations 2002, the manufacturer of medical devices referred to in Article 1(1) of this Regulation or their UK responsible person must carry out the risk analysis and risk management scheme set out in Annex I to this Regulation.".

11. In Article 4 (which relates to verification of the fitness of notified bodies, which are now approved bodies)—

(a) for paragraph 1 substitute—

"The Secretary of State must verify on a regular basis that approved bodies designated under Part 5 of the Medical Devices Regulations 2002 have up-to-date knowledge and expertise of the medical devices referred to in Article 1(1), in order to assess the conformity of those devices with the provisions of those Regulations and with the particular requirements of Annex I to this Regulation.";

(b) omit paragraph 2.

12. In Article 5 (which relates to conformity assessment procedures)—

(a) in paragraph 1, for "Directive 90/385/EEC or Directive 93/42/EEC" substitute "Part 3 or Part 2 of the Medical Devices Regulations 2002";

(b) in paragraph 2, for "Notified bodies" substitute "Approved bodies";

(c) in paragraph 3—

(i) in the first sub-paragraph, for "Notified bodies" substitute "Approved bodies";

(ii) in the second sub-paragraph, for "notified bodies" substitute "approved bodies";

(d) for paragraphs 4 to 6 substitute—

"**4.** Before issuing a design-examination certificate or a type-examination certificate the approved body must inform the Secretary of State of their assessment carried out pursuant to paragraph 2 by means of a summary evaluation report in accordance with Annex II to this Regulation.

5. The Secretary of State may submit comments on the summary evaluation report referred to in paragraph 4 within the following deadlines:

(a) in relation to medical devices using starting materials for which a TSE certificate of suitability as referred to in paragraph 3 has been submitted, within four weeks from the date on which the approved body informed the Secretary of State pursuant to paragraph 4;

(b) in relation to medical devices using starting materials for which a TSE certificate of suitability has not been submitted, within 12 weeks from the date on which the approved body informed the Secretary of State pursuant to paragraph 4.

6. The approved bodies must—

(a) give due consideration to any comments received in accordance with paragraph 5;

(b) provide an explanation as regards this consideration, including any due justification not to take account of one or more of the comments received, along with their final decisions to the Secretary of State.";

(e) in paragraph 7—

(i) for "notified body" substitute "approved body",

(ii) for "paragraphs 1-6" substitute "paragraphs 1 to 3".

13. Omit Articles 6 (which relates to the obligation on Member States to ensure compliance with the requirements of the Regulation), 7 (which relates to certificates issued before 29th August 2013) and 8 (which relates to the repeal of an earlier piece of EU legislation).

14. In Article 9 (which relates to entry into force and application) omit "This Regulation is binding in its entirety and directly applicable in all Member States".

15. In Annex I (which relates to risk assessment, management and evaluation of notified bodies which have now become approved bodies)—

(a) in section 1.2, in the fifth paragraph, for "European or" to the end of that paragraph, substitute "international scientific committees or bodies.";

(b) in section 1.2.5.2, in the second paragraph, omit "European or";

(c) in section 2—

(i) for the heading substitute "EVALUATION BY APPROVED BODIES",

(ii) for "notified bodies referred to in Article 4" substitute "approved bodies referred to in Article 4";

(d) in section 2.1—

(i) for the heading substitute "Information of the Approved Body regarding changes and new information",

(ii) for "notified body", in both places it occurs, substitute "approved body";

(e) in section 2.2—

(i) for "an EC", in both places it occurs, substitute "a",

(ii) for "Article 9(8) of Directive 90/385/EEC or Article 11(11) of Directive 93/42/EEC" substitute "regulation 18(3) or regulation 31(3) of the Medical Devices Regulations 2002",

(iii) for "notified body" substitute "approved body";

(f) in section 2.3—

(i) for "a notified body" substitute "an approved body",

(ii) for "this notified body" substitute "this approved body".

16. In Annex II (which relates to summary evaluation reports)—

(a) in the table headed "Details relating to the submitting notified body"—

(i) for the heading substitute "Details relating to the submitting approved body",

(ii) in entry 1 for "notified body" substitute "approved body",

(iii) in entry 2 for "Notified body" substitute "Approved body",

(iv) in entry 10, for the stem substitute—

"Confirmation that the submitting approved body has been designated by the Secretary of State for the conformity assessment of";

(b) in the box headed "Notified Body Statement"—

(i) for the heading substitute "Approved Body Statement",

(ii) for "Council Directive 90/385/EEC" substitute "Part 3 of the Medical Devices Regulations 2002",

(iii) for "Council Directive 93/42/EEC" substitute "Part 2 of the Medical Devices Regulations 2002".

PART 4

Amendments to Commission Implementing Regulation 920/2013

17. In Article 1(a) (definitions), for "Article 1(2)(c) of Directive 90/385/EEC or medical devices and their accessories as defined in Article 1(2) of Directive 93/42", substitute "regulation 2(1) of the Medical Devices Regulations 2002".

18. For Article 1(c) substitute—

"(c) "approved body" has the same meaning as in regulation 2(1) of the Medical Devices Regulations 2002;".

19. For Article 1(d) substitute—

"(d) "accreditation" means an attestation by a national accreditation body conveying formal recognition that a conformity assessment body is competent to carry out a specific activity;".

20. Omit Article 1(e) and 1(f).

21. In Article 1(g), for "designating authority" substitute "Secretary of State".

22. In Article 1(i), for "a designating authority's" substitute "the Secretary of State's".

23. After Article 1insert—

"Article 1a

In this Regulation, any reference to Annex 8 to Directive 90/385 or to Annex XI to Directive 93/42 is to be construed as a reference to those Annexes as they applied immediately before IP completion day and as modified by Schedule 2A to the Medical Devices Regulations 2002.".

24. In Article 3 (which relates to the procedure for the designation of notified bodies, now of approved bodies)—

(a) In its heading, for "notified" substitute "approved";

(b) in paragraph 1, in the first sub-paragraph, for "a notified body" substitute "an approved body";

(c) in paragraph 1, in the second sub-paragraph—

(i) for "notified" substitute "approved",

(ii) for "used in the New Approach Notified Designated Organisations Information System and subdivisions of those fields." substitute "found in Guidance: UK approved bodies for medical devices https://www.gov.uk/publications/medical-devices-uk-approved-bodies-for-medical-devices.";

(d) in paragraph 2—

(i) in the first sub-paragraph, for "The designating authority of the Member State where the conformity assessment body is established" substitute "The Secretary of State";

(ii) omit the second sub-paragraph.

(e) omit paragraphs 3 to 6;

(f) in paragraph 7 omit the first sub-paragraph.

25. In Article 4(extension of renewal of designation)—

(a) in paragraph 1, for "notified" substitute "approved";

(b) in paragraph 2, for "notified" substitute "an approved";

(c) for paragraph 5, substitute—

"5. An approved body, within the meaning of regulation A45(1)(b) of the Medical Devices Regulations 2002, whose designation does not have a stated validity period or has a validity period exceeding five years, is to be subject to a renewal within five years of IP completion day".

26. In Article 5 (surveillance and monitoring)—

(a) in paragraph 1—

(i) for "notified" in each place it occurs, substitute "approved",

(ii) in the first sub-paragraph, for "designating authority of the Member State where the notified body is established" substitute "Secretary of State",

(iii) in the third sub-paragraph, for "That designating authority" substitute "The Secretary of State";

(b) in paragraph 2, for "designating authorities", substitute "Secretary of State";

(c) in paragraph 3—

(i) for the first sub-paragraph substitute—

"The Secretary of State shall continuously monitor that body to ensure ongoing compliance with the applicable requirements. The Secretary of State shall provide for a systematic follow-up of complaints, vigilance reports and other information, including from outside the United Kingdom, which might indicate the non-fulfilment of the obligations by an approved body or its deviation from common or best practice.",

(ii) in the second sub-paragraph, for "designating authority of the Member State where the notified body is established" substitute "Secretary of State".

27. For Article 6 (investigation of competence of notified bodies) substitute—

"Investigation of the competence of an approved body

The Secretary of State may investigate cases regarding the competence of an approved body or the fulfilment of the requirements and responsibilities to which an approved body is subject under the Medical Devices Regulations 2002.".

28. Omit Articles 7 (exchange of experience on investigation and supervision of conformity assessment bodies) and 8 (operating of designated authorities).

29. For Article 9 (co-operation with accrediting bodies) substitute (without changing the numbering or heading)—

"Where designation is based on accreditation within the meaning of Regulation (EC) No 765/2008, the Secretary of State shall ensure that the accreditation body that has accredited a particular approved body is kept informed of incident reports and other information that relate to matters under the control of the approved body when the information may be relevant for the assessment of the performance of the approved body. The Secretary of State must ensure that the accreditation body in charge of the accreditation of a particular conformity assessment body is kept informed of findings relevant for the accreditation. The accreditation body shall inform the Secretary of State of its findings.".

30. In Article 10 (which relates to entry into force and application), omit "This Regulation shall be binding in its entirety and directly applicable in all Member States.".

31. In Annex I (which relates to interpretation of the conformity assessment body criteria) —

(a) in section 1.3(b)—

(i) for "authorised representative" substitute "UK responsible person",

(ii) omit "Union";

(b) omit section 1.5.

32. In Annex II (the application form to be submitted when applying for designation as an approved body) —

(a) in the title for "notified" substitute "an approved";

(b) in the fourth line of the application form, for "EU Notified" substitute "Approved";

(c) in the table of documents to be submitted—

(i) in box 4 omit from ",either within the Member State" to the end,

(ii) in box 15 for "the designating authority" to the end substitute "the Secretary of State",

(iii) in boxes 17 and 18 for "notified body", substitute "approved body",

(iv) in box 31 for "notified" in each place it occurs substitute "approved",

(v) in box 41 for "Communications from regulatory authorities including competent authorities and designating authorities" substitute "Communications from the Secretary of State or other regulatory authorities".

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations are made in order to address failures of retained EU Law to operate effectively and to correct other deficiencies.

Schedule 1 makes amendments to the Medical Devices Regulations 2002 (S.I. 2002/618) (as they apply in Great Britain) to correct a number of deficiencies. In particular, this Schedule makes textual amendments to references to EU legislation or EU bodies so that those references are to domestic legislation or to domestic UK based bodies.

Schedule 2 makes amendments to a number of pieces of EU tertiary legislation, retained under the EU Withdrawal Act 2108, which relate to medical devices to ensure that the legislation operates effectively in the context of UK Medical Devices regulation (as it applies in Great Britain). In particular, this Schedule makes amendments to four pieces of EU tertiary legislation to remove processes and procedures which are not relevant to the operation of that legislation in a domestic context and 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.

An impact assessment has not been produced for this instrument as no, or no significant, impact on private, public or voluntary sectors is foreseen.

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