Draft Regulations laid before Parliament under paragraphs 8F(1) and 12(1) of Schedule 7 to the European Union (Withdrawal) Act 2018, for approval by resolution of each House of Parliament.

DRAFT STATUTORY INSTRUMENTS

2023 No.

MEDICAL DEVICES

CONSUMER PROTECTION

The Medical Devices (In Vitro Diagnostic Devices etc.) (Amendment) Regulations 2023

Made - - - - ***

Coming into force in accordance with regulation 1(2)

The Secretary of State, in exercise of the powers conferred by section 8C of, and paragraph 1(1)(ab) of Schedule 4, and paragraph 21 of Schedule 7 to, the European Union (Withdrawal) Act 2018(**a**), makes the following Regulations.

The Treasury has consented to the making of these Regulations as required by paragraph 3(1) of Schedule 4 to that Act.

A draft of this instrument has been approved by a resolution of each House of Parliament, in accordance with paragraphs 8F(1)(**b**) and 12(1) of Schedule 7 to that Act.

PART 1

Preliminary

Citation and commencement

1.—(1) These Regulations may be cited as the Medical Devices (In Vitro Diagnostic Devices etc.) (Amendment) Regulations 2023.

(2) These Regulations come into force on the 28th day after the day on which they are made.

(**a**) 2018 c. 16. The European Union (Withdrawal) Act 2018 ("the 2018 Act") was amended by the European Union (Withdrawal Agreement) Act 2020 (c. 1) ("the 2020 Act"). Section 8C of, and paragraph 1(1)(ab) of Schedule 4 to, the 2018 Act were inserted by section 21 and section 28 respectively of the 2020 Act. Paragraph 21 of Schedule 7 to the 2018 Act was amended by paragraph 53(2) of Schedule 5 to the 2020 Act. Section 8C was also amended by section 55(3) of the United Kingdom Internal Market Act 2020 (c. 27). There are other amending instruments but none is relevant.

(**b**) Paragraph 8F of Schedule 7 to the 2018 Act was inserted by paragraph 51 of Schedule 5 to the 2020 Act and it was amended by paragraph 3 of Schedule 3 to the Retained EU Law (Revocation and Reform) Act 2023 (c. 28).

Extent and application

2.—(1) Subject to paragraphs (2) to (4), any amendment or revocation made by these Regulations has the same extent as the provision amended or revoked.

(2) Regulations 23, 33, 34 and 36 extend to Northern Ireland only.

(3) Regulation 9 applies in relation to Great Britain only.

(4) Regulations 10, 14 and 19 apply in relation to Northern Ireland only.

PART 2

Amendments to primary legislation

Amendment to the Human Tissue Act 2004

3. In section 1(**a**) of the Human Tissue Act 2004(**b**) (authorisation of activities for scheduled purposes), in subsection (12), for paragraph (a), substitute—

"(a) the use of relevant material to the extent that such use is regulated by—

(i) the Medical Devices Regulations 2002 (S.I. 2002/618),

(ii) Regulation (EU) 2017/745(**c**) of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, or

(iii) Regulation (EU) 2017/746(**d**) of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU, or".

Amendment to the Consumer Rights Act 2015

4. In the Consumer Rights Act 2015(**e**), Schedule 5(**f**) (investigatory powers etc.) is amended as follows—

(a) in paragraph 8, after the definition of "Regulation (EU) 2017/745 on medical devices" insert—

""Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices" means Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU;";

(b) in paragraph 19(7A)(a)—

(i) at the end of sub-paragraph (iii), omit "or";

(ii) at the end of sub-paragraph (iv), omit "and" and insert—

"or

(v) Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices, and";

(c) in paragraph 30A(3)(b), after "Regulation (EU) 2017/745 on medical devices" insert "or Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices".

(**a**) Section 1 was amended but none is relevant to these Regulations.
(**b**) 2004 c. 30.
(**c**) OJ No. L 117, 05.05.2017, p. 1, as amended OJ No. L 130, 24.04.2020, p.18; OJ No. L 70, 08.03.2023, p.1; and OJ No. L 80, 20.03.2023, p.24.
(**d**) OJ No. L 117, 05.05.2017, p.176, as amended by OJ No. L 19, 28.01.2022, p.3; OJ No. L 70, 08.03.2023, p.3; and OJ No. L 80, 20.03.2023, p.24.
(**e**) 2015 c. 15.
(**f**) Schedule 5 was amended by the Medicines and Medical Devices Act 2021, S.I. 2021/858 and S.I. 2021/905; there are other amending instruments but none is relevant.

Amendment to the Medicines and Medical Devices Act 2021

5. The Medicines and Medical Devices Act 2021(**a**) is amended in accordance with regulations 6 and 7.

Amendment to section 21 (compliance notices)

6. In section 21(**b**), in subsection (1A) for paragraph (d) substitute—

"(d) the EU Medical Devices Regulations.".

Amendment to section 42 (interpretation of Part 4)

7. In section 42(**c**), in subsection (2), in the definition of "manufacturer", for paragraph (b) substitute—

"(b) the EU Medical Devices Regulations;".

PART 3

Amendments to secondary legislation

Amendment to the Medical Devices Regulations 2002

8. The Medical Devices Regulations 2002(**d**) are amended in accordance with regulations 9 to 19.

Amendment to regulation 2 (interpretation) in relation to Great Britain

9. In regulation 2(1)(**e**) after the definition of "Regulation (EU) 2017/746" insert—

""Regulation (EU) 2022/1107" means Commission Implementing Regulation (EU) 2022/1107 of 4 July 2022 laying down common specifications for certain class D *in vitro* diagnostic medical devices in accordance with Regulation (EU) 2017/746 of the European Parliament and of the Council(**f**);".

Amendment to regulation 2 (interpretation) in relation to Northern Ireland

10. In regulation 2(1)(**g**) after the definition of "Regulation (EU) 2017/745" insert—

""Regulation (EU) 2017/746" means Regulation (EU) 2017/746(**h**) of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU;

"Regulation (EU) 2022/1107" means Commission Implementing Regulation (EU) 2022/1107 of 4 July 2022 laying down common specifications for certain class D *in vitro* diagnostic medical devices in accordance with Regulation (EU) 2017/746 of the European Parliament and of the Council(**i**);".

(**a**) 2021 c. 3.
(**b**) Section 21 was amended by S.I. 2021/905.
(**c**) Section 42 was amended by S.I. 2021/905.
(**d**) S.I. 2002/618.
(**e**) Relevant amending instruments are S.I. 2013/2327, 2021/873 and 2023/627.
(**f**) OJ No. L 178, 05.07.2022, p.3.
(**g**) Amended by S.I. 2021/905; there are other amending instruments but none is relevant.
(**h**) OJ No. L 117, 05.05.2017, p.176; amended by OJ No. L 19, 28.01.2022, p.3; OJ No. L 70, 08.03.2023, p.3; and OJ No. L 80, 20.03.2023, p.24.
(**i**) OJ No. L 178, 05.07.2022, p.3.

Amendment to regulation 2A (medical devices which are qualifying Northern Ireland goods)

11. In regulation 2A(**a**)—

(a) in paragraph (1)—

(i) before "Notwithstanding" insert "Subject to paragraph (1A),";

(ii) for sub-paragraph (a) substitute—

"(a) which meets the requirements of—

(i) these Regulations as they apply in Northern Ireland;

(ii) Regulation (EU) 2017/745; or

(iii) Regulation (EU) 2017/746; and";

(b) after paragraph (1) insert—

"(1A) Before 25 July 2024, paragraph (1) only applies to a coronavirus test device that meets the requirements of Regulation (EU) 2017/746 if the device also meets the requirements of—

(a) regulation 34A (approval requirement for coronavirus test devices); or

(b) the common specifications set out in Annex I and XIII to Regulation (EU) 2022/1107.".

Amendment to regulation 3ZA (revocation, transitional and saving provisions in respect of Regulation (EU) 2017/745)

12. In regulation 3ZA(**b**)—

(a) at the end of the heading insert "and Regulation (EU) 2017/746";

(b) for paragraph (1) substitute—

"(1) Subject to paragraph (2), Parts 2 to 7 only apply in Northern Ireland for the purpose of regulating qualifying devices.";

(c) in paragraph (2)—

(i) omit "whether or not the device to which they apply is referred to in paragraph (1)";

(ii) for sub-paragraph (a) substitute—

"(a) for the purposes of the registration of medical devices (whether or not they are qualifying devices) and persons placing medical devices on the market in Northern Ireland—

(i) regulation 19 (registration of persons placing general medical devices on the market),

(ii) regulation 21B (registration of persons placing active implantable medical devices on the market),

(iii) regulation 44 (registration of persons placing in vitro diagnostic medical devices on the market or for performance evaluation), and

(iv) regulation 53 (fees in connection with the registration of devices and changes to registration details),

only apply until the date which is 24 months after the date of publication of the notice referred to in Article 34(3) of Regulation (EU) 2017/745;

(aa) regulations 34A to 34D, 38A to 38C, 39A, 56A, 59 and 61 continue to apply in relation to coronavirus test devices whether or not they are qualifying devices;";

(iii) in sub-paragraph (b) after "5 to 7" insert "also";

(**a**) Regulation 2A was inserted by S.I. 2019/791 and amended by S.I. 2021/905.
(**b**) Regulation 3ZA was inserted by S.I. 2021/905.

(d) in paragraph (3)—

(i) for "For the purposes of paragraph (1)" substitute "For the purposes of this regulation";

(ii) after "Regulation (EU) 2017/745" insert "or Article 110 of Regulation (EU) 2017/746";

(iii) in sub-paragraph (a) for the words from "Directive 93/42" to the end, substitute "Directive 90/385, Directive 93/42 or Directive 98/79, rather than Regulation (EU) 2017/745 or Regulation (EU) 2017/746; and";

(iv) in sub-paragraph (b), omit ", 3 and 5".

Amendment to regulation 4T (references in other legislation to Directives 90/385, 93/42 and 98/79)

13. In regulation 4T(**a**), omit paragraph (1).

Revocation of regulation 19B (requirement to appoint a UK responsible person for general medical devices)

14. Omit regulation 19B(**b**).

Revocation of regulation 21C (requirement to appoint a UK responsible person for active implantable medical devices)

15. Omit regulation 21C(**c**).

Amendment to regulation 34A (approval requirement for coronavirus test devices)

16. In regulation 34A(**d**), in paragraphs (1) and (2), for "34B, 34C" substitute "34B to 34D".

New regulation 34D (exemption for coronavirus test devices in conformity with Regulation (EU) 2017/746 and Regulation (EU) 2022/1107)

17. After regulation 34C (transitional provisions for coronavirus test devices)(**e**) insert—

"Exemption for coronavirus test devices in conformity with Regulation (EU) 2017/746 and Regulation (EU) 2022/1107

34D. Regulation 34A does not apply in Northern Ireland—

(a) in relation to a coronavirus test device that is in conformity with Regulation (EU) 2017/746 and the common specifications set out in Annex I and XIII to Regulation (EU) 2022/1107;

(b) after 24 July 2024, in relation to a coronavirus test device that is in conformity with Regulation (EU) 2017/746.".

Amendment to regulation 44 (registration of persons placing in vitro diagnostic medical devices on the market or for performance evaluation)

18. In regulation 44(**f**)—

(**a**) Regulation 4T was inserted by S.I. 2019/791 and was amended by S.I. 2021/873.
(**b**) Regulation 19B was inserted by S.I. 2020/1478.
(**c**) Regulation 21C was inserted by S.I. 2020/1478.
(**d**) Regulation 34A was inserted by S.I. 2021/910.
(**e**) Regulation 34C was inserted by S.I. 2021/910.
(**f**) Regulation 44 was substituted by S.I. 2020/1478.

(a) omit paragraph (1)(a)(ii);

(b) omit paragraph (2)(c);

(c) omit paragraph (5);

(d) omit paragraph (6).

Revocation of regulation 44ZA (requirement to appoint a UK responsible person for placing in vitro diagnostic medical devices on the market or for performance evaluation)

19. Omit regulation 44ZA(**a**).

Amendment to the Blood Safety and Quality Regulations 2005

20. In the Blood Safety and Quality Regulations 2005(**b**), in regulation 2(**c**) (designation of the competent authority for Northern Ireland and scope of the Regulations) for paragraph (3) substitute—

"(3) These Regulations apply without prejudice to—

(a) the Medical Devices Regulations 2002,

(b) Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, and

(c) Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.".

Amendment to the Human Tissue (Quality and Safety for Human Application) Regulations 2007

21. In the Human Tissue (Quality and Safety for Human Application) Regulations 2007(**d**), in regulation 2(**e**) (extent and application), paragraph (3) is amended as follows—

(a) at the end of sub-paragraph (d), omit "or";

(b) at the end of sub-paragraph (e), insert—

", or

(f) Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.".

Amendment to the Legislative and Regulatory Reform (Regulatory Functions) Order 2007

22. In the Legislative and Regulatory Reform (Regulatory Functions) Order 2007(**f**), in Part 2 of the Schedule(**g**), in the section headed "Medicines", after "Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC" insert—

(**a**) Regulation 44ZA was inserted by S.I. 2020/1478. In that S.I. as originally printed it was inserted as regulation 44A. It was renumbered as regulation 44ZA by a correction slip (ISBN 978-0-34-821688-2).
(**b**) S.I. 2005/50.
(**c**) Regulation 2 was amended by S.I. 2019/4 and S.I. 2021/905.
(**d**) S.I. 2007/1523.
(**e**) Regulation 2 was amended by S.I. 2012/1916, 2018/335, 2019/481 and 2021/905.
(**f**) S.I. 2007/3544.
(**g**) Part 2 was amended by S.I. 2021/905; there are other amending instruments but none is relevant.

"Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU".

Amendment to the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012

23.—(1) In the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012(**a**), regulation 2(**b**) (interpretation) is amended in accordance with this regulation.

(2) After the definition of "infringing EEE" insert—

""in vitro diagnostic medical device" has the meaning given in Article 2 of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU;".

(3) For the definition of "medical device", "active implantable medical device", and "in vitro diagnostic medical device", substitute—

""medical device" and "active implantable medical device" have the meanings given in regulation 2(1) of the Medical Devices Regulations 2002;".

Amendment to the Waste Electrical and Electronic Equipment Regulations 2013

24. In the Waste Electrical and Electronic Equipment Regulations 2013(**c**), in regulation 2(**d**) (interpretation), for the definition of "in vitro diagnostic medical device", substitute—

""in vitro diagnostic medical device" means an in vitro diagnostic device or accessory within the meaning of—

(a) regulation 2(1) of the Medical Devices Regulations 2002 in relation to England and Wales and Scotland, and

(b) Article 2 of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU in relation to Northern Ireland,

which is EEE;".

Amendment to the Economic Growth (Regulatory Functions) Order 2017

25. In the Economic Growth (Regulatory Functions) Order 2017(**e**), in Part 3 of the Schedule(**f**), under the cross-heading "Medicines", after "Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC" insert—

"Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU".

(**a**) S.I. 2012/3032.
(**b**) Regulation 2 was amended but none is relevant to these Regulations.
(**c**) S.I. 2013/3113.
(**d**) Regulation 2 was amended by S.I. 2019/188; there are other amending instruments but none is relevant.
(**e**) S.I. 2017/267.
(**f**) Part 3 was amended by S.I. 2021/905; there are other amending instruments but none is relevant.

Amendment to the Market Surveillance (Northern Ireland) Regulations 2021

26. In the Market Surveillance (Northern Ireland) Regulations 2021(**a**), Schedule 1(**b**) (investigatory powers) is amended as follows—

(a) in paragraph 1, after the definition of "Regulation (EU) 2017/745 on medical devices" insert—

""Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices" means Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.";

(b) in paragraph 16—

(i) for sub-paragraph (2) substitute—

"(2) The officer may decommission or switch off any medical device to which the Medical Devices Regulations 2002, Regulation (EU) 2017/745 on medical devices or Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices apply which is installed at a given location.";

(ii) at the end of sub-paragraph (3)(a)(iv) omit "and" and insert—

"(v) Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices; and".

PART 4

Amendments to the Medical Devices (Northern Ireland Protocol) Regulations 2021

Amendment to the Medical Devices (Northern Ireland Protocol) Regulations 2021

27. The Medical Devices (Northern Ireland Protocol) Regulations 2021(**c**) are amended in accordance with regulations 28 to 44.

Amendment to regulation 2 (extent and application)

28. In regulation 2(2)—

(a) after "Parts 2," insert "2A,"; and

(b) after "3" insert ", 3A".

Amendment to regulation 3 (interpretation)

29. In regulation 3—

(a) in paragraph (1)—

(i) after the definition of "Regulation (EU) 2017/745" insert—

""Regulation (EU) 2017/746" means Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU;"

(ii) after the definition of "ethics committee" insert—

""Institute" means the charitable organisation with registered number 803725 and known as the Chartered Institute of Arbitrators;

(**a**) S.I. 2021/858.
(**b**) Schedule 1 was amended by S.I. 2021/905.
(**c**) S.I. 2021/905.

"UK(NI) indication" means the marking in the form set out in Schedule 1 to the Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020(**a**).";

(b) for paragraph (2) substitute—

"(2) Unless otherwise defined in these Regulations—

(a) terms used in Parts 2 and 3 have the same meaning as in Regulation (EU) 2017/745;

(b) terms used in Parts 2A and 3A have the same meaning as in Regulation (EU) 2017/746.";

(c) for paragraph (3) substitute—

"(3) In these Regulations, a reference to an Article or an Annex is—

(a) in Parts 2 and 3, a reference to an Article or an Annex of Regulation (EU) 2017/745;

(b) in Parts 2A and 3A, a reference to an Article or an Annex of Regulation (EU) 2017/746.".

Amendment to regulation 4 (scope)

30. For regulation 4 substitute—

"**Scope**

4. In these Regulations—

(a) Parts 4, 5 and 6 apply to all devices to which Regulation (EU) 2017/745 and Regulation (EU) 2017/746 apply;

(b) Parts 2 and 3 apply to all devices to which Regulation (EU) 2017/745 applies;

(c) Parts 2A and 3A apply to all devices to which Regulation (EU) 2017/746 applies.".

Amendment to regulation 8 (certificates of free sale – fee)

31. In the heading of regulation 8, after "free sale" insert "under Regulation (EU) 2017/745".

Amendment to regulation 10 (UK(NI) indication)

32. In regulation 10—

(a) at the end of the heading insert "under Regulation (EU) 2017/745";

(b) in paragraph (4)(b) omit "or putting the device into service";

(c) in paragraph (5) omit "or put into service";

(d) omit paragraph (6).

New Part 2A (Making available on the market and putting into service under Regulation (EU) 2017/746)

33. After Part 2 insert—

(**a**) S.I. 2020/1460.

"Part 2A

Making available on the market and putting into service under Regulation (EU) 2017/746

Certificates of free sale under Regulation (EU) 2017/746 – fee

10A. A manufacturer or authorised representative who requests a certificate of free sale from the Secretary of State under Article 55 must pay to the Secretary of State a fee of £75.

Retention of documentation relating to conformity assessments

10B.—(1) The liquidator or trustee in bankruptcy of a manufacturer, or of an authorised representative, must—

(a) retain for the required period any documentation that consists of, or reasonably could consist of, information to which section 7 of Annex IX applies, and

(b) comply with any request made by the Secretary of State during the required period to provide the Secretary of State with the retained documentation.

(2) In this regulation, the required period is 10 years after the last device was placed on the market.

UK(NI) indication under Regulation (EU) 2017/746

10C.—(1) This regulation applies if the CE marking is affixed in accordance with Article 18 on the basis of a certificate issued by a notified body established in the United Kingdom.

(2) The CE marking must be accompanied by the UK(NI) indication.

(3) The UK(NI) indication may be less than 5mm high provided that it is the same height as the CE marking that it accompanies.

(4) The manufacturer must affix the UK(NI) indication—

(a) visibly, legibly and indelibly, and

(b) before placing the device on the market.

(5) A person may only make available on the market a device to which this regulation applies if the manufacturer has affixed the UK(NI) indication in accordance with this regulation.".

New regulation A11 (legal representatives and contact persons for clinical investigations)

34. In Part 3 (clinical investigations under Regulation (EU) 2017/745), before regulation 11 insert—

"Legal representatives and contact persons for clinical investigations

A11.—(1) The first subparagraph of Article 62(2) (requirement to have a legal representative established in the Union) does not apply to a clinical investigation conducted in Northern Ireland if all of the following conditions are met—

(a) the clinical investigation is also being conducted in Great Britain;

(b) the clinical investigation is not also being conducted in a Member State;

(c) the sponsor—

(i) is established in Great Britain, or

(ii) has a written agreement with a legal representative established in Great Britain who is responsible for ensuring compliance with the sponsor's obligations pursuant to Regulation (EU) 2017/745;

(d) the sponsor has a contact person established in Northern Ireland in respect of the clinical investigation.

(2) A contact person referred to in this regulation must be the addressee for all communications with the sponsor provided for in Regulation (EU) 2017/745 and any communication with that contact person is deemed to be a communication with the sponsor.

(3) The agreement referred to in paragraph (1)(c)(ii) must provide for—

(a) the legal representative to be responsible for ensuring compliance with the sponsor's obligations pursuant to Regulation (EU) 2017/745,

(b) the legal representative to immediately inform the sponsor of all communications received in its capacity as the sponsor's legal representative, and

(c) the sponsor to share with its legal representative all communications and documentation necessary to enable the legal representative to fulfil its obligations under this regulation.

(4) A legal representative referred to in paragraph (1)(c)(ii) must have a written agreement with the contact person to provide for—

(a) the contact person to immediately inform the legal representative of all communications received in its capacity as the sponsor's contact person, and

(b) the legal representative to share with the contact person all communications and documentation necessary to enable the contact person to fulfil its obligations under this regulation.

(5) Where the sponsor is established in Great Britain, the sponsor must have a written agreement with the contact person to provide for—

(a) the contact person to immediately inform the sponsor of all communications received in its capacity as the sponsor's contact person, and

(b) the sponsor to share with the contact person all communications and documentation necessary to enable the contact person to fulfil its obligations under this regulation.

(6) Where the sponsor has a legal representative established in Great Britain, the application form and the clinical investigation plan drawn up in accordance with chapter II of Annex XV must include the name, address and contact details of the legal representative established in Great Britain.".

Amendment to regulation 13 (arbitration following the refusal of a clinical investigation application)

35. In regulation 13 omit paragraph (6).

New Part 3A (Performance studies under Regulation (EU) 2017/746)

36. After Part 3 insert—

"Part 3A

Performance studies under Regulation (EU) 2017/746

Legal representatives and contact persons for performance studies

17B.—(1) The first subparagraph of Article 58(4) (requirement to have a legal representative established in the Union) does not apply to a performance study conducted in Northern Ireland if all of the following conditions are met—

(a) the performance study is also being conducted in Great Britain;

(b) the performance study is not also being conducted in a Member State;

(c) the sponsor—

(i) is established in Great Britain, or

(ii) has a written agreement with a legal representative established in Great Britain who is responsible for ensuring compliance with the sponsor's obligations under Regulation (EU) 2017/746;

(d) the sponsor has a contact person established in Northern Ireland in respect of the performance study.

(2) A contact person referred to in this regulation must be the addressee for all communications with the sponsor provided for in Regulation (EU) 2017/746 and any communication with that contact person is deemed to be a communication with the sponsor.

(3) The agreement referred to in paragraph (1)(c)(ii) must provide for—

(a) the legal representative to be responsible for ensuring compliance with the sponsor's obligations under Regulation (EU) 2017/746,

(b) the legal representative to immediately inform the sponsor of all communications received in its capacity as the sponsor's legal representative, and

(c) the sponsor to share with its legal representative all communications and documentation necessary to enable the legal representative to fulfil its obligations under this regulation.

(4) A legal representative referred to in paragraph (1)(c)(ii) must have a written agreement with the contact person to provide for—

(a) the contact person to immediately inform the legal representative of all communications received in its capacity as the sponsor's contact person, and

(b) the legal representative to share with the contact person all communications and documentation necessary to enable the contact person to fulfil its obligations under this regulation.

(5) Where the sponsor is established in Great Britain, the sponsor must have a written agreement with the contact person to provide for—

(a) the contact person to immediately inform the sponsor of all communications received in its capacity as the sponsor's contact person, and

(b) the sponsor to share with the contact person all communications and documentation necessary to enable the contact person to fulfil its obligations under this regulation.

(6) Where the sponsor has a legal representative established in Great Britain, the application form drawn up in accordance with Chapter I of Annex XIV and any clinical performance study plan drawn up in accordance with Part A of Annex XIII must include the name, address and contact details of the legal representative established in Great Britain.

Ethical review of performance studies

17C.—(1) In Regulation (EU) 2017/746 a reference to an ethics committee is a reference to an ethics committee within the meaning of regulation 3(1).

(2) In relation to a performance study to which Article 58(5)(b) applies, the sponsor must submit to the Secretary of State a copy of the opinion of the ethics committee as soon as it becomes available and before the performance study starts.

Arbitration following the refusal of a performance study application

17D.—(1) A sponsor notified of a refusal under Articles 66(3), 67(4) or 74(10) may, within 28 days of being notified, apply to the Institute to appoint an adjudicator to review the refusal.

(2) The adjudicator must provide a report to the Secretary of State and the sponsor, setting out any recommendations in respect of the disputed refusal.

(3) The Secretary of State must take the report of the adjudicator into account and decide whether to—

(a) confirm or alter the grounds for the refusal of the application,

(b) authorise the performance study, or

(c) in the case of a refusal under Article 66(3), proceed to consider the application under Article 66.

(4) The Secretary of State must notify the sponsor of the decision in paragraph (3).

(5) The sponsor must pay any fees, costs and expenses of the Institute and its appointed adjudicator that are payable in connection with the application made under paragraph (1).

Damage compensation in relation to performance studies

17E. A sponsor of a performance study must hold sufficient insurance (or equivalent financial resources) to meet any potential financial liability in the event of injury or death attributable to participation in the performance study.

Retention of documentation relating to performance studies

17F.—(1) The liquidator or trustee in bankruptcy of a sponsor of a performance study, or of a sponsor's legal representative or contact person under Article 58(4), must—

(a) retain for the required period any documentation that consists of, or reasonably could consist of, any of the documentation referred to in Annex XIV, and

(b) comply with any request made by the Secretary of State during the required period to provide the Secretary of State with the retained documentation.

(2) In this regulation, the required period is—

(a) in the case of documentation relating to the performance study of a device that was subsequently placed on the market, 10 years after the last device was placed on the market;

(b) in any other case, 10 years after the performance study ended.".

Amendment to Part 4

37. In the heading of Part 4, after "Regulation (EU) 2017/745" insert "and Regulation (EU) 2017/746".

Amendment to regulation 18 (notified bodies)

38. In regulation 18—

(a) in paragraph (1), after "Article 35" insert "of Regulation (EU) 2017/745 and Article 31 of Regulation (EU) 2017/746";

(b) in paragraph (2), after "Article 46(6)" insert "of Regulation (EU) 2017/745 and Article 42(6) of Regulation (EU) 2017/746".

Amendment to regulation 19 (fees payable in connection with the designation of notified bodies)

39. In regulation 19—

(a) in paragraph (2)—

(i) in sub-paragraph (a), after "Article 38" insert "of Regulation (EU) 2017/745 or Article 34 of Regulation (EU) 2017/746";

(ii) in sub-paragraph (b), after "Article 44(10)" insert "of Regulation (EU) 2017/745 or Article 40(10) of Regulation (EU) 2017/746";

(iii) in sub-paragraph (c), after "Article 46(1)" insert "of Regulation (EU) 2017/745 or Article 42(1) of Regulation (EU) 2017/746";

(b) in paragraph (3) after "under Article 42" insert "of Regulation (EU) 2017/745";

(c) in paragraph (8)(a), after "Article 42" insert "of Regulation (EU) 2017/745 or Article 38 of Regulation (EU) 2017/746".

Amendment to regulation 20 (language requirements)

40. In regulation 20 for "provides" substitute "or Regulation (EU) 2017/746 provide".

Amendment to regulation 23 (offence of breaching certain provisions)

41. For regulation 23(1) substitute—

"(1) A person commits an offence if the person contravenes a prohibition or fails to comply with a requirement in a provision of—

(a) the regulations listed in Table 1;

(b) the articles of Regulation (EU) 2017/745 listed in Table 2;

(c) the articles of Regulation (EU) 2017/746 listed in Table 3;

in Schedule 3 to these Regulations.".

Amendment to regulation 26 (enforcement)

42. In regulation 26—

(a) in paragraph (1), for "and Regulation (EU) 2017/745" substitute ", Regulation (EU) 2017/745 and Regulation (EU) 2017/746";

(b) in paragraph (2), for "and Regulation (EU) 2017/745" substitute ", Regulation (EU) 2017/745 and Regulation (EU) 2017/746".

Amendment to Schedule 2 (fees in connection with the designation of notified bodies)

43. In Schedule 2—

(a) the first column (application) in Table 1 (application fees) is amended as follows—

(i) at the end of entry 1 insert "of Regulation (EU) 2017/745 or Article 34 of Regulation (EU) 2017/746";

(ii) in entry 2, after "Article 38" insert "of Regulation (EU) 2017/745 or Article 34 of Regulation (EU) 2017/746";

(iii) at the end of entry 3 insert "of Regulation (EU) 2017/745 or Article 40(10) of Regulation (EU) 2017/746";

(iv) in entry 4—

(aa) after "Article 46(1)" insert "of Regulation (EU) 2017/745 or Article 42(1) of Regulation (EU) 2017/746";

(bb) after "an Annex" insert "to Regulation (EU) 2017/745 or Regulation (EU) 2017/746";

(v) in entry 5, after "Article 46(1)" insert "of Regulation (EU) 2017/745 or Article 42(1) of Regulation (EU) 2017/746";

(b) the first column (activity) in Table 2 (fees for assessments and reviews) is amended as follows—

(i) in entry 1—

(aa) after "Article 39(4)" insert "of Regulation (EU) 2017/745 or Article 35(4) of Regulation (EU) 2017/746";

(bb) after "Article 38" insert "of Regulation (EU) 2017/745 or Article 34 of Regulation (EU) 2017/746";

(cc) at the end insert "of Regulation (EU) 2017/745 or Article 40(10) of Regulation (EU) 2017/746";

(ii) at the end of entry 2 insert "of Regulation (EU) 2017/745 or Article 40(4) of Regulation (EU) 2017/746";

(iii) at the end of entry 3 insert "of Regulation (EU) 2017/745 or Article 40(5) of Regulation (EU) 2017/746";

(iv) in entry 5—

(aa) after "Article 44(7)" insert "of Regulation (EU) 2017/745 or Article 40(7) of Regulation (EU) 2017/746";

(bb) in sub-paragraph (b), after "Regulation (EU) 2017/745" insert ", or Regulation (EU) 2017/746".

Amendment to Schedule 3 (provisions breach of which is an offence under regulation 23)

44. In Schedule 3—

(a) for Table 1 substitute—

"Table 1

"Regulation	*Title of the regulation*
5	Reprocessing of single-use devices
6	Requirement on health institutions relating to implanted devices
7	Provision of information relating to custom-made devices
9	Retention of documentation relating to conformity assessments and custom-made devices
10	UK(NI) indication under Regulation (EU) 2017/745
10B	Retention of documentation relating to conformity assessments
10C	UK(NI) indication under Regulation (EU) 2017/746
11	Ethical review of clinical investigations
12(1)	Prior authorisation of clinical investigations by the Secretary of State
14	Damage compensation in relation to clinical investigations
15	Retention of documentation relating to clinical investigations
17C	Ethical review of performance studies
17E	Damage compensation in relation to performance studies
17F	Retention of documentation relating to performance studies";

(b) in Table 2—

(i) for "general obligations on manufacturers" substitute "general obligations of manufacturers";

(ii) for "32(1), (2)" substitute "32(1) (except the second sentence of the third sub-paragraph), (2)";

(iii) for "86" substitute "86 (except the second and third sentences of paragraph (2))";

(c) after Table 2 insert—

"Table 3

Article	*Title of the article*
5(1) to (3), (5)	Placing on the market and putting into service
6(1) to (3)	Distance sales
7	Claims
9(3)	Common specifications
10 (except the second, third or fourth sub-paragraphs of paragraph 13)	General obligations of manufacturers
11(1), (3), (6)	Authorised representative
12	Change of authorised representative
13	General obligations of importers
14	General obligations of distributors
15	Person responsible for regulatory compliance
16(3), (4)	Cases in which obligations of manufacturers apply to importers, distributors or other persons
20(1)	Parts and components
22	Identification within the supply chain
29(1) (except the second sentence of the third sub-paragraph), (2)	Summary of safety and performance
48(1), (2), (3) (except the third sub-paragraph), (4) (except the second sub-paragraph), (7) (except the third sub-paragraph), (8) (except the second sub-paragraph), (9) and (10)	Conformity assessment procedures
49(3)	Involvement of notified bodies in conformity assessment procedures
53(1)	Voluntary change of notified body
57	General requirements regarding performance studies
58(1), (2), (4) (except the second sub-paragraph), (5), (6) and (8)	Additional requirements for certain performance studies
79	Post-market surveillance plan

Article	*Title of the article*
80	Post-market surveillance report
81 (except the second and third sentences of paragraph (2))	Periodic safety update report
84(1), (3) (except the first sub-paragraph), (5) and (8)	Analysis of serious incidents and field safety corrective actions
89 (only the final paragraph)	Evaluation of devices suspected of presenting an unacceptable risk or other non-compliance ”.

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

Name
Address — Parliamentary Under Secretary of State,
Date — Department of Health and Social Care

We consent

Name
Address — *Name*
Date — Two of the Lords Commissioners of His Majesty’s Treasury

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make provision for the implementation in respect of Northern Ireland of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (“Regulation (EU) 2017/746”). Article 5(4) of the Windsor Framework between the United Kingdom and the European Union(**a**) (“the Windsor Framework”) provides that the EU law listed in Annex 2 to the Windsor Framework will apply to and in the UK, in respect of Northern Ireland. Regulation (EU) 2017/746 is listed in Annex 2 and applied from 26 May 2022. Section 7A of the European Union (Withdrawal) Act 2018 gives effect to Regulation (EU) 2017/746 in domestic law.

Part 2 of these Regulations amends the Human Tissue Act 2004, the Consumer Rights Act 2015 and the Medicines and Medical Devices Act 2021. The Human Tissue Act 2004 is amended to exclude from its scope devices regulated by Regulation (EU) 2017/746. The Consumer Rights Act 2015 and the Medicines and Medical Devices Act 2021 are amended to ensure the enforcement powers they provide for are available in the enforcement of Regulation (EU) 2017/746.

Part 3 makes transitional and consequential amendments to secondary legislation. These amendments provide for the definition of “in vitro diagnostic medical device” by reference to Regulation (EU) 2017/746 in Northern Ireland. They also provide for further enforcement powers under the Market Surveillance (Northern Ireland) Regulations 2021 to be available in the enforcement of Regulation (EU) 2017/746.

(**a**) Following Joint Declaration No 1/2023, the Protocol on Ireland/Northern Ireland in the EU Withdrawal Agreement as amended by Decision No 1/2023 of the Joint Committee, is now referred to as the Windsor Framework. Joint Declaration No 1/2023 can be accessed at: https://eur-lex.europa.eu/legal-content/EN/TXT/?toc=OJ%3AL%3A2023%3A102%3ATOC&uri=uriserv%3AOJ.L_.2023.102.01.0087.01.ENG

Part 4 amends the Medical Devices (Northern Ireland Protocol) Regulations 2021 ("the 2021 Regulations"). Regulation 33 creates a new Part 2A regarding the making available on the market and putting into service of devices under Regulation (EU) 2017/746. Regulation 34 creates a new regulation A11 setting out new requirements in relation to legal representatives and contact persons in clinical investigations. Similar provisions in relation to performance studies are set out in new Part 3A. Regulation 36 creates a new Part 3A in relation to performance studies under Regulation (EU) 2017/746. Regulations 39 and 43 amend regulation 19 of, and Schedule 2 to, the 2021 Regulations in relation to fees. Regulations 41 and 44 amend regulation 23 of, and Schedule 3 to, the 2021 Regulations to make it a criminal offence to breach a prohibition or requirement in a provision listed in Table 1 or Table 3 in Schedule 3.

A full impact assessment has not been produced for this instrument as no, or no significant, impact on the private, public or voluntary sector is foreseen. The Explanatory Memorandum is published alongside these Regulations on www.legislation.gov.uk.

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