STATUTORY INSTRUMENTS

2021 No. 905

MEDICAL DEVICES

CONSUMER PROTECTION

The Medical Devices (Northern Ireland Protocol) Regulations 2021

Made - - - -	*26th July 2021*
Coming into force - -	*27th July 2021*

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.

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.

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

PART 1

Preliminary

Citation and commencement

1.—(1) These Regulations may be cited as the Medical Devices (Northern Ireland Protocol) Regulations 2021.

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

Extent and application

2.—(1) Parts 1, 4, 5, 7 and 8 extend to England and Wales, Scotland and Northern Ireland.

(2) Parts 2, 3 and 6 extend to Northern Ireland only.

(3) Any amendment made by Part 9 has the same extent as the provision amended.

(4) In Part 8—

(**a**) 2018 c.16. The European Union (Withdrawal) Act 2018 was amended by the European Union (Withdrawal Agreement) Act 2020 (c. 1) ("the 2020 Act"). Section 8C was inserted by section 21 of the 2020 Act, and paragraph 1(1)(ab) of Schedule 4 by section 28 of that Act. Paragraph 21 of Schedule 7 was amended by paragraph 53(2) of Schedule 5 to the 2020 Act.

(**b**) Paragraph 8F was inserted by paragraph 51 of Schedule 5 to the 2020 Act.

(a) Regulations 30, and 32 to 37 apply in relation to Northern Ireland only;

(b) Regulation 31 applies in relation to Great Britain only.

Interpretation

3.—(1) In these Regulations—

"Regulation (EU) 2017/745" means Regulation (EU) 2017/745 of the European Parliament and of the Council of 5th 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(**a**);

"ethics committee" means a research ethics committee recognised or established by, or on behalf of, the Scottish Ministers, the Welsh Ministers, the Department of Health in Northern Ireland or the Health Research Authority(**b**).

(2) Unless otherwise defined in these Regulations, terms used have the same meaning as in Regulation (EU) 2017/745.

(3) In these Regulations a reference to—

(a) an Article is a reference to an Article of Regulation (EU) 2017/745;

(b) an Annex is a reference to an Annex to Regulation (EU) 2017/745.

Scope

4. These Regulations apply to all devices to which Regulation (EU) 2017/745 applies.

PART 2

Making available on the market and putting into service under Regulation (EU) 2017/745

Reprocessing of single-use devices

5. The reprocessing and further use of single-use devices is permitted only when it is carried out in accordance with Article 17.

Requirement on health institutions to provide information relating to implanted devices

6. A health institution which has implanted a device to which Article 18 applies, must make available to the patient in whom the device has been implanted—

(a) the implant card for the device bearing the health institution's identity, and

(b) the information provided by the manufacturer with the device pursuant to Article 18(1), by any means that allow rapid access to that information.

Registration of custom-made devices

7.—(1) A manufacturer who makes custom-made devices available on the market in Northern Ireland must register that type of device with the Secretary of State.

(2) Registration—

(a) must take place within 28 days beginning with the day on which that type of device is first made available on the market, and

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(**a**) OJ No. L 117, 05.05.2017, p. 1., amended by Regulation (EU) 2020/561 of the European Parliament and of the Council of 23 April 2020, OJ No. L 130, 24.04.2020, p.18.

(**b**) The Health Research Authority is established by section 109 of the Care Act 2014 (c.23).

(b) requires the manufacturer to submit to the Secretary of State the information specified in paragraph (3).

(3) The information to be submitted to the Secretary of State is—

(a) the name, business address and contact details of the manufacturer of the device;

(b) if an authorised representative has been designated by the manufacturer, the authorised representative's name, business address, contact details and evidence of that designation;

(c) a description of the type of device concerned.

(4) The manufacturer must ensure that the information submitted to the Secretary of State remains up to date.

(5) The fee payable to the Secretary of State for registering a device or amending the registration of a device under this regulation is £100.

(6) This regulation does not apply before 1st September 2021 in respect of any class IIa or class IIb non-implantable devices made available on the market by a manufacturer who is not established in the United Kingdom.

Certificates of free sale - fee

8. A manufacturer or authorised representative who requests a certificate of free sale from the Secretary of State under Article 60(1), must pay to the Secretary of State a fee of £75.

Retention of documentation relating to conformity assessments and custom-made devices

9.—(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 8 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—

(a) in the case of information relating to an implantable device, 15 years after the last device was placed on the market, and

(b) in any other case, 10 years after the last device was placed on the market.

UK(NI) indication

10.—(1) This regulation applies if the CE marking is affixed in accordance with Article 20 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 or putting the device into service.

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

(6) In this regulation, "the 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**).

PART 3

Clinical investigations under Regulation (EU) 2017/745

Ethical review of clinical investigations

11.—(1) A sponsor proposing to conduct a clinical investigation of a device in Northern Ireland must apply to an ethics committee for an ethical review of the proposed clinical investigation.

(2) 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 clinical investigation is started.

Prior authorisation of clinical investigations by the Secretary of State

12.—(1) A clinical investigation to which Article 70(7)(a) applies must not start unless—

(a) it has been authorised by the Secretary of State, and

(b) a favourable opinion in respect of the clinical investigation has been issued by an ethics committee.

(2) For the purposes of paragraph (1)(a) and subject to paragraph (3), the Secretary of State must notify the sponsor of whether the clinical investigation is authorised within—

(a) 65 days of the validation date provided for in Article 70(5), if the Secretary of State decides to consult experts for advice on whether the clinical investigation should be authorised, or

(b) 45 days of the validation date in any other case.

(3) If the Secretary of State requests additional information from the sponsor under Article 70(6), the expiry of the periods in paragraph (2) is suspended from the date of the first request until such time as the additional information has been received.

Arbitration following the refusal of a clinical investigation application

13.—(1) A sponsor notified of a refusal under Article 70(3), 71(4), or 78(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 clinical investigation, or

(c) in the case of a refusal under Article 70(3), proceed to consider the application under Article 70.

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

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

(6) In this regulation, "Institute" means the charitable organisation with registered number 803725 and known as the Chartered Institute of Arbitrators.

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

Damage compensation in relation to clinical investigations

14. A sponsor of a clinical investigation 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 clinical investigation.

Retention of documentation relating to clinical investigations

15.—(1) The liquidator or trustee in bankruptcy of a sponsor of a clinical investigation or of a sponsor's legal representative or contact person under Article 62(2), 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 XV, 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 clinical investigation of a device that was subsequently placed on the market—

(i) if the device was an implantable device, 15 years after the last device was placed on the market, and

(ii) if the device was not an implantable device, 10 years after the last device was placed on the market;

(b) in any other case, 10 years after the clinical investigation ended.

Clinical investigation fees

16.—(1) The sponsor of a clinical investigation must pay the relevant fee for—

(a) an application submitted to the Secretary of State under Article 70(1);

(b) a notification to the Secretary of State of a substantial modification under Article 75(1).

(2) The relevant fee is payable when the application or notification to which it relates is made to the Secretary of State.

(3) If a sponsor fails to pay the relevant fee, the Secretary of State may reject the application, reject the notification or suspend the clinical investigation until the fee is paid.

(4) Fees for clinical investigations are set out in Schedule 1.

(5) In this regulation, "the relevant fee" means—

(a) for a clinical investigation of a class I device, class IIa device or non-invasive class IIb device, the fee in table 1 in Schedule 1, and

(b) for a clinical investigation of an invasive class IIb device or class III device, the fee in table 2 in Schedule 1.

Clinical investigations not carried out for a purpose specified in Article 62(1)

17.—(1) The provisions in paragraph (2) apply to clinical investigations of custom-made devices carried out for a purpose other than one of the purposes specified in Article 62(1), in addition to the provisions specified in Article 82(1).

(2) The provisions are—

(a) those of Article 62(4) not already specified in Article 82(1);

(b) Article 62(5) and (7);

(c) Article 63 except—

(i) in paragraph (2)(e), not the words "include the Union-wide unique single identification number of the clinical investigation referred to in Article 70(1) and"; and

(ii) in paragraph (6), not the words "in the electronic system on clinical investigations referred to in Article 73";

(d) Articles 64 to 69;

(e) Article 70 except—

(i) in paragraph (1), not the first sentence of the second subparagraph;

(ii) in paragraph (2), not the final sentence of the paragraph, and in the first sentence the words "data in the electronic system referred to in Article 73" to the end are to be read "documentation and submit the updated documentation to the Secretary of State";

(iii) in paragraph (3), in the first subparagraph, not the words "by means of the electronic system referred to in Article 73"; and

(iv) paragraphs (8) and (9);

(f) Article 71;

(g) Article 72;

(h) Article 75 except in paragraph (1), not the words "by means of the electronic system referred to in Article 73";

(i) Article 76 except—

(i) in paragraph (3), not the words "by means of the electronic system referred to in Article 73"; and

(ii) in paragraph (4), not the words "through the electronic system referred to in Article 73";

(j) Article 77 except—

(i) in paragraphs (1) and (7), not the words "through the electronic system referred to in Article 73";

(ii) paragraph (4);

(iii) in paragraph (5), not the second sentence of the second subparagraph;

(iv) paragraph (6); and

(v) in paragraph (7), in the second subparagraph, the words "entered into the electronic system pursuant to paragraph (5) of this Article" are to be read "submitted pursuant to paragraph (5) of this Article";

(k) Article 80 except—

(i) in paragraphs (2) and (3), not the words "by means of the electronic system referred to in Article 73"; and

(ii) paragraphs (4) and (5);

(l) Annex XV except section 3.1.1 in Chapter II.

PART 4

Notified bodies designated under Regulation (EU) 2017/745

Notified bodies

18.—(1) The Secretary of State is the appointed authority responsible for notified bodies under Article 35.

(2) In the event of restriction, suspension, or withdrawal of a designation, the notified body must provide the Secretary of State with any documents requested for the purposes of enabling the Secretary of State to exercise the functions of the authority responsible for notified bodies under Article 46(6).

Fees payable in connection with the designation of notified bodies

19.—(1) Fees in connection with the designation of notified bodies are set out in Schedule 2.

(2) The applicant must pay the Secretary of State the fee specified in table 1 in Schedule 2 for an application—

(a) for initial designation as a notified body under Article 38;

(b) for reassessment under Article 44(10);

(c) to extend the scope of a designation under Article 46(1).

(3) A notified body designated by the Secretary of State under Article 42 that submits a summary evaluation report to the Secretary of State in accordance with Article 5(4) of Regulation (EU) 722/2012, must pay to the Secretary of State a fee of £532.

(4) A fee specified in table 1 in Schedule 2 or paragraph (3) is payable when the application or submission to which it relates is made to the Secretary of State.

(5) If an applicant fails to pay a fee specified in table 1 in Schedule 2 or paragraph (3), the Secretary of State may reject the application or submission to which it relates.

(6) If the Secretary of State conducts an assessment or review listed in table 2 in Schedule 2, the fee payable by the conformity assessment body is—

(a) the fee specified for that assessment or review in table 2 in Schedule 2,

(b) an amount for time spent by each member of staff to undertake the assessment or review at a rate—

(i) for the time spent on site, of £361.20 per half day (period of less than a half day counting as a half day) up to a maximum of 2 half days on any one date, and

(ii) for the time spent travelling to and from the site, of £90.30 per hour,

(c) the actual costs of travel, accommodation and subsistence, and

(d) out of pocket expenses.

(7) A fee under paragraph (6) is payable within one month of receipt by the conformity assessment body of a written notice from the Secretary of State requiring payment of the fee.

(8) If a conformity assessment body fails to pay a fee under paragraph (6), the Secretary of State may—

(a) refuse to designate the body under Article 42;

(b) if the body has already been designated, suspend, restrict, or fully or partially withdraw, the designation.

(9) In this regulation, "Regulation (EU) 722/2012" means 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(**a**).

PART 5

General provision about language requirements and fees

Language requirements

20. Where Regulation (EU) 2017/745 provides for the UK in respect of Northern Ireland to determine the language requirements for information and documentation, such information and documentation must be written in English.

(**a**) OJ No. L 212, 09.08.2012, p. 3.

Unpaid fees

21. All unpaid sums due by way of, or on account of, any fees payable under these Regulations are recoverable as debts due to the Crown.

Waivers, reductions and refunds

22. The Secretary of State may—

(a) waive payment of any fee or reduce any fee or part of a fee otherwise payable under these Regulations;

(b) refund the whole or part of any fee paid pursuant to these Regulations.

PART 6

Enforcement

Offence of breaching certain provisions

23.—(1) A person commits an offence if the person contravenes a prohibition or fails to comply with a requirement in a provision of the regulations listed in Table 1 or the Articles listed in Table 2 in Schedule 3 to these Regulations.

(2) A person guilty of an offence under paragraph (1) is liable on summary conviction to imprisonment for a term not exceeding 6 months, to a fine not exceeding level 5 on the standard scale or to both.

(3) In respect of an offence under this regulation, a magistrates' court in Northern Ireland may hear and determine any complaint made before the earlier of—

(a) the end of the period of 1 year beginning with the day on which evidence which the prosecutor thinks is sufficient to justify a prosecution comes to the knowledge of the prosecutor, and

(b) the end of the period of 3 years beginning with the day on which the offence was committed.

(4) For the purposes of paragraph (3)(a)—

(a) a certificate signed by or on behalf of the prosecutor and stating the date on which such evidence came to the prosecutor's knowledge is conclusive evidence of that fact, and

(b) a certificate stating that matter and purporting to be so signed is to be treated as so signed until the contrary is proved.

Defence of due diligence

24.—(1) It is a defence for a person charged with an offence under regulation 23(1) to show that the person took all reasonable steps and exercised all due diligence to avoid commission of the offence.

(2) If in any proceedings for such an offence the defence provided by paragraph (1) involves an allegation that the commission of the offence was due to—

(a) an act or default of another person, or

(b) reliance on information given by another person,

the defendant is not, without leave of the court, entitled to rely on that defence unless the requirement in paragraph (3) is satisfied.

(3) The requirement is that at least 7 clear days before the hearing of the proceedings the defendant has served on the prosecutor a notice giving such information identifying or assisting in the identification of that other person as was then in the defendant's possession.

(4) A defendant is not entitled to rely on the defence provided by paragraph (1) by reason of the defendant's reliance on information supplied by another person unless the defendant shows that it was reasonable in all the circumstances to rely on the information, having regard in particular to—

(a) the steps which the defendant took or might reasonably have taken to verify the information, and

(b) whether the defendant had any reason to disbelieve the information.

Offences by bodies corporate

25.—(1) Where an offence under regulation 23(1) committed by a body corporate or a Scottish partnership is proved to have been committed with the consent or connivance of, or to be attributable to any neglect on the part of, an officer, the officer (as well as the body corporate or partnership) commits the offence and is liable to be proceeded against and punished accordingly.

(2) In relation to a body corporate, "officer" means—

(a) a director, manager, secretary or other similar officer of the body, or

(b) a person purporting to act in any such capacity.

(3) In paragraph (2)(a), "director", in relation to a body corporate whose affairs are managed by its members, means a member of the body corporate.

(4) In relation to a Scottish partnership, "officer" means—

(a) a partner, or

(b) a person purporting to act as a partner.

Enforcement

26.—(1) It is the duty of the Secretary of State to enforce these Regulations and Regulation (EU) 2017/745.

(2) It is the duty of each district council in Northern Ireland to enforce these Regulations and Regulation (EU) 2017/745 within its area (concurrently with the Secretary of State) in relation to devices that are ordinarily intended for private use or consumption.

PART 7

Amendment of primary legislation

Investigatory powers under the Consumer Rights Act 2015

27.—(1) Schedule 5 to the Consumer Rights Act 2015(**a**)(investigatory powers etc) is amended in accordance with this regulation.

(2) In paragraph 8 (interpretation of Schedule 5), after the definition of "online interface order" insert—

> ""Regulation (EU) 2017/745 on medical devices" means 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."

(3) In paragraph 10 (enforcer's legislation: duties and powers mentioned in paragraph 9(1)(a)) at the end insert "regulation 26 of the Medical Devices (Northern Ireland Protocol) Regulations 2021".

(**a**) 2015 c.15.

(4) In paragraph 19 (exercise of powers in Part 4), in sub-paragraph (7A)(a)(**a**), for the words from "a breach of" to the end substitute—

"a breach of—

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

(ii) regulations made under section 15(1) of the Medicines and Medical Devices Act 2021,

(iii) the Medical Devices (Northern Ireland Protocol) Regulations 2021, or

(iv) Regulation (EU) 2017/745 on medical devices, and".

(5) In paragraph 30A(**b**) (power to decommission or switch off fixed medical devices)—

(a) in sub-paragraph (1), for the words from "pursuant to" to the end substitute—

"pursuant to—

(a) the duty in regulation 61(1A) or (1B) of the Medical Devices Regulations 2002 (S.I. 2002/618),

(b) a duty in regulations made under section 15(1) of the Medicines and Medical Devices Act 2021, or

(c) the duty in regulation 26 of the Medical Devices (Northern Ireland Protocol) Regulations 2021.";

(b) in sub-paragraph (2), for "medical device to which the Medical Devices Regulations 2002 apply" substitute "relevant medical device";

(c) after sub-paragraph (2), insert—

"(3) In sub-paragraph (2), "relevant medical device" means—

(a) where a domestic enforcer is acting pursuant to a duty mentioned in sub-paragraph (1)(a) or (b), any medical device to which the Medical Devices Regulations 2002 apply;

(b) where a domestic enforcer is acting pursuant to the duty mentioned in sub-paragraph (1)(c), any medical device to which Regulation (EU) 2017/745 on medical devices applies."

Amendment of the Medicines and Medical Devices Act 2021

28.—(1) The Medicines and Medical Devices Act 2021(**c**) is amended in accordance with this regulation.

(2) In section 17 (fees, information, offences), in subsection (2), for "this Part" substitute "this Chapter".

(3) In section 21 (compliance notices), after subsection (1), insert—

"(1A) In this Chapter, "medical devices provision" means a provision in—

(a) regulations under section 15(1),

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

(c) the Medical Devices (Northern Ireland Protocol) Regulations 2021, or

(d) 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."

(4) In section 34 (recovery of expenses of enforcement), in subsection (1)(a), for the words from "offence under" to the end substitute—

(**a**) Sub-paragraph (7A) was inserted by section 41(2)(c) of the Medicines and Medical Devices Act 2021 (c.3).
(**b**) Paragraph 30A was inserted by section 41(2)(d) of the Medicines and Medical Devices Act 2021 (c.3).
(**c**) 2021 c.3.

"offence under—

(i) section 28,

(ii) regulation 60A of the Medical Devices Regulations 2002 (S.I. 2002/618) (offence of breaching certain provisions in the Regulations), or

(iii) regulation 23 of the Medical Devices (Northern Ireland Protocol) Regulations 2021 (offence of breaching certain provisions),

in relation to a medical device, or".

(5) In section 39 (disclosure of information)—

(a) in subsection (10)(a), omit the "or" at the end;

(b) in subsection (10)(b), at the end insert—

", or

(c) contravenes any obligation or restriction created or arising by or under the Protocol on Ireland/Northern Ireland in the EU withdrawal agreement, whether or not an obligation or restriction to which section 7A(2) of the European Union (Withdrawal) Act 2018 applies.".

(6) In section 42 (interpretation of Part 4), in subsection (2)—

(a) for the definition of "manufacturer" substitute—

""manufacturer" means any person who is a manufacturer for the purposes of any provision in—

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

(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;";

(b) for the definition of "medical devices provision" substitute—

""medical devices provision"—

(a) in Chapter 1, has the meaning given by section 17(2), and

(b) in Chapter 3, has the meaning given by section 21(1A);".

(7) In Schedule 2 (medical devices: civil sanctions)—

(a) in paragraph 1(1) (imposition of monetary penalty)—

(i) in paragraph (a), omit the "or" at the end;

(ii) in paragraph (b), at the end insert—

", or

(c) regulation 23 of the Medical Devices (Northern Ireland Protocol) Regulations 2021 (offence of breaching certain provisions).";

(b) in paragraph 4 (monetary penalties: criminal proceedings and conviction)—

(i) in sub-paragraph (1)(a), from "offence under" to the end substitute—

"offence under—

(i) section 28,

(ii) regulation 60A of the Medical Devices Regulations 2002, or

(iii) regulation 23 of the Medical Devices (Northern Ireland Protocol) Regulations 2021,

may be instituted against the person in respect of the act or omission to which the notice relates before the end of the period within which the person's liability may be discharged as mentioned in paragraph 2(2) (see paragraph 3(2)(a));";

(ii) in sub-paragraph (1)(b), from "section 28" to the end substitute "the provisions mentioned in paragraph (a) in relation to that act or omission.";

(iii) in sub-paragraph (2), from "section 28" to the end substitute "any of the provisions mentioned in sub-paragraph (1)(a) in respect of the act or omission giving rise to the penalty.";

(c) paragraph 5 (enforcement undertakings)—

(i) in sub-paragraph (1)(a), from "offence under" to the end substitute—

"offence under—

(i) section 28,

(ii) regulation 60A of the Medical Devices Regulations 2002, or

(iii) regulation 23 of the Medical Devices (Northern Ireland Protocol) Regulations 2021,";

(ii) in sub-paragraph (2)(a), from "section 28" to the end substitute "any of the provisions mentioned in sub-paragraph (1)(a) in respect of the act or omission to which the undertaking relates;";

(d) in paragraph 13 (guidance as to enforcement), in sub-paragraph (1)(a), for "or regulation 60A" to the end substitute ", regulation 60A of the Medical Devices Regulations 2002 or regulation 23 of the Medical Devices (Northern Ireland Protocol) Regulations 2021;".

PART 8

Amendment of the Medical Devices Regulations 2002

Amendments to the Medical Devices Regulations 2002

29. The Medical Devices Regulations 2002(**a**) are amended in accordance with this Part.

Amendment of regulation 2 (interpretation)

30. In regulation 2, in paragraph (1)—

(a) for the definition of "medical device" substitute—

""medical device" has the meaning given in Article 2(1) of Regulation (EU) 2017/745 and includes devices intended to administer a medicinal product or which incorporate as an integral part a substance which, if used separately, would be a medicinal product and which is liable to act upon the body with action ancillary to that of the device;";

(b) after the definition of "Regulation 722/2012" insert—

""Regulation (EU) 2017/745" means 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;".

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

31. In regulation 2A—

(a) in paragraph (1)(a), after "Northern Ireland" insert "or of Regulation (EU) 2017/745";

(b) in paragraph (2)—

(i) the words from ""qualifying Northern Ireland good"" to the end become sub-paragraph (a); and

(ii) after that sub-paragraph insert—

(**a**) S.I. 2002/618, as amended by S.I. 2003/1400, 2003/1697, 2005/2759, 2909, 2007/400, 803, 2008/2936, 2009/383, 2010/557, 2012/1426, 2013/525, 2327, 2017/207, 2019/791, 1385 and 2020/1478.

"(b) "Regulation (EU) 2017/745" means 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.".

Revocation and transitional provision

32. After regulation 3 (scope), insert—

"**Revocation, transitional and saving provisions in respect of Regulation (EU) 2017/745**

3ZA.—(1) Subject to paragraph (2)—

(a) Parts 2 and 3 only apply in Northern Ireland for the purposes of regulating qualifying devices.

(b) Parts 5 to 7 only apply in Northern Ireland for the purposes of regulating qualifying devices and devices within the scope of Part 4.

(2) The following provisions continue to apply in Northern Ireland in accordance with this paragraph whether or not the device to which they apply is referred to in paragraph (1)—

(a) for the purposes of registration of medical 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), and

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

apply until the date which is 6 months after the date of publication of the notice referred to in Article 34(3) of Regulation (EU) 2017/745.

(b) Parts 5 to 7 apply for purposes related to the designation of conformity assessment bodies for the purposes of a UK mutual recognition agreement.

(3) For the purposes of paragraph (1), a device is a qualifying device if, by virtue of Article 120 of Regulation (EU) 2017/745—

(a) it may be placed on the market, put into service or made available in Northern Ireland in accordance with the requirements of Directive 93/42 or Directive 90/385, rather than Regulation (EU) 2017/745; and

(b) it is placed on the market, put into service or made available in Northern Ireland in accordance with, and subject to the requirements of and the arrangements set out in, Parts 2, 3 and 5 to 7."

Amendment of regulation 10A (UK(NI) indication: general medical devices)

33. In regulation 10A, after paragraph (3), insert—

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

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

34. In regulation 19—

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

(b) in paragraph (1)(b) for "and custom-made devices" substitute "that are not custom-made devices";

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

(d) omit paragraph (5); and

(e) omit paragraph (6).

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

35. In regulation 21B—

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

(b) omit paragraph (1)(b);

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

(d) omit paragraph (5); and

(e) omit paragraph (6).

Amendment of regulation 24A (UK(NI) indication: active implantable medical devices)

36. In regulation 24A, after paragraph (3), insert—

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

Amendment of regulation 36A (UK(NI) indication: in vitro diagnostic medical devices)

37. In regulation 36A, after paragraph (3), insert—

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

PART 9

Amendments of other secondary legislation

Amendment of the Blood Safety and Quality Regulations 2005

38. In the Blood Safety and Quality Regulations 2005(**a**), in regulation 2 (scope of the regulations), in paragraph (3), at the end insert "and 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".

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

39. In the Human Tissue (Quality and Safety for Human Application) Regulations 2007(**b**), in regulation 2 (extent and application)—

(a) in paragraph (3)(c), omit the "or" at the end; and

(b) in paragraph (3)(d), at the end insert—

", or

(**a**) S.I. 2005/50; regulation 2 was amended by S.I. 2019/4.
(**b**) S.I. 2007/1523; regulation 2 was amended by S.I. 2012/1916, 2018/335, and 2019/481.

(e) 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."

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

40.—(1) The Legislative and Regulatory Reform (Regulatory Functions) Order 2007(**a**) is amended as follows.

(2) In Part 2 of the Schedule, in the section headed "Medicines", after "Human Medicines Regulations 2012", insert—

"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

Medical Devices (Northern Ireland Protocol) Regulations 2021".

(3) In Part 3 of the Schedule, in the section headed "Public health and safety", after "The Personal Protective Equipment (Enforcement) Regulations 2018", insert "The Medical Devices (Northern Ireland Protocol) Regulations 2021".

Amendment of the Medicines (Products for Human Use) (Fees) Regulations 2016

41. In the Medicines (Products for Human Use) (Fees) Regulations 2016(**b**), in regulation 10(5) (fee for advice for other purposes)—

(a) in paragraph (a), omit the "or" at the end; and

(b) in paragraph (b), at the end insert—

"; or

(c) obtaining an EU technical documentation assessment certificate or EU type-examination certificate of the type mentioned in section 5 of Annex IX and section 6 of Annex X of 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, for a medical device incorporating that product or a product of that type."

Amendment of the Economic Growth (Regulatory Functions) Order 2017

42. In the Economic Growth (Regulatory Functions) Order 2017(**c**), in Part 3 of the Schedule, in the section headed "Medicines", after "Regulation (EC) No 1901/2006 of the European Parliament and of the Council on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004", insert—

"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

Medical Devices (Northern Ireland Protocol) Regulations 2021".

(**a**) S.I. 2007/3544, to which there are amendments not relevant to these Regulations.
(**b**) S.I. 2016/190, amended by S.I. 2019/775; there are other amending instruments but none is relevant.
(**c**) S.I. 2017/267, to which there are amendments not relevant to these Regulations.

Amendment of the Market Surveillance (Northern Ireland) Regulations 2021

43.—(1) The Market Surveillance (Northern Ireland) Regulations 2021(**a**) are amended as follows.

(2) In regulation 6 (enforcer's legislation), at the end insert—

"(rr) regulation 26 of the Medical Devices (Northern Ireland Protocol) Regulations 2021."

(3) In Schedule 1 (investigatory powers)—

(a) in paragraph 1 (interpretation of terms used in this schedule), at the end insert—

""Regulation (EU) 2017/745 on medical devices" means 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."

(b) in paragraph 16 (power to decommission or switch off any medical device)—

(i) in sub-paragraph (1), for the words from "pursuant to" to the end substitute—

"pursuant to—

(a) the duty in regulation 61(1A) or (1B) of the Medical Devices Regulations 2002,

(b) a duty in regulations made under section 15(1) of the Medicines and Medical Devices Act 2021, or

(c) the duty in regulation 26(1) or (2) of the Medical Devices (Northern Ireland Protocol) Regulations 2021.";

(ii) in sub-paragraph (2), after "Medical Devices Regulations 2002" insert "or Regulation (EU) 2017/745 on medical devices";

(iii) in sub-paragraph (3)(a)(ii), after "Medicines and Medical Devices Act 2021;", omit "and";

(iv) after sub-paragraph (3)(a)(ii) insert—

"(iii) the Medical Devices (Northern Ireland Protocol) Regulations 2021;

(iv) Regulation (EU) 2017/745 on medical devices; and".

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

Nadhim Zahawi
Parliamentary Under-Secretary of State,
26th July 2021 Department of Health and Social Care

We consent

Alan Mak
David Rutley
21st July 2021 Two Lords Commissioners of Her Majesty's Treasury

(**a**) S.I. 2021/858

SCHEDULE 1

Regulation 16

Fees for clinical investigations

Table 1

Clinical investigation of a class I device, class IIa device or non-invasive class IIb device

Activity	*Fee*
1. Application submitted under Article 70(1)	£3,820
2. Application re-submitted under Article 70(1) where the changes from the immediately preceding application are limited to addressing the grounds on which the Secretary of State previously refused the application under Article 71(4)	£2,920
3. Notification of a substantial modification under Article 75(1)	£207

Table 2

Clinical investigation of an invasive class IIb device or class III device

Activity	*Fee*
1. Application submitted under Article 70(1)	£5,040
2. Application re-submitted under Article 70(1) where the changes from the immediately preceding application are limited to addressing the grounds on which the Secretary of State previously refused the application under Article 71(4)	£3,570
3. Notification of a substantial modification under Article 75(1)	£331

SCHEDULE 2

Regulation 19

Fees in connection with the designation of notified bodies

Table 1

Application fees

Application	*Fee*
1. For initial designation submitted under Article 38	£8,252
2. For initial designation re-submitted under Article 38 where the changes from the immediately preceding application are limited to addressing the grounds on which the Secretary of State previously refused the application	£2,063
3. For reassessment under Article 44(10)	£8,252
4. For an extension of the scope of the designation under Article 46(1)	£6,504

Table 2

Fees for assessments and reviews

Activity	*Fee*
1. On-site assessment under Article 39(4) in connection with an application for initial designation under Article 38, or an application for reassessment under Article 44(10)	£15,904
2. On-site audit as part of an annual reassessment under Article 44(4)	£10,160
3. Observed audit of notified body personnel under Article 44(5)	£4,404
4. On-site assessment of a subsidiary	£3,876
5. 'For-cause' review under Article 44(7) to—	
(a) review assessments by the notified body, including clinical evaluation documentation;	(a) £2,586
(b) otherwise verify compliance with the requirements of Regulation (EU) 2017/745 or address a particular issue	(b) £3,876

SCHEDULE 3

Regulation 23

Provisions breach of which is an offence under regulation 23

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
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

Table 2

Article	*Title of the article*
5(1) to (3), (5)	Placing on the market and putting into service
6(1)-(3)	Distance sales
7	Claims
9(3), (4)	Common specifications
10 (except in paragraph 14, only the first sub-paragraph)	General obligations on 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.
17(1)	Single-use devices and their reprocessing
18(1)	Implant card and information to be supplied to the patient with an implanted device
21(2)	Devices for special purposes
22(1), (3) to (5)	Systems and procedure packs
23(1)	Parts and components
25(1), (2)	Identification within the supply chain
32(1), (2)	Summary of safety and clinical performance
52(1) to (4), (6) to (11), (13)	Conformity assessment procedures
53(3)	Involvement of notified bodies in conformity assessment procedures
58(1)	Voluntary change of notified body
62(1), (2) (only the first sub-paragraph), (3) (only the first sub-paragraph), (4), (5), (7)	General requirements regarding clinical investigations conducted to demonstrate conformity of devices
82(1)	Requirements regarding other clinical investigations
84	Post-market surveillance plan
85	Post-market surveillance report
86	Periodic safety update report
89(1), (3) (only the second sub-paragraph),(5), (8)	Analysis of serious incidents and field safety corrective actions
94 (only the final paragraph)	Evaluation of devices suspected of presenting an unacceptable risk or other non-compliance

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) 2017/745 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 (OJ L 117, 5.5.2017) ("Regulation (EU) 2017/745"). Article 5(4) of the Protocol on Ireland/Northern Ireland to the Withdrawal Agreement between the United Kingdom and the European Union ("the Protocol") provides that the EU law listed in Annex 2 to the Protocol will apply to and in the UK, in respect of Northern Ireland. Regulation (EU) 2017/745 is listed in Annex 2 and applied from 26 May 2021. Section 7A of the European Union (Withdrawal) Act 2018 gives effect to Regulation (EU) 2017/745 in domestic law.

Part 2 of these Regulations makes supplementary provision in relation to placing devices on the market and putting devices into service in Northern Ireland under Regulation (EU) 2017/745.

Part 3 makes provision in relation to clinical investigations in Northern Ireland under Regulation (EU) 2017/745. Regulation 16 and Schedule 1 set out the fees for making applications and notifying of substantial modifications.

Part 4 of these Regulations makes provision in relation to notified bodies. It provides that the Secretary of State is the authority responsible for notified bodies under Article 35 of Regulation (EU) 2017/745. Regulation 19 and Schedule 2 set out the fees for making applications and for on-site assessments and reviews.

Part 5 makes general provision about language requirements and the fees imposed by these Regulations.

Part 6 deals with enforcement. Regulation 23 makes it a criminal offence to breach a prohibition or requirement in a provision listed in Table 1 or Table 2 in Schedule 3. Table 1 lists regulations in these Regulations and Table 2 lists Articles in Regulation (EU) 2017/745. Regulation 26 confers duties on the Secretary of State and each district council in Northern Ireland to enforce these Regulations and Regulation (EU) 2017/745.

Part 7 amends the Consumer Rights Act 2015 and the Medicines and Medical Devices Act 2021.

Part 8 amends the Medical Devices Regulations 2002. Regulation 32 revokes parts of the Medical Devices Regulations 2002 as they apply to Northern Ireland, and makes transitional provision. The Medical Devices Regulations 2002 implemented Directives 90/385/EEC and 93/42/EEC, which are repealed by Regulation (EU) 2017/745. Regulations 33, 36 and 37 insert provision about the size of the UK(NI) indication. The requirement to affix the UK(NI) indication is imposed by Article 7(3) of the Protocol.

Part 9 makes consequential amendments to other pieces of secondary legislation.

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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