Draft Regulations laid before Parliament under paragraphs 8F(1) and (2c) and (f),and 12(1) of Schedule 7 to the European Union (Withdrawal) Act 2018 (c.16), and section 47(3) and (6)(a) of the Medicines and Medical Devices Act 2021 (c. 3), for approval by resolution of each House of Parliament.

DRAFT STATUTORY INSTRUMENTS

2026 No. ****

MEDICAL DEVICES

Medical Devices (Amendment) Regulations 2026

Made - - - - ***

Coming into force in accordance with regulation 1

The Secretary of State makes the following Regulations in exercise of the powers conferred by—

(a) section 8C of, and paragraph 1(1)(ab) of Schedule 4 and paragraphs 21 and 38 of Schedule 7 to, the European Union (Withdrawal) Act 2018(**a**) ("the 2018 Act"); and

(b) sections 15(1), 16(1)(a) to (e) and (g) to (i), 16(2), 17(1)(a) to (c), and 43(2)(a) and (d) of the Medicines and Medical Devices Act 2021(**b**) ("the 2021 Act").

In accordance with section 45(1) of the 2021 Act(**c**), the Secretary of State has carried out a public consultation in relation to these Regulations.

The Treasury has consented in accordance with paragraph 3(1) of Schedule 4 to the 2018 Act.

A draft of this instrument has been approved by a resolution of each House of Parliament, in accordance with paragraphs 8F(1), (2)(c) and (f) and 12(1) of Schedule 7 to the 2018 Act and section 47(3) and (6)(a) of the 2021 Act.

DRAFT

(**a**) 2018 c. 1; paragraph 8F of Schedule 7 was inserted by paragraph 51 of Schedule 5 to the European Union (Withdrawal Agreement) Act 2020 (c. 1).
(**b**) 2021 c. 3; section 17 was amended by S.I. 2021/905.
(**c**) There are amendments to section 45, but none are relevant.

PART 1

General provision

Citation and commencement

1.—(1) These Regulations may be cited as the Medical Devices (Amendment) Regulations 2026.

(2) Subject to paragraph (3) they come into force six months after the day on which they are made.

(3) Part 10 comes into force 18 months after the day on which they are made.

Extent and application

2.—(1) These Regulations extend to England and Wales, Scotland and Northern Ireland.

(2) In these Regulations—

(a) the amendments made by Parts 2 to 11 apply to England and Wales, and Scotland;

(b) the amendments made by regulations 6 (amendment to regulation 3ZA - revocation, transitional and saving provisions in respect of Regulation (EU) 2017/745 and Regulation (EU) 2017/746), 46 (revocation of provision relating to approval of coronavirus test devices), 52 (Amendments to regulation 44 - registration of persons placing in vitro diagnostic medical devices on the market or for performance evaluation) and 53 (Amendment to regulation 44ZB - obligations in Part 4 which are met by complying with obligations in Regulation (EU) 2017/746) also apply to Northern Ireland.

Interpretation

3. In these Regulations, reference to a regulation, Part or Schedule by number alone is a reference to the regulation in, Part of, or Schedule to, the Medical Devices Regulations 2002(**a**).

PART 2

Amendments to Part 1 - introductory provisions relating to all medical devices

Amendment to regulation 1A - Schedules

4. For regulation 1A (Schedules)(**b**) substitute—

"Schedules

1A. The following Schedules have effect—

(a) Schedule 2 (mutual recognition agreement countries);

(b) Schedule 2A (Modification of Annexes to Directives 90/385, 93/42, 98/79);

(c) Schedule 8A (Electronic instructions for use)."

(**a**) S.I. 2002/618.
(**b**) Inserted by S.I. 2019/791.

DRAFT

Amendments to regulation 2 - interpretation

5.—(1) Regulation 2 (interpretation)(**a**) is amended as follows.

(2) In paragraph (1)—

(a) at the appropriate places insert the following definitions—

""the 2026 Regulations" means the Medical Devices (Amendment) Regulations 2026(**b**);";

""clinical evaluation" means a structured, planned and method driven process carried out on a continuous basis to generate, collect, analyse, and assess clinical data related to a device, to verify its safety, performance, and clinical benefits when used as intended by the manufacturer;";

""implantable device" means a device intended, through a clinical procedure—

(a) to be introduced into the human body completely, and to remain in place after the procedure,

(b) to replace an epithelial surface or the surface of the eye, and to remain in place after the procedure, or

(c) to be introduced into the human body partially, and to remain in place for at least 30 days after the procedure,

and includes such a device which is wholly or mainly absorbed by the body;";

""lifetime of the device" means the shelf life of a device (if there is one) plus the period that the manufacturer expects that device to perform as intended;";

""UDI" means the unique device identifier which is the series of numeric or alphanumeric characters that is created through internationally accepted device identification and coding standards and that allows the identification of a specific device on the market by every stakeholder in the supply chain;";

(b) omit the definition of "coronavirus test device";

(c) for the definition of "intended purpose" substitute—

""intended purpose" means the use for which a device is intended, when viewed objectively, according to —

(a) the manufacturer's labelling,

(b) the manufacturer's instructions for use,

(c) the manufacturer's promotion or sales material, and

(d) any information provided by the manufacturer, including technical documentation, such as documentation relating to the clinical evaluation or performance evaluation of the device;";

(d) in the definition of "*in vitro* diagnostic medical device"—

(i) in paragraph (a), after "equipment" insert ", software";

(ii) in paragraph (b)—

(aa) omit sub-paragraph (ii),

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

(cc) after sub-paragraph (iv) insert—

(**a**) Amended by S.I.s 2003/1697, 2005/2759, 2007/400, 2008/2936, 2011/1043, 2012/1426, 2013/2327, 2019/791, 2020/1478, 2021/873 and 905, 2023/377, and 2024/221 and section 41(4) of the Medicines and Medical Devices Act 2021 (c. 3).
(**b**) S.I. 2026/***.

DRAFT

"(v) concerning a physical or mental impairment,

(vi) concerning the predisposition to a medical condition or disease, or

(vii) to predict treatment responses or reactions."

(e) for the definition of "medical device" that applies to England and Wales, and Scotland(**a**) substitute—

""medical device" means any instrument, apparatus, appliance, software, material or other article (whether used alone or in combination) which—

(a) is intended by the manufacturer to be used for one or more of the following purposes—

(i) the diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease in human beings;

(ii) the diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability in human beings;

(iii) the investigation, replacement or modification of—

(aa) the anatomy of human beings, or

(bb) a physiological process in human beings;

(iv) the control or support of conception in human beings;

(v) the cleaning, disinfection or sterilisation of a device which is a medical device by virtue of paragraphs (i)-(iv), or an accessory, and

(b) does not achieve its principle intended action in or on the human body by pharmacological, immunological or metabolic means, even if it is assisted in its function by such means, and

it includes a device whose purpose is described in paragraph (a) which is intended to administer a medicinal product, or which incorporates 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 an action ancillary to that of the medical device;";

(f) in the definition of "relevant essential requirements"—

(i) for "Annex 1 of Directive 90/385, Annex I of Directive 93/42" substitute "Annex I to Regulation (EU) 2017/745 (as modified by, and as it has effect under, Schedule 2B)";

(ii) for "Directive 98/79" substitute "Regulation (EU) 2017/746 (as modified by, and has it has effect under, Schedule 2C)".

(3) In paragraph (1A)—

(a) for "Annexes 1" substitute "Annexes 2";

(b) for "Annexes I" substitute "Annexes II";

(c) for "Annex I" substitute "Annexes II".

(4) After paragraph (1B) insert—

"(1C) In these Regulations, any reference to Annex I to Regulation (EU) 2017/745 is a reference to that Annex as it had effect on 31 December 2020 and as modified by, and as it has effect under, Schedule 2B.

(**a**) The definition of "medical device" was substituted in relation to Northern Ireland by S.I. 2021/905. The definition of "medical device" in relation to England and Wales and Scotland was amended by S.I. 2008/2936.

DRAFT

(1D) In these Regulations, any reference to Annex I to Regulation (EU) 2017/746 is a reference to that Annex as it had effect on 31 December 2020 and as modified by, and as it has effect under, Parts 1 and 2 of Schedule 2C."

Amendments to regulation 3ZA - revocation, transitional and saving provisions in respect of Regulation (EU) 2017/745 and Regulation (EU) 2017/746

6. In regulation 3ZA(2) (revocation, transitional and saving provisions in respect of Regulation (EU) 2017/745 and Regulation (EU) 2017/746)(**a**)—

(a) in sub-paragraph (a), for "24 months" substitute "6 months",

(b) omit sub-paragraph (aa).

Amendments to regulation 4O - revocation of Regulation (EU) 2017/745

7.—(1) Regulation 4O (revocation of Regulation (EU) 2017/745)(**b**) is amended as follows.

(2) In the heading, after "Revocation" insert "and re-application".

(3) At the end of the regulation add—

"(3) From [*cif date*]—

(a) in relation to the following provisions applying in GB—

(i) regulation 5 (interpretation of Part II);

(ii) regulation 7A (registration of persons placing general medical devices on the market);

(iii) regulation 8 (essential requirements for general medical devices);

(iv) regulation 8A (technical documentation requirements for medical devices);

(v) regulation 8B (inspection of general medical device technical documentation by the Secretary of State);

(vi) regulation 9 (determining compliance of general medical devices with essential requirements);

(vii) regulation 14 (procedures for systems and procedure packs, and devices to be sterilised before use);

(viii) regulation 15 (procedures for custom-made general medical devices);

(ix) regulation 19C (obligations in Part II and III of these Regulations which are met by complying with obligations in Regulation (EU) 2017/745);

(x) regulation 20 (interpretation of Part III);

(xi) regulation 21 (scope of Part III);

(xii) regulation 21A (registration of persons placing active implantable medical devices on the market);

(xiii) regulation 22 (essential requirements for active implantable medical devices);

(xiv) regulation 22A (technical documentation requirements for active implantable medical devices);

(xv) regulation 22B (inspection of active implantable medical device technical documentation by the Secretary of State);

(**a**) Inserted by S.I. 2021/905 and amended by S.I. 2024/221.
(**b**) Inserted by S.I. 2019/791 (as amended by S.I. 2020/1478).

DRAFT

(xvi) regulation 23 (determining compliance of active implantable medical devices with relevant essential requirements);

(xvii) regulation 28 (procedures for custom-made active implantable medical devices);

(xviii) regulation 52 (interpretation of Part VI);

(xix) regulation 80 (labelling requirements relating to specific substances);

(xx) Schedule 2A (modification of Annexes to Directives 90/385, 93/42, 98/79),

(b) the following apply—

(i) Regulation (EU) 2017/745, as it had effect on 31 December 2020, and where relevant as modified by Schedule 2B;

(ii) Schedule 2B (modification of Annexes to Regulation (EU) 2017/745)."

Amendments to regulation 4P - revocation of Regulation (EU) 2017/746

8.—(1) Regulation 4P (revocation of Regulation (EU) 2017/746)(**a**) is amended as follows.

(2) In the heading, after "Revocation" insert "and re-application".

(3) At the end of the regulation add—

"(3) From [*cif date*]—

(a) in relation to the following provisions applying in GB—

(i) regulation 32 (interpretation of Part 4);

(ii) regulation 33A (registration etc. of persons placing *in vitro* diagnostic medical devices on the market);

(iii) regulation 33B (technical documentation requirements for *in vitro* diagnostic medical devices);

(iv) regulation 33C (inspection of *in vitro* diagnostic medical device technical documentation by the Secretary of State);

(v) regulation 34 (essential requirements for *in vitro* diagnostic medical devices);

(vi) regulation 35 (determining compliance of *in vitro* diagnostic medical devices with relevant essential requirements);

(vii) regulation 40 (procedure for affixing a UK marking to in vitro diagnostic medical devices);

(viii) regulation 44ZB (obligations in Part 4 which are met by complying with obligations in Regulation (EU) 2017/746);

(ix) regulation 68 (interpretation of Part VIII),

(x) Schedule 2A (modification of Annexes to Directives 90/385, 93/42, 98/79),

(b) the following apply—

(i) Regulation (EU) 2017/746, as it had effect on 31 December 2020, where relevant as modified by Schedule 2C;

(ii) Schedule 2C (modification of Annexes to Regulation (EU) 2017/746);

(iii) Commission Implementing Regulation (EU) 2022/1107 of 4 July 2022 laying down common specifications in accordance with Regulation (EU) 2017/746, as modified by Schedule 2D;

(**a**) Inserted by S.I. 2019/791 (as amended by S.I. 2020/1478).

DRAFT

(iv) Schedule 2D (modification of Commission Implementing Regulation (EU) 2022/1107).”

New regulations 4U-4Z6 - transitional provisions

9. After regulation 4T (references in other legislation to Directives 90/385, 93/42 and 98/79)(**a**), insert—

“Transitional provisions for general medical devices - certified by an approved body

4U.—(1) This regulation applies where immediately before [*cif date*] a manufacturer of a general medical device within scope of Part 2 (general medical devices) (as provided for in regulation 6) held a current conformity certificate issued by an approved body under any of the following—

(a) regulation 13 (procedures for affixing a UK marking to general medical devices),

(b) regulation 14 (procedures for systems and procedure packs, and for devices to be sterilised before use),

(c) regulation 17 (manufacturers etc and conformity assessment procedures for general medical devices),

(d) regulation 18 (approved bodies and the conformity assessment procedures for general medical devices).

(2) The transitional period for this regulation ends on the soonest of the following—

(a) [3 *years from cif date/ 1st April 2029*],

(b) the expiry of the conformity certificate,

(c) the date on which the device requires reassessment for conformity due to a significant change.

(3) The following provisions of the 2026 Regulations do not apply in relation to the devices within scope of paragraph (1) during the transitional period for this regulation—

(a) regulation 5 (amendments to regulation 2 - interpretation), with the exception of the definition of “the 2026 Regulations”,

(b) Part 3 (amendments to Part 2 - general medical devices), with the exception of regulation 24 (new regulation 19D - misleading or unsubstantiated claims about medical devices).

Transitional provisions for general medical devices - declaration of conformity

4V.—(1) This regulation applies where immediately before [*cif date*] a manufacturer of a general medical device within scope of Part 2 (as provided for in regulation 6) held a current declaration of conformity under any of the following regulations—

(a) regulation 13,

(b) regulation 14,

(c) regulation 15 (procedures for custom-made general medical devices),

(d) regulation 17.

(2) The transitional period for this regulation ends on the soonest of the following—

(a) *3 years from cif date/ 1st April 2029,*

(**a**) Regulation 4T was inserted by S.I. 2019/791.

DRAFT

(b) the date on which the device requires reassessment for conformity due to a significant change.

(3) The following provisions of the 2026 Regulations do not apply in relation to the devices within scope of paragraph (1) during the transitional period for this regulation—

(a) regulation 5, with the exception of the definition of "the 2026 Regulations",

(b) Part 3, with the exception of regulation 24.

Transitional provisions for general medical devices - applications for recertification of a certified device

4W.—(1) This regulation applies where immediately before [*cif date*] an approved body—

(a) has a contract with a manufacturer to conformity assess a device, and

(b) is in receipt of an application in relation to a general medical device that has been previously certified under Part 2, either—

(i) for an extension of the current certificate under regulation 18(3), or

(ii) for conformity assessment due to a significant change to the device since its previous certificate.

(2) The transitional period for this regulation ends on [*12 month from the cif date/ 1st April 2027*].

(3) The following provisions of the 2026 Regulations do not apply in relation to the devices within scope of paragraph (1) during the transitional period for this regulation—

(a) regulation 5, with the exception of the definition of "the 2026 Regulations",

(b) Part 3, with the exception of regulation 24.

(4) Any application within scope of paragraph (1) that is not determined before [*the end of the transitional period in paragraph (2)/ 1st April 2027*] shall be considered under the procedures introduced by the amendments made by the 2026 Regulations.

(5) Any extension of a current certificate issued in relation to a device covered by paragraph (1) shall expire [*3 years after the cif date/ on 1st April 2029*].

Transitional provisions for general medical devices - applications for certification of an uncertified device

4X.—(1) This regulation applies where immediately before [*the cif date*] an approved body—

(a) has a contract with a manufacturer to conformity assess a general medical device, and

(b) is in receipt of an application for certification in respect of an uncertified general medical device, where—

(i) the device has never been certified under Part 2, and

(ii) lawful supply of the device is covered by a conformity certificate issued by an approved body under regulation 18.

(2) The transitional period for this regulation ends on [*12 months from the cif date/ 1st April 2027*].

(3) The following provisions of the 2026 Regulations do not apply in relation to the devices within the scope of paragraph (1) during the transitional period for this regulation—

(a) regulation 5, with the exception of the definition of "the 2026 Regulations",

DRAFT

(b) Part 3, with the exception of regulation 24.

(4) Any application within scope of paragraph (1) that is not determined before [*the end of the transitional period in paragraph (2)/ 1st April 2027*] shall be considered under the procedures introduced by the amendments made by the 2026 Regulations.

(5) Any certificate issued in relation to a device covered by paragraph (1) shall expire [*3 years after the cif date/ on 1st April 2029*].

Transitional provisions for active implantable medical devices - certified by an approved body

4Y.—(1) This regulation applies where immediately before [*cif date*] a manufacturer of an active implantable medical device within scope of Part 3 (active implantable medical devices) (as provided for in regulation 21) held a current conformity certificate issued by an approved body under any of the following—

(a) regulation 27 (procedures for affixing a UK marking to active implantable devices),

(b) regulation 30 (manufacturers etc and conformity assessment procedures for active implantable devices),

(c) regulation 31 (approved bodies and the conformity assessment procedures for active implantable devices).

(2) The transitional period for this regulation ends on the soonest of the following—

(a) *[3 years from cif date/ 1st April 2029*],

(b) the expiry of the conformity certificate,

(c) the date on which the device requires reassessment for conformity due to a significant change.

(3) The following provisions of the 2026 Regulations do not apply in relation to the devices within scope of paragraph (1) during the transitional period for this regulation—

(a) regulation 5, with the exception of the definition of "the 2026 Regulations",

(b) Part 4 (amendments to Part 3 - active implantable medical devices), with the exception of regulation 37 (new regulation 31A - misleading or unsubstantiated claims about active implantable medical devices).

Transitional provisions for active implantable medical devices - recertification of a certified device

4Z.—(1) This regulation applies where immediately before [*cif date*] an approved body—

(a) has a contract with a manufacturer to conformity assess an active implantable medical device, and

(b) is in receipt of an application in relation to an active implantable medical device that has previously been certified under Part 3, either—

(i) for an extension of the current certificate under regulation 31(3), or

(ii) for conformity assessment due to a significant change to the device since its previous certificate.

(2) The transitional period for this regulation ends on [*12 months from the cif date/ 1st April 2027*].

(3) The following provisions of the 2026 Regulations do not apply in relation to the devices within the scope of paragraph (1) during the transitional period for this regulation—

(a) regulation 5, with the exception of the definition of "the 2026 Regulations",

DRAFT

(b) Part 4, with the exception of regulation 37.

(4) Any application within scope of paragraph (1) that is not determined before [the end of the transitional period in paragraph (2)] shall be considered under the procedures introduced by the amendments made by the 2026 Regulations.

(5) Any extension of a current certificate issued in relation to a device covered by paragraph (1) shall expire [*3 years after cif date/ 1st April 2029*].

Transitional provisions for active implantable medical devices – applications for certification of an uncertified device

4Z1.—(1) This regulation applies where immediately before [*cif date*] an approved body—

(a) has a contract with a manufacturer to conformity assess an active implantable medical device, and

(b) is in receipt of an application for certification in respect of an uncertified active implantable medical device where—

(i) the device has never been certified under Part 3, and

(ii) the lawful supply of the device is covered by a conformity certificate issued by an approved body under regulation 31.

(2) The transitional period for this regulation ends on [*12 months from the cif date/ 1st April 2027*].

(3) The following provisions of the 2026 Regulations do not apply in relation to the devices within the scope of paragraph (1) during the transitional period for this regulation—

(a) regulation 5, with the exception of the definition of "the 2026 Regulations",

(b) Part 4, with the exception of regulation 37.

(4) Any application within scope of paragraph (1) that is not determined before [*the end of the transitional period in paragraph (2)*] shall be considered under the procedures introduced by the amendments made by the 2026 Regulations.

(5) Any certificate issued in relation to a device covered by paragraph (1) shall expire [*3 years after cif date/ on 1st April 2029*].

Transitional provisions for *in vitro* diagnostic medical devices – certified by an approved body

4Z2.—(1) This regulation applies where immediately before [*cif date*] a manufacturer of an *in vitro* diagnostic medical device within scope of Part 4 (*in vitro* diagnostic medical devices) (as provided for in regulation 33) held a current conformity certificate issued by an approved body under any of the following—

(a) regulation 40 (procedures for affixing a UK marking to *in vitro* diagnostic medical devices),

(b) regulation 41 (manufacturers etc and conformity assessment procedures for *in vitro* diagnostic medical devices),

(c) regulation 42 (approved bodies and the conformity assessment procedures for *in vitro* diagnostic medical devices).

(2) The transitional period for this regulation ends on the soonest of the following—

(a) *[5 years from cif date/ 1st April 2031*],

(b) the expiry of the conformity certificate,

DRAFT

(c) the date on which the device requires reassessment for conformity due to a significant change.

(3) The following provisions of the 2026 Regulations do not apply in relation to the devices within the scope of paragraph (1) during the transitional period for these regulations—

(a) regulation 5, with the exception of the definition of "the 2026 Regulations",

(b) Part 5 (amendments to Part 4 - *in vitro* diagnostic medical devices), with the exception of regulation 54 (new regulation 44ZBA - misleading or unsubstantiated claims about *in vitro* diagnostic medical devices).

Transitional provisions for *in vitro* diagnostic medical devices – declaration of conformity

4Z3.—(1) This regulation applies where immediately before [*cif date*] a manufacturer of an *in vitro* diagnostic medical device within the scope of Part 4 (as provided for in regulation 33) held a current declaration of conformity under either of the following—

(a) regulation 40,

(b) regulation 41.

(2) The transitional period for this regulation ends on the soonest of the following—

(a) *5 years from the cif date/ 1st April 2031,*

(b) the date on which the device requires reassessment for conformity due to a significant change.

(3) The following provisions of the 2026 Regulations do not apply in relation to the devices within the scope of paragraph (1) during the transitional period for this regulation—

(a) regulation 5, with the exception of the definition of "the 2026 Regulations".

(b) Part 5, with the exception of regulation 54.

Transitional provisions for *in vitro* diagnostic medical devices – application for recertification of a certified device

4Z4.—(1) This regulation applies where immediately before [*cif date*] an approved body—

(a) has a contract with a manufacturer to conformity assess of an *in vitro* diagnostic medical device, and

(b) is in receipt of an application in relation to an *in vitro* diagnostic medical device that has been previously certified under provisions in Part 4, either—

(i) for an extension for the current certificate under regulation 42(3), or

(ii) for conformity assessment due to a significant change to the device since its previous certificate.

(2) The transitional period for this regulation ends on [*12 months from the cif date/ 1st April 2027*].

(3) The following provisions of the 2026 Regulations do not apply in relation to the devices within the scope of paragraph (1) during the transitional period for this regulation—

(a) regulation 5, with the exception of the definition of "the 2026 Regulations",

(b) Part 5, with the exception of regulation 54.

(4) Any application within scope of paragraph (1) that is not determined before [*the end of the transitional period in paragraph (2)/ 1st April 2027*] shall be considered under the procedures introduced by the amendments made by the 2026 Regulations.

DRAFT

(5) Any extension of a current certificate issued in relation to a device covered by paragraph (1) shall expire [*5 years after cif date/ on 1st April 2031*].

Transitional provisions for *in vitro* diagnostic medical devices – application for certification of an uncertified device

4Z5.—(1) This regulation applies where immediately before [*cif date*] an approved body—

(a) has a contract with a manufacturer for conformity assessment of *in vitro* diagnostic medical devices, and

(b) is in receipt of an application for certification in respect of an uncertified *in vitro* diagnostic medical device, where—

(i) the device has never been certified under Part 4, and

(ii) lawful supply of the device is covered by a conformity certificate issued by an approved body under regulation 35.

(2) The transitional period for this regulation ends on [*12 months from the cif date/ 1st April 2027*].

(3) The following provisions of the 2026 Regulations do not apply to the devices within the scope of paragraph (1) during the transitional period for this regulation—

(a) regulation 5, with the exception of the definition of "the 2026 Regulations",

(b) Part 5, with the exception of regulation 54.

(4) Any application covered by paragraph (1) that is not determined before [*the end of the transitional period in paragraph (2)/ 1st April 2027*] shall be considered under the procedures introduced by the amendments made by the 2026 Regulations.

(5) Any certificate issued in relation to a device covered by paragraph (1) shall expire [*5 years after cif date/ on 1st April 2031].*

Transitional provisions for clinical investigations

4Z6.—(1) This regulation applies where immediately before [*the cif date*] a clinical investigation has been commenced and not yet completed under either of the following—

(a) regulation 16 (procedures for general medical devices clinical investigations),

(b) regulation 29 (procedures for active implantable medical devices for clinical investigations).

(2) The transitional period for this regulation ends on [*5 years from the cif date/ 1st April 2031*].

(3) Regulation 71 (amendments to Schedule 2A - modifications of Annexes to Directives 90/385, 93/42 and 98/47) of the 2026 Regulations does not apply in relation to clinical investigations within the scope of paragraph (1) during the transitional period for this regulation, with the exception of paragraphs (6)(c) and (16)(d) (provisions relating to document retention) of that regulation.

(4) Any clinical investigation being carried out under paragraph (1) that is not determined before [*the end of the transitional period in paragraph (2)/ 1st April 2031*] shall be determined under the procedures introduced by the 2026 Regulations."

DRAFT

PART 3

Amendments to Part 2 - general medical devices

Amendments to regulation 5 - interpretation of Part 2

10.—(1) Regulation 5 (interpretation of Part 2)(**a**) is amended as follows.

(2) In paragraph (1)—

(a) in the definition of "custom-made device", in paragraph (a)—

(i) omit "written";

(ii) after "prescription", insert "(in a written or electronic format)";

(b) at the appropriate places insert the following definitions—

""approved PCCP" means a PCCP that has been approved by an approved body in accordance with regulation 18(3A)(a) or (b);";

""PCCP" means, in relation to a device that is software, a pre-determined change control plan, describing what modifications can be made to the software and how the modifications will be assessed;";

(3) In paragraph (2), after "that number" insert ", unless the reference provides otherwise".

Amendment to regulation 6 - scope of Part 2

11. In regulation 6 (scope of Part 2)(**b**), after "stable derivatives devices" insert "and implantable devices".

Amendments to regulation 7 - classification of general medical devices

12. For regulation 7 (classification of general medical devices)(**c**) substitute—

"Classification of general medical devices

7.—(1) For the purposes of this Part and Part VI, devices must be classified as belonging to a class in accordance with the classification criteria set out in Schedule 9.

(2) In the event of a dispute between a manufacturer and an approved body over the classification of a device—

(a) the matter must be referred to the Secretary of State, and

(b) the Secretary of State must determine the classification of the device in accordance with the classification criteria set out in Schedule 9."

Amendments to regulation 7A - registration of persons placing general medical devices on the market

13.—(1) Regulation 7A (registration of persons placing general medical devices on the market)(**d**) is amended as follows.

(2) For paragraph (1) substitute—

(**a**) Amended by S.I. 2003/1697 and 2008/2936.
(**b**) Amended by S.I. 2021/873.
(**c**) Amended by S.I.s 2003/1697, 2007/400 and 2019/791.
(**d**) Inserted by S.I. 2019/791.

DRAFT

"No person may place a relevant device on the market in accordance with this Part unless the requirements in paragraph (2) have been complied with."

(3) In paragraph (2)—

(a) for the opening words substitute—

"The requirements to be complied with before a person may place the relevant device on the market are—";

(b) in sub-paragraph (a)—

(i) in paragraph (i)—

(aa) omit "that person is";

(bb) omit "and";

(cc) for "the person" substitute "the manufacturer";

(dd) for "registered" substitute "established";

(ii) in paragraph (ii)—

(aa) omit "that person is";

(bb) omit the first "and";

(cc) after "provides the Secretary of State with" insert "the address of the UK responsible person's established place of business in the United Kingdom and";

(dd) at the end omit "or";

(iii) for paragraph (iii), substitute—

"(iii) the person placing a device on the market is not the manufacturer of the device or the UK responsible person, the address of that person's established place of business in the United Kingdom has been provided to the Secretary of State by the manufacturer (where the manufacturer is based in Great Britain) or by the UK responsible person (where the manufacturer is based outside of the United Kingdom);";

(iv) after sub-paragraph (a) insert—

(aa) the manufacturer ensures—

(i) a UDI is assigned to the relevant device;

(ii) the UDI has been assigned according to the rules of a UDI issuing entity that is registered in accordance with Part 2 of Schedule 8 (UDI issuing entities, UDIs and registration requirements);

(iii) the requirements in Schedule 8 have been complied with, except for the UDI requirements in relation to custom-made devices; and

(iv) for custom-made devices, a UDI or another identifier is assigned to the device to enable its identification throughout the supply chain.";

(c) for sub-paragraph (b) substitute—

"(b) the manufacturer of the device, or the UK responsible person (if there is one), ensures the information set out in paragraphs 12 and 13 of Schedule 8 is submitted to the Secretary of State; and";

(d) in sub-paragraph (c), for "that person" substitute "the manufacturer of the device, or the UK responsible person (if there is one),".

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(4) In paragraph (2A), after "in accordance with" insert "a requirement in".

(5) In paragraph (3)—

(a) in sub-paragraph (a), for "declaration of conformity and technical documentation have been drawn up" substitute "declaration of conformity has been drawn up, and the technical documentation has been drawn up in accordance with regulation 8A(1)";

(b) for sub-paragraph (b) substitute—

"(b) keep available for inspection by the Secretary of State copies of the documents referred to in regulation 8A(4), for the period specified in regulation 8A(5);";

(c) for sub-paragraph (c) substitute—

"(c) comply with a request for information from the Secretary of State in accordance with regulation 8B;".

(6) In paragraph (4) —

(a) in sub-paragraph (a), for "Annex II, III or VII" substitute "regulation 8A(3)";

(b) after sub-paragraph (b) insert—

"UDI issuing entity" means a person who operates a system for the assignment of UDIs to devices and is registered in accordance with Part 2 of Schedule 8;

"established place of business" means a place in the UK which is either the person's—

(a) registered address shown in the public registers held by Companies House, or

(b) permanent principal business address,

at which place the person is physically located in the UK and from which the person carries out the activities from which the relevant device is being placed on the market."

Amendments to regulation 8 - essential requirements for general medical devices

14.—(1) Regulation 8 (essential requirements for general medical devices)(**a**) is amended as follows.

(2) In paragraph (1), after "Annex I" insert "to Regulation (EU) 2017/745 (as modified by, and as it has effect under, Parts 1 and 2 of Schedule 2B)".

(3) In paragraph (2), after "Annex I" insert "to Regulation (EU) 2017/745 (as modified by, and as it has effect under, Parts 1 and 2 of Schedule 2B)".

(4) In paragraph (3), for "to Directive 93/42" substitute "in Annex I to Regulation (EU) 2017/745 (as modified by, and as it has effect under, Parts 1 and 2 of Schedule 2B)".

New regulation 8A - technical documentation requirements for general medical devices

15. After regulation 8 insert—

(**a**) Amended by S.I. 2008/2936, 2013/2327 and 2019/791.

"Technical documentation requirements for general medical devices

8A.—(1) The manufacturer of a relevant device other than a custom-made device must draw up and keep up to date technical documentation for that device.

(2) The technical documentation in paragraph (1) must—

(a) be drawn up in a manner which allows the conformity of the device with the requirements of this Part to be assessed, and

(b) be presented in English and in a readily searchable format.

(3) For the purposes of this regulation, the "technical documentation" is—

(a) the documentation listed in Annex II to Regulation (EU) 2017/745 (as modified by, and as it has effect under, Part 3 of Schedule 2B),

(b) in relation to implantable devices, the implant card and leaflet relating to the device which is required under regulation 19E (information about implantable devices),

(c) documentation relating to the device that the manufacturer is required to retain under regulation 44ZQ (retention of post-market surveillance documentation), and

(d) in the case of devices that are software, the PCCP relating to the device where the manufacturer has chosen to have one under regulation 19F.

(4) The manufacturer of a relevant device and the UK responsible person (if there is one) must retain the following for the period specified in paragraph (5)—

(a) the technical documentation,

(b) the declaration of conformity of the device, and

(c) certificates in respect of the device, including any amendments and supplements where one is required.

(5) The period for the purposes of paragraph (4)—

(a) begins with the date of the last manufacture of the device by the manufacturer, and

(b) ends with the later of—

(i) the lifetime of the device, and

(ii) 15 years in the case of an implantable device, or 10 years in the case of any other device.

(6) A manufacturer who is based outside the UK must ensure the UK responsible person keeps available the documentation referred to in paragraph (4) for the required periods.".

New regulation 8B - inspection of general medical device technical documentation by the Secretary of State

16. After the new regulation 8A (new regulation 8A - technical documentation requirements for general medical devices) insert—

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"Inspection of general medical device technical documentation by the Secretary of State

8B.—(1) A manufacturer and the UK responsible person (if there is one) must keep available a copy of the documentation retained under regulation 8A(4) for inspection by the Secretary of State.

(2) A manufacturer or the UK responsible person (if there is one) must make the documentation retained under regulation 8A(4) available to the Secretary of State upon request.

(3) The Secretary of State may request that the documentation be provided in summary form.

(4) The manufacturer or the UK responsible person (if there is one) must comply with a request made by the Secretary of State under paragraph (2) or (3) before the end of—

(a) the period of three working days beginning with the day on which the Secretary of State makes the request, or

(b) such longer period as may be agreed by the Secretary of State in a particular case.

(5) The requirements of this regulation cease to have effect in relation to a device at the end of the period specified in regulation 8A(5).".

Amendments to regulation 9 - determining compliance of general medical devices with relevant essential requirements

17.—(1) Regulation 9 (determining compliance of general medical devices with relevant essential requirements)(**a**) is amended as follows.

(2) For paragraph (2) substitute—

"(2) Where confirmation of conformity with the essential requirements must be based on clinical data, such data must be established in accordance with—

(a) the requirements set out in Annex X, and

(b) where the manufacturer is using clinical data to demonstrate in a clinical evaluation that a relevant device is equivalent to one or more devices in accordance with paragraph 1.1.1 of Annex X, the requirements set out in regulation 9A."

(3) In paragraph (3)—

(a) in sub-paragraph (a)—

(i) for "Sections 8.7 and 13" substitute "Sections 11.8 and 23";

(ii) after "Annex I" insert "to Regulation (EU) 2017/745 (as modified by, and as it has effect under, Parts 1 and 2 of Schedule 2B)";

(b) in sub-paragraph (b)—

(i) for "Sections 11.4 and 13" substitute "Sections 16.1(b) and 23";

(ii) after "Annex I" insert "to Regulation (EU) 2017/745 (as modified by, and as it has effect under, Parts 1 and 2 of Schedule 2B)".

(4) In paragraph (5)—

(a) in sub-paragraph (a), for "Annex VIII" substitute "regulation 15";

(b) in sub-paragraph (b), for "Section 1 of Annex VIII" substitute "regulation 15(1)(a)".

(**a**) Amended by S.I.s 2008/2936, 2019/791 and 2021/873.

DRAFT

(5) In paragraph (5A), for "Sections 1 and 2 of Annex VIII", wherever occurring, substitute "regulation 15(1)(a) and (4)".

(6) In paragraph (6), for "Section 2.1 of Annex VIII" substitute "regulation 15(5)(b)".

(7) In paragraph (8), after "Annex I" insert "to Regulation (EU) 2017/745 (as modified by, and as it has effect under, Parts 1 and 2 of Schedule 2B)".

New regulation 9A - equivalence in relation to general medical devices

18. After regulation 9 insert—

"Equivalence in relation to general medical devices

9A.—(1) A manufacturer may only use clinical data from another device in a clinical evaluation for a relevant device when it is demonstrated that the relevant device is equivalent to one or more other devices in accordance with this regulation.

(2) The manufacturer must demonstrate that the relevant device is equivalent to each device to which equivalence is claimed in accordance with paragraphs (3) to (6).

(3) In order to demonstrate equivalence between the relevant device and the device to which equivalence is claimed, the manufacturer must take into consideration—

(a) technical characteristics, where the relevant device and the device to which equivalence is claimed—

(i) are of similar design;

(ii) are used under similar conditions of use;

(iii) have similar specifications and properties including physicochemical properties such as intensity of energy, tensile strength, viscosity, surface characteristics, wavelength and software algorithms;

(iv) use similar deployment methods, and

(v) have similar principles of operation and critical performance requirements;

(b) biological characteristics, where the relevant device and the device to which equivalence is claimed use materials or substances that do not result in new or increased biological risks;

(c) clinical characteristics, where the relevant device and the device to which equivalence is claimed—

(i) are used for a similar clinical condition or purpose, including similar severity and stage of disease, in a similar population taking into account characteristics including age, sex, anatomy, ethnicity and physiology;

(ii) are used at the same site in the body;

(iii) have the same category of user, and

(iv) have similar relevant critical performance in view of the expected clinical effect for a specific intended purpose.

(4) The technical, biological and clinical characteristics must demonstrate no clinically significant difference between the safety and clinical performance of the relevant device and the device to which equivalence is claimed, unless the difference has been introduced to improve the safety and clinical performance of the relevant device.

(5) Consideration of the technical, biological and clinical characteristics must be based on—

(a) scientific justification, and

DRAFT

(b) when identifying and assessing characteristics of a relevant device that may affect performance and safety, a risk-based approach.

(6) In the case of a relevant device that is software, the manufacturer must ensure that—

(a) the intended purpose is the same as the device to which equivalence is claimed, and

(b) data inputs and outputs including, where applicable, model type and training data, of the relevant device are similar to those of the device to which equivalence is claimed.

(7) A manufacturer's demonstration of equivalence for a relevant device does not need to include software that is—

(a) only for the purpose of configuration of the relevant device, and

(b) not related to the intended purpose of the relevant device.

(8) The clinical data used by the manufacturer to demonstrate equivalence must relate to a specific version of the device to which equivalence is claimed.

(9) Where a manufacturer is demonstrating equivalence in respect of a relevant device which is an implantable device falling within Class IIb or Class III, the device to which equivalence is claimed must—

(a) bear a UK marking,

(b) bear a CE marking, or

(c) have a Certificate of International Reliance pursuant to regulation 74 (certificate of international reliance).

(10) The manufacturer must—

(a) document the demonstration of equivalence, and

(b) keep available for the Secretary of State the documentation demonstrating that the relevant device is equivalent to one or more devices, for the period specified in paragraph (11).

(11) The period ends with the later of—

(a) the lifetime of the device,

(b) in the case of an implantable device, 15 years, and

(c) in the case of any other device, 10 years."

Amendments to regulation 13 - procedures for affixing a UK marking to general medical devices

19.—(1) Regulation 13 (procedures for affixing a UK marking to general medical devices)(**a**) is amended as follows.

(2) After paragraph (1) insert—

"(1A) For the purposes of the declaration in paragraph (1)(b), in relation to a relevant device that is software, where—

(a) a manufacturer has chosen to have a PCCP under regulation 19F, and

(b) where applicable, that PCCP has been approved by an approved body under regulation 18(3A)(a) or (b),

(**a**) Amended by S.I. 2003/1697, S.I. 2013/2327 and S.I. 2019/791.

DRAFT

the manufacturer must include in the declaration of conformity a reference to the PCCP and, where applicable, the approved PCCP."

(3) After paragraph (2) insert—

"(2A) For the purposes of the declaration in paragraph (2)(b), in relation to a relevant device that is software, where—

(a) a manufacturer has chosen to have a PCCP under regulation 19F, and

(b) that PCCP has been approved by an approved body under regulation 18(3A)(a) or (b),

the manufacturer must ensure that any certificate issued by the approved body in connection with the conformity procedure set out in the Annexes referred to in paragraph (2)(a) includes a reference to the approved PCCP."

(4) After paragraph (3) insert—

"(3A) For the purposes of the declaration in paragraph (3)(b), in relation to a relevant device that is software, where—

(a) a manufacturer has chosen to have a PCCP under regulation 19F, and

(b) that PCCP has been approved by an approved body under regulation 18(3A)(a) or (b),

the manufacturer must ensure that any certificate issued by the approved body in connection with the conformity procedure set out in the Annexes referred to in paragraph (3)(a) includes a reference to the approved PCCP."

(5) After paragraph (4) insert—

"(4A) For the purposes of the declaration in paragraph (4)(b), in relation to a relevant device that is software, where—

(a) a manufacturer has chosen to have a PCCP under regulation 19F, and

(b) that PCCP has been approved by an approved body under regulation 18(3A)(a) or (b),

the manufacturer must ensure that any certificate issued by the approved body in connection with the conformity procedure set out in the Annexes referred to in paragraph (4)(a) includes a reference to the approved PCCP."

Amendments to regulation 14 - procedures for systems and procedure packs, and for devices to be sterilised before use

20.—(1) Regulation 14 (procedures for systems and procedure packs, and for devices to be sterilised before use)(**a**) is amended as follows.

(2) In paragraph (5), in sub-paragraph (b)—

(a) for "Section 13" substitute "Section 23";

(b) after "Annex I" insert "to Regulation (EU) 2017/745 (as modified by, and as it has effect under, Parts 1 and 2 of Schedule 2B)".

(3) In paragraph (6), for "a the period of five years" substitute—

"the later of—

(a) the lifetime of the device;

(**a**) Amended by S.I.s 2008/2936 and 2019/791.

DRAFT

(b) in the case of an active implantable medical device, 15 years from the date of the last manufacture of the device by the manufacturer;

(c) in the case of any device that is not an active implantable medical device, 10 years from the date of the last manufacture of the device by the manufacturer."

Amendments to regulation 15 - procedures for custom-made general medical devices

21.—(1) The version of regulation 15 that applies to England and Wales, and Scotland (procedures for custom-made general medical devices)(**a**) is amended as follows.

(2) The existing provision becomes paragraph (1).

(3) In the new paragraph (1)—

(a) at the start insert "Subject to paragraph (2),";

(b) in sub-paragraph (a), for "Sections 1, 2 and 2.1 of Annex VIII, read with Regulation (EU) No 722/2012" substitute "paragraph (4)";

(c) in sub-paragraph (b)—

(i) for "Directive 93/42" substitute "Annex I to Regulation (EU) 2017/745 (as modified, and as it has effect under, by Parts 1 and 2 of Schedule 2B), read with Regulation No 722/2012";

(ii) omit the "and" at the end;

(d) in sub-paragraph (c), for "the first paragraph of Section 3.1 of Annex VIII" substitute "sub-paragraph (b)";

(e) for sub-paragraph (d), substitute—

"(d) keeps available for the Secretary of State, for the period specified in paragraph (6)—

(i) the information contained in the statement referred to in sub-paragraph (a) and in the undertaking referred to in sub-paragraph (b), and

(ii) the documentation relating to the custom-made device that the manufacturer is required to retain under regulation 44ZQ (retention of post-market surveillance documentation); and";

(f) in sub-paragraph (e), after "patient" insert "or user".

(4) After paragraph (1), insert—

"(2) A custom-made implantable device falling within Class IIb or Class III may be supplied only if the manufacturer fulfils the obligations imposed by Section 1 and Section 3 of Annex II (as modified by Schedule 2A), with regard to establishing a quality system for the device which must be certified by an approved body.

(3) A custom-made implantable device falling within Class IIb or Class III shall be treated as complying with paragraph (2) if it conforms as respects that requirement to a relevant designated standard, unless there are reasonable grounds for suspecting that it does not comply with that requirement.

(4) For the purposes of paragraph (1)(a), the statement must contain—

(a) information, including the product name, the product code (if applicable), and the UDI or other identifier assigned to the device which enables the device in question to be identified throughout the supply chain;

(**a**) Amended by S.I.s 2008/2936, 2013/2327 and 2019/791.

DRAFT

(b) a declaration that the device is intended for the sole use of a named patient or user;

(c) sufficient blank space for the provider of the custom-made device to record—

(i) the name of the patient or user;

(ii) the name of the registered medical practitioner or authorised person in accordance with the prescription generated for the manufactured device and, if applicable, the name of the medical facility in question;

(d) a description of the particular features of the device as specified in the prescription for the manufacture of the device, and

(e) a declaration under paragraph (5).

(5) The declaration must contain—

(a) a statement that the device conforms to the relevant essential requirements set out in Annex I to Regulation (EU) 2017/745 (as modified by, and as it has effect under, Parts 1 and 2 of Schedule 2B), read with Regulation (EU) No 722/2012, or

(b) in cases where the manufacturer has not met all relevant essential requirements a statement—

(i) indicating which of the relevant essential requirements mentioned in paragraph (a) are and are not met in relation to the device, and

(ii) explaining why that is the case.

(6) The period for the purposes of paragraph (1)(d)—

(a) begins with the date on which the device was last manufactured by the manufacturer, and

(b) ends with the later of—

(i) the lifetime of the device,

(ii) in the case of an implantable device, 15 years, and

(iii) in the case of any other device, 10 years."

Amendments to regulation 17 - manufacturers etc. and conformity assessment procedures for general medical devices

22.—(1) Regulation 17 (manufacturers etc. and conformity assessment procedures for general medical devices)(**a**) is amended as follows.

(2) In paragraph (1), for "A manufacturer" substitute "Subject to paragraph (1A), a manufacturer".

(3) After paragraph (1) insert—

"(1A) The requirements in Section 3.4 of Annex II relating to notifying the approved body of substantial changes to the product range do not apply to changes to a device which is software and—

(a) the change is set out in an approved PCCP,

(b) the change has been made in accordance with the approved PCCP, and

(c) the manufacturer has—

(i) notified the approved body within 10 working days beginning with the day of the change, and

(**a**) Amended by S.I.s 2003/1697, 2013/2327 and 2019/791.

(ii) confirmed that the requirements of sub-paragraphs (a) and (b) have been met."

(4) After paragraph (2) insert—

"(2A) Subject to paragraph (2B), a manufacturer of a relevant device that is a software who—

(a) is required to follow a conformity procedure set out in this Part which requires the involvement of an approved body, and

(b) has chosen to have a PCCP under regulation 19F,

must include the PCCP in the manufacturer's application to an approved body for the conformity procedure, for approval by the approved body.

(2B) If a manufacturer is unable to include a PCCP in the application at the time the application is made, it may be supplied at such later date as may be agreed with the approved body."

Amendments to regulation 18 - approved bodies and the conformity assessment procedures for general medical devices

23.—(1) Regulation 18 (approved bodies and the conformity assessment procedures for general medical devices)(**a**) is amended as follows.

(2) In paragraph (2), after "in accordance with" insert "paragraph (3A) or".

(3) After paragraph (3) insert—

"(3A) Where a manufacturer has submitted a PCCP to an approved body in accordance with regulation 17(2A), the approved body may—

(a) approve the PCCP with no conditions or restrictions, if the PCCP meets the requirements specified in regulation 19F(2)(a),

(b) approve the PCCP subject to such conditions or restrictions that the approved body considers appropriate, with which the manufacturer must comply prior to implementing the proposed modifications described in the PCCP, or

(c) refuse to approve the PCCP,

and the approved body must notify the manufacturer of its decision.

(3B) In the event of a dispute between a manufacturer and an approved body over the conditions or restrictions applied to the PCCP under paragraph (3A)(b), the matter must be referred for determination by the Secretary of State.

(3C) Where an approved body has approved a PCCP in accordance with paragraph (3A)(a) or (b), it must include a reference to the approved PCCP in the certificate issued in connection with the relevant conformity procedure carried out in accordance with regulation 13."

New regulation 19D - misleading or unsubstantiated claims about general medical devices

24. After regulation 19C (obligations in Part 2 and 3 of these Regulations which are met by complying with obligations in Regulation (EU) 2017/745) (**b**) insert—

(**a**) Amended by S.I.s 2003/1697, 2008/2936, 2013/2327 and 2019/791.
(**b**) Inserted by S.I. 2019/791. Regulation 19C was amended by regulation 1ZA of S.I. 2002/618. It is partially in force in relation to England and Wales, and Scotland, and is not yet in force in relation to Northern Ireland.

DRAFT

"Misleading or unsubstantiated claims about general medical devices

19D.—(1) A person who creates or modifies a relevant article relating to a relevant device, or who promotes a relevant device for financial or other material advantage, must not mislead the user or the patient with regard to the device's intended purpose, safety or performance by—

(a) suggesting through the article or promotion that the device has a function or property which it does not have or which cannot be established from available evidence,

(b) failing to inform the user or patient of any significant risk associated with the use of the device for its intended purpose,

(c) suggesting through the article or promotion uses for the device other than those stated to form part of the intended purpose for which the conformity assessment was carried out, including using the device in combination with other devices or equipment where that combination has not been conformity assessed, or

(d) in relation to devices intended for clinical investigation, suggesting through the article or promotion uses for the device other than those stated to form part of the intended purpose which the clinical investigation is being carried out to verify.

(2) Where the Secretary of State is determining whether a person has complied with paragraph (1), the Secretary of State may, in particular—

(a) take into account whether the language or imagery used in the relevant article or promotion was liable to mislead the intended audience;

(b) have regard to suggestions made explicitly or implicitly, through language or imagery, or through a particular feature or combination of features of the relevant article or promotion.

(3) For the purposes of this regulation, "relevant article" includes instructions for use, labelling, packaging and any promotional or sales material relating to the relevant device."

New regulation 19E - information about implantable devices

25. After the new regulation 19D insert—

"Information about implantable devices

19E.—(1) A person who places an implantable device on the market must ensure that the device is accompanied by—

(a) a printed or electronic copy of a leaflet meeting the requirements of paragraphs (2), (3) and (5), and

(b) a printed copy of an implant card meeting the requirements of paragraphs (4) and (5).

(2) The leaflet must include—

(a) information allowing for the identification of the device, including the device's name, and device model;

(b) the name, address and website of the device's manufacturer;

(c) a statement of the expected lifetime of the device and any requirements relating to the safety or performance of the device;

DRAFT

(d) warnings, precautions or measures to be taken by the patient or a healthcare professional regarding reciprocal interference with reasonably foreseeable external influences, medical examinations or environmental conditions;

(e) qualitative and quantitative information on the materials and substances in the implantable device to which the patient could be exposed;

(f) any other warnings or information necessary for the safe use of the device by the patient; and

(g) the address of the website where an online copy of the leaflet and implant card, including any updates, can be accessed.

(3) The leaflet must be written in English and in a manner intended to be comprehensible to a lay person.

(4) The implant card must—

(a) contain information allowing for the identification of the device, including the device's name, serial number or lot number, UDI and device model;

(b) have sufficient blank space for an entity providing healthcare that implants a device to record the patient's name, the name of the entity and the date of implantation;

(c) be made of material suitable for long-term use and legibility; and

(d) include the name, address and website of the manufacturer of the device.

(5) The characters used to convey the information contained in a leaflet and implant card in accordance with paragraph (2) or (4)(a) must be at least 3 millimetres in height.

(6) The manufacturer of the implantable device must maintain an updated copy of the leaflet and the implant card on its website for the period specified in paragraph (7).

(7) The period—

(a) begins with the day on which the device is placed on the market, and

(b) ends with the later of—

(i) the lifetime of the device, and

(ii) 15 years.

(8) An entity providing healthcare that implants a device in a patient must—

(a) provide to the patient a copy of the leaflet and the implant card relating to the device; and

(b) record and maintain information sufficient for the implantable device, including the UDI, to be associated with the patient in which it was implanted.

(9) This regulation does not apply in relation to sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips or connectors."

New regulation 19F - pre-determined change control plan option for software

26. After the new regulation 19E insert—

"Pre-determined change control plan option for software

19F.—(1) A manufacturer of a relevant device that is software may choose to have a PCCP for that software.

(2) A manufacturer that chooses to have a PCCP must—

(a) include within that PCCP—

DRAFT

(i) a description of the proposed modifications to the software and a statement confirming that the proposed modifications fall within the device's intended purpose,

(ii) a modification protocol which describes the process to be followed by the manufacturer in implementing the proposed modifications, and

(iii) a review of the risk management system,

(b) include the PCCP in the device's technical documentation in accordance with regulation 8A, and

(c) subject to paragraph (4), report any substantial deviation from the PCCP to the approved body for that device.

(3) Subject to paragraph (4), a manufacturer may not implement the proposed modifications described in the PCCP unless—

(a) the PCCP has been reviewed and approved by the approved body in accordance with regulation 18(3A)(a), and

(b) the PCCP has been reviewed and approved by the approved body, and the manufacturer has complied with the conditions or restrictions applied to the PCCP in accordance with regulation 18(3A)(b).

(4) Paragraphs (2)(c) and (3) only apply to a relevant device that is software if—

(a) it is a Class I device for which the conformity assessment procedure under Annex VII requires the involvement of an approved body, or

(b) it falls within Class IIa, IIb or III."

PART 4

Amendments to Part 3 - active implantable medical devices

Amendments to regulation 20 - interpretation of Part 3

27.—(1) Regulation 20(1) (interpretation of Part 3)(**a**) is amended as follows.

(2) At the appropriate place insert—

""accessory"means an article which, whilst not being a medical device, is intended specifically by its manufacturer to be used together with a medical device to enable it to be used in accordance with the use of the medical device intended by its manufacturer;".

(3) In the definition of "custom-made device", in paragraph (a)—

(a) omit "written";

(b) after "prescription" insert "(in a written or electronic format)".

(4) In paragraph (2), after "that number" insert ", unless the reference provides otherwise".

Amendment to regulation 21 - scope of Part 3

28. In regulation 21(2) (scope of Part 3)(**b**), for "Directive 90/385" substitute "Regulation (EU) 2017/745 (as modified by, and as it has effect under, Parts 1 and 2 of Schedule 2B)".

(**a**) Amended by S.I. 2003/1697.
(**b**) Amended by S.I.s 2008/2936, 2019/791, and 2021/873.

DRAFT

New regulation 21ZA - classification of active implantable medical devices

29. After regulation 21 insert—

"Classification of active implantable medical devices

21ZA.—(1) For the purposes of this Part and Part VI, devices must be classified as belonging to a class in accordance with the classification criteria set out in Schedule 9.

(2) In the event of a dispute between a manufacturer and an approved body over the classification of a device—

(a) the matter must be referred to the Secretary of State; and

(b) the Secretary of State must determine the classification of the device in accordance with the classification criteria set out in Schedule 9."

Amendments to regulation 21A - registration of persons placing active implantable medical devices on the market

30.—(1) Regulation 21A(**a**) is amended as follows.

(2) For paragraph (1) substitute—

"(1) No person may place a relevant device on the market in accordance with this Part unless that person has complied with the requirements in paragraph (2)."

(3) For paragraph (2) substitute—

"(2) The requirements are—

(a) where—

(i) the manufacturer of that device is based in Great Britain, the manufacturer informs the Secretary of State of the address of their established place of business in Great Britain;

(ii) the manufacturer of that device is based outside the United Kingdom, and the manufacturer appoints a sole UK responsible person, and that UK responsible person provides the Secretary of State with—

(aa) the address of the UK responsible person's established place of business in the United Kingdom, and

(bb) written evidence that they have the manufacturer's authority to act as their UK responsible person; or

(iii) the person placing a device on the market is not the manufacturer of the device or the UK responsible person, the address of that person's established place of business in the United Kingdom has been provided to the Secretary of State by the manufacturer (where the manufacturer is based in Great Britain) or by the UK responsible person (where the manufacturer is based outside the United Kingdom);

(aa) the manufacturer ensures—

(i) a UDI is assigned to the relevant device,

(ii) the UDI has been assigned according to the rules of a UDI issuing entity that is registered in accordance with Part 2 of Schedule 8;

(**a**) Inserted by S.I. 2019/791.

DRAFT

(iii) other than for custom-made devices, the requirements in Schedule 8 have been complied with; and

(iv) for custom-made devices, a UDI or another identifier is assigned to the device, to enable its identification throughout the supply chain.

(b) the manufacturer of the device, or the UK responsible person (if there is one) ensures the information set out in paragraphs 12 and 13 of Schedule 8 is submitted to the Secretary of State; and

(c) the manufacturer of the device, or the UK responsible person (if there is one), pays to the Secretary of State the relevant fee in accordance with regulation 53."

(4) In paragraph (3)—

(a) in sub-paragraph (a), for "declaration of conformity and technical documentation have been drawn up" substitute "declaration of conformity has been drawn up and the technical documentation has been drawn up in accordance with regulation 22A(1)";

(b) for sub-paragraph (b) substitute—

"(b) keep available for inspection by the Secretary of State copies of the documents referred to in regulation 22A(4) for the period specified in regulation 22A(5);";

(c) for sub-paragraph (c), substitute—

"(c) comply with a request for information from the Secretary of State in accordance with regulation 22B;".

(5) In paragraph (4)—

(a) in sub-paragraph (a), for "Annex 2, 3 or 5" substitute "regulation 22A(3)";

(b) after sub-paragraph (b), insert—

"UDI issuing entity" means a person who operates a system for the assignment of UDIs to devices and is registered in accordance with Part 2 of Schedule 8;

"established place of business" means a place in the UK which is either the person's—

(i) registered address shown in the public registers held by Companies House, or

(ii) permanent principal business address, from which the person is physically located in the UK and from which the person carries out business activities from which the relevant device to be placed on the market."

Amendments to regulation 22 - essential requirements for active implantable medical devices

31.—(1) Regulation 22(**a**) is amended as follows.

(2) In paragraph (1), after "Annex 1" insert "to Regulation (EU) 2017/745 (as modified by, and as it has effect under, Parts 1 and 2 of Schedule 2B)".

(3) In paragraph (2), after "Annex 1" insert "to Regulation (EU) 2017/745 (as modified by, and as it has effect under, Parts 1 and 2 of Schedule 2B)".

(**a**) Amended by S.I. 2013/2327.

DRAFT

New regulation 22A - technical documentation requirements for active implantable medical devices

32. After regulation 22 insert—

"Technical documentation requirements for active implantable medical devices

22A.—(1) The manufacturer of a relevant device, other than a custom-made device, must draw up and keep up to date technical documentation for that device.

(2) The technical documentation in paragraph (1) must—

(a) be drawn up in a manner which allows the conformity of the device with the requirements of this Part to be assessed, and

(b) be presented in English and in a readily searchable format.

(3) For the purposes of this regulation, "technical documentation" is—

(a) the documentation listed in Annex II to Regulation (EU) 2017/745 (as modified by, as has it has effect under, Part 3 of Schedule 2B),

(b) the implant card and leaflet relating to the device, which is required under Regulation 31B, and

(c) documentation relating to the device that the manufacturer is required to retain under regulation 44ZQ (retention of post-market surveillance documentation).

(4) The manufacturer of a relevant device and the UK responsible person (if there is one) must retain the following for the period specified in paragraph (5)—

(a) the technical documentation,

(b) the declaration of conformity of the device, and

(c) any certificates in respect of the device, including any amendments and supplements.

(5) The period—

(a) begins with the date on which the device was last manufactured by the manufacturer, and

(b) ends with the later of—

(i) the lifetime of the device, and

(ii) 15 years.

(6) A manufacturer who is based outside the UK must ensure the UK responsible person keeps available the documentation referred to in paragraph (4) for the period specified in paragraph (5)."

New regulation 22B - inspection of active implantable device technical documentation by the Secretary of State

33. After the new regulation 22A, insert—

DRAFT

"Inspection of active implantable device technical documentation by the Secretary of State

22B.—(1) A manufacturer and the UK responsible person (if there is one) must keep available a copy of the documentation retained under regulation 22A(4) for inspection by the Secretary of State.

(2) A manufacturer or the UK responsible person (if there is one) must make the documentation referred to in regulation 22A(4) available to the Secretary of State upon request.

(3) Secretary of State may request that such documentation is provided in summary form.

(4) The manufacturer or the UK responsible person (if there is one) must comply with a request made by the Secretary of State under paragraph (2) or (3) before the end of—

(a) the period of three working days beginning with the day on which the Secretary of State makes the request, or

(b) such longer period as may be agreed by the Secretary of State in a particular case.

(5) The requirements of this regulation cease to have effect in relation to a device at the end of the period specified in regulation 22A(5)."

Amendments to regulation 23 - determining compliance of active implantable medical devices with relevant essential requirements

34.—(1) Regulation 23(**a**) is amended as follows.

(2) In paragraph (2), in sub-paragraph (a)—

(a) for "paragraphs 1 to 5" substitute "Sections 1 to 8";

(b) after "Annex 1" insert "to Regulation (EU) 2017/745 (as modified by, and as it has effect under, Parts 1 and 2 of Schedule 2B)".

(3) After paragraph (2) insert—

"(2A) Where a manufacturer is using clinical data to demonstrate in a clinical evaluation that a relevant device is equivalent to one or more devices in accordance with paragraph 1.1.1 of Annex 7, such data must be established in accordance with the requirements set out in regulation 23A."

(4) In paragraph (3)—

(a) in sub-paragraph (a)—

(i) for "paragraph 14" substitute "Sections 23.2 and 23.3";

(ii) after "Annex 1" insert "to Regulation (EU) 2017/745 (as modified by, and as it has effect under, Parts 1 and 2 of Schedule 2B)";

(b) in sub-paragraph (b)—

(i) for "paragraph 13" substitute "Section 21.3";

(ii) after "Annex 1", wherever occurring, insert "to Regulation (EU) 2017/745 (as modified by, and as it has effect under, Parts 1 and 2 of Schedule 2B)";

(iii) for "paragraph 15" substitute "Section 23.4".

(5) In paragraph (5)—

(a) for the first "Annex 6" substitute "regulation 28";

(**a**) Amended by S.I. 2021/873.

DRAFT

(b) for "paragraph 1 of Annex 6" substitute "regulation 28(1)(a)".

New regulation 23A - equivalence in relation to active implantable medical devices

35.—(1) After regulation 23, insert—

"Equivalence in relation to active implantable medical devices

23A.—(1) A manufacturer may only use clinical data from another device in a clinical evaluation for a relevant device when it is demonstrated that the relevant device is equivalent to one or more other devices in accordance with this regulation.

(2) The manufacturer must demonstrate that the relevant device is equivalent to each device to which equivalence is claimed in accordance with paragraphs (3) to (5).

(3) In order to demonstrate equivalence between the relevant device and the device to which equivalence is claimed, the manufacturer must take into consideration—

(a) technical characteristics, where the relevant device and the device to which equivalence is claimed—

(i) are of similar design;

(ii) are used under similar conditions of use;

(iii) have similar specifications and properties including physicochemical properties such as intensity of energy, tensile strength, viscosity, surface characteristics and wavelength and software algorithms;

(iv) use similar deployment methods, and

(v) have similar principles of operation and critical performance requirements;

(b) biological characteristics where the relevant device and the device to which equivalence is claimed use materials or substances that do not result in new or increased biological risks;

(c) clinical characteristics where the relevant device and the device to which equivalence is claimed—

(i) are used for a similar clinical condition or purpose, including similar severity and stage of disease, in a similar population, including as regards age, sex, anatomy, ethnicity and physiology;

(ii) are used at the same site in the body;

(iii) have the same category of user, and

(iv) have similar relevant critical performance in view of the expected clinical effect for a specific intended purpose.

(4) The technical, biological and clinical characteristics must demonstrate no clinically significant difference between the safety and clinical performance of the relevant device and the device to which equivalence is claimed, unless the difference has been introduced to improve the safety and clinical performance of the relevant device.

(5) Consideration of the technical, biological and clinical characteristics must be based on—

(a) scientific justification, and

(b) when identifying and assessing characteristics of a relevant device that may affect performance and safety, a risk-based approach.

(6) The clinical data used by the manufacturer to demonstrate equivalence must relate to a specific version of the device to which equivalence is claimed.

DRAFT

(7) The device to which equivalence is claimed must—

(a) bear a UK marking,

(b) bear a CE marking, or

(c) have a Certificate of International Reliance pursuant to regulation 74.

(8) The manufacturer must—

(a) document the demonstration of equivalence, and

(b) keep available for the Secretary of State the documentation demonstrating that the relevant device is equivalent to one or more devices, for the period specified in paragraph (9).

(9) The period ends with the later of—

(a) the lifetime of the device, and

(b) 15 years."

Amendments to regulation 28 - procedures for custom-made active implantable medical devices

36.—(1) The version of regulation 28(**a**) that applies to England and Wales, and Scotland is amended as follows.

(2) The existing provision becomes paragraph (1).

(3) In paragraph (1)—

(a) for "No" substitute "Subject to paragraph (2), no";

(b) in sub-paragraph (a), for "Section 2.1 of Annex 6, read with Regulation (EU) No 722/2012" substitute "paragraph (4)";

(c) in sub-paragraph (b), for "referred to in Section 3.1 of Annex 6" substitute "allowing an understanding of the design, manufacturer and performances of the devices, including the expected performances, so as to allow assessment of conformity of the device with the requirements of Annex I to Regulation (EU) 2017/745 (as modified by, and as it has effect under, Parts 1 and 2 of Schedule 2B), read with Regulation (EU) No 722/2012";

(d) in sub-paragraph (c), for "the first paragraph of Section 3.1 of Annex 6" substitute "sub-paragraph (b)";

(e) for sub-paragraph (d) substitute—

"(d) keeps available for the Secretary of State, for the period specified in paragraph (6)—

(i) the information contained in the statement referred to in sub-paragraph (a) and in the undertaking referred to in sub-paragraph (b), and

(ii) the documentation relating to the custom-made device that the manufacturer is required to retain under regulation 44ZQ (retention of post-market surveillance documentation);";

(f) after sub-paragraph (d) insert—

"(e) ensures that the statement is passed on with the custom-made device so that it may be made available to the patient or user."

(4) After paragraph (1) insert—

(**a**) Amended by S.I.s 2013/2327 and 2019/791.

DRAFT

"(2) A custom-made active implantable medical device may be supplied only if the manufacturer fulfils the obligations imposed by Section 1 and Section 3 of Annex 2, with regard to establishing a quality system for the device which must be certified by an approved body.

(3) A custom-made active implantable medical device shall be treated as complying with paragraph (2) if it conforms as respects that requirement to a relevant designated standard, unless there are reasonable grounds for suspecting that it does not comply with that requirement.

(4) For the purposes of paragraph (1)(a), the statement must contain—

(a) information, including the product name, the product code (if applicable), and the UDI or other identifier assigned to the device which enables the device in question to be identified throughout the supply chain;

(b) a declaration that the device is intended for the sole use of a named patient or user,

(c) sufficient blank space for the provider of the custom-made device to record—

(i) the name of the patient or user;

(ii) the name of the registered medical practitioner or authorised person in accordance with whose prescription the device is manufactured and, if applicable, the name of the medical facility in question;

(d) a description of the particular features of the device as specified in the prescription for the manufacture of the device; and

(e) a declaration under paragraph (5).

(5) The declaration must contain—

(a) a statement that the device in question conforms to the relevant essential requirements set out in Annex I to Regulation (EU) 2017/745 (as modified by, and as it has effect under, Parts 1 and 2 of Schedule 2B), read with Regulation (EU) No 722/2012, or

(b) in cases where the manufacturer has not met all relevant essential requirements a statement—

(i) indicating which of the relevant essential requirements mentioned in paragraph (a) are and are not met in relation to the device, and

(ii) explaining why that is the case.

(6) The period for the purposes of sub-paragraph (1)(d)—

(a) begins with the date on which the device was last manufactured by the manufacturer, and

(b) ends with the later of—

(i) the lifetime of the device, and

(ii) 15 years."

New regulation 31A - misleading or unsubstantiated claims about active implantable medical devices

37. After regulation 31 insert—

DRAFT

"Misleading or unsubstantiated claims about active implantable medical devices

31A.—(1) A person who creates or modifies a relevant article relating to a relevant device, or who promotes a relevant device for financial or other material advantage, must not mislead the user or the patient with regard to the device's intended purpose, safety or performance by—

(a) suggesting through the article or promotion that the device has a function or property which it does not have or which cannot be established from available evidence,

(b) failing to inform the user or patient of any significant risk associated with the use of the device for its intended purpose,

(c) suggesting through the article or promotion uses for the device other than those stated to form part of the intended purpose for which the conformity assessment was carried out, including using the device in combination with other devices or equipment where that combination has not been conformity assessed, or

(d) where the device is intended for clinical investigation, suggesting through the article or promotion a medical use for the device other than a use stated to form part of the intended purpose which the clinical investigation is being carried out to verify.

(2) Where the Secretary of State is determining whether a person has complied with paragraph (1), the Secretary of State may, in particular—

(a) take into account whether the language or imagery used in the relevant article or promotion was liable to mislead the intended audience;

(b) have regard to suggestions made explicitly or implicitly, through language or imagery, or through a particular feature or combination of features of the relevant article or promotion.

(3) For the purposes of this regulation, "relevant article" includes instructions for use, labelling, packaging and any promotional or sales material relating to the relevant device."

New regulation 31B - information about active implantable medical devices

38. After the new regulation 31A, insert—

"Information about active implantable medical devices

31B.—(1) A person who places an active implantable medical device on the market must ensure that the device is accompanied by—

(a) a printed or electronic copy of a leaflet meeting the requirements of paragraphs (2), (3) and (5), and

(b) a printed copy of an implant card meeting the requirements of paragraphs (4) and (5).

(2) The leaflet must include—

(a) information allowing for the identification of the device, including the device's name, and device model;

(b) the name, address and website of the device's manufacturer;

(c) a statement of the expected lifetime of the device and any requirements relating to the safety or performance of the device;

DRAFT

(d) warnings, precautions or measures to be taken by the patient or a healthcare professional regarding reciprocal interference with reasonably foreseeable external influences, medical examinations or environmental conditions;

(e) qualitative and quantitative information on the materials and substances in the implantable device to which the patient could be exposed;

(f) any other warnings or information necessary for the safe use of the device by the patient; and

(g) the address of the website where an online copy of the leaflet and implant card, including any updates, can be accessed.

(3) The leaflet must be written in English and in a manner intended to be comprehensible to a lay person.

(4) The implant card must—

(a) contain information allowing for the identification of the device, including the device's name, serial number or lot number, UDI and device model;

(b) have sufficient blank space for an entity providing healthcare that implants a device to record the patient's name, the name of the entity and the date of implantation;

(c) be made of material suitable for long-term use and legibility; and

(d) include the name, address and website of the manufacturer of the device.

(5) The characters used to convey the information contained in a leaflet or implant card in accordance with paragraph (2) or (4)(a) must be at least 3 millimetres in height.

(6) The manufacturer of a relevant device must maintain an updated copy of the leaflet and the implant card on its website for the period specified in paragraph (7).

(7) The period—

(a) begins with the date of the last manufacture of the device by the manufacturer, and

(b) ends with the later of—

(i) the lifetime of the device, and

(ii) 15 years.

(8) An entity providing healthcare that implants a device in a patient must—

(a) provide to the patient a copy of the leaflet and the implant card relating to the device; and

(b) record and maintain information sufficient for the implantable device, including the UDI, to be associated with the patient in which it was implanted."

PART 5

Amendments to Part 4 - *in vitro* diagnostic medical devices

Amendments to regulation 32 - interpretation of Part 4

39.—(1) Regulation 32(**a**) is amended as follows.

(2) In paragraph (1)—

(**a**) Amended by S.I.s 2003/1697, 2011/1043 and 2021/873.

DRAFT

(a) for the definition of "common technical specification" that applies to England and Wales, and Scotland substitute—

""common specification" means a technical specification set out in the Annexes to Commission Implementing Regulation (EU) 2022/1107 of 4 July 2022 laying down common specifications for certain Class D *in vitro* diagnostic medical devices as modified by Schedule 2D, and in accordance with Regulation (EU) 2017/746 of the European Parliament and of the Council, as it applied immediately before IP completion day and as modified by Schedule 2C;";

(b) for "device for self-testing" substitute—

""device for self-testing" means an *in vitro* diagnostic medical device intended for use by a lay user who is responsible for collecting the data or specimen, by themselves and on themselves, relying solely on the instructions provided by the manufacturer. This use can also include performing the test and interpreting the results by themselves and on themselves;".

(c) at the appropriate places insert the following definitions—

""approved PCCP" means a PCCP that has been approved by an approved body in accordance with regulation 42(3A)(a) or (b);"

""PCCP" means, in relation to an *in vitro* diagnostic medical device that is software, a pre-determined change control plan, describing what modifications can be made to the software and how the modifications will be assessed;"

(3) For paragraph (2), substitute—

"(2) In this Part, a reference to a numbered article or Annex is to the article or Annex of Directive 98/79 bearing that number unless the reference provides otherwise."

Amendment to regulation 33 - scope of Part 4

40. In regulation 33(1)(**a**), omit "(including coronavirus test devices)".

New regulation 33ZA - classification of *in vitro* diagnostic medical devices and accessories

41. After regulation 33 insert—

"Classification of *in vitro* diagnostic medical devices and accessories

33ZA.—(1) For the purposes of this Part and Part VI, devices must be classified as belonging to a class in accordance with the classification criteria set out in Schedule 23.

(2) In the event of a dispute between a manufacturer and an approved body over the classification of a device—

(a) the matter must be referred to the Secretary of State; and

(b) the Secretary of State must determine the classification of the device in accordance with the classification criteria set out in Schedule 23."

(**a**) Amended by S.I.s 2021/873 and 910.

DRAFT

Amendments to regulation 33A - registration etc. of persons placing *in vitro* diagnostic medical devices on the market

42.—(1) Regulation 33A(**a**) is amended as follows.

(2) For paragraph (1) substitute—

"(1) No person may place a relevant device on the market in accordance with this Part unless the requirements in paragraph (2) have been complied with."

(3) In paragraph (2)—

(a) for the opening words substitute "The requirements referred to in paragraph (1) are—";

(b) in sub-paragraph (a)—

(i) in paragraph (i)—

(aa) omit "that person is";

(bb) omit "and";

(cc) for "the person" substitute "the manufacturer";

(dd) for "registered" substitute "established";

(ii) in paragraph (ii)—

(aa) omit "that person is";

(bb) omit the first "and";

(cc) after "provides the Secretary of State with" insert "the address of the UK responsible person's established place of business in the United Kingdom and";

(iii) for paragraph (iii) substitute—

"(iii) the person placing a device on the market is not the manufacturer of the device or the UK responsible person, the address of that person's established place of business in the United Kingdom has been provided to the Secretary of State by the manufacturer (where the manufacturer is based in Great Britain) or by the UK responsible person (where the manufacturer is based outside the United Kingdom);";

(iv) after sub-paragraph (a) insert—

"(aa) the manufacturer ensures—

(i) a UDI is assigned to the relevant device,

(ii) the UDI has been assigned according to the rules of a UDI issuing entity that is registered in accordance with Part 2 of Schedule 8, and

(iii) the requirements in Schedule 8 have been complied with, except for the UDI requirements in relation to devices undergoing performance evaluation studies;";

(c) for sub-paragraph (b), substitute—

"(b) the manufacturer of the device, or the UK responsible person (if there is one) ensures the information set out in paragraphs 14 and 15 of Schedule 8 is submitted to the Secretary of State;";

(d) for sub-paragraph (c), substitute—

(**a**) Inserted by S.I. 2019/791.

DRAFT

"(c) the manufacturer of the device, or the UK responsible person (if there is one) pays to the Secretary of State the relevant fee in accordance with regulation 53."

(4) In paragraph (3)—

(a) in sub-paragraph (a), for "declaration of conformity and technical documentation have been drawn up" substitute "declaration of conformity has been drawn up and the technical documentation has been drawn up in accordance with regulation 33B(1)";

(b) for sub-paragraph (b), substitute—

"(b) keep available for inspection by the Secretary of State a copy of the documents referred to in regulation 33B(4), for the period specified in regulation 33B(5);";

(c) for sub-paragraph (c), substitute—

"(c) comply with a request for information from the Secretary of State in accordance with regulation 33C;".

(5) In paragraph (4)—

(a) in sub-paragraph (d)—

(i) for "devices in a list in Annex II and devices for self-testing" substitute "Class A, Class B, Class C and Class D devices";

(ii) in paragraph (i), for "Section 3 of Part A of Annex 1" substitute "Section 9 of Annex I to Regulation (EU) 2017/746 (as modified by, and as it has effect under, Parts 1 and 2 of Schedule 2C)";

(b) in sub-paragraph (e)—

(i) for "either to devices referred to in a list in Annex II or to devices for self-testing" substitute "to Class A, Class B, Class C and Class D devices";

(ii) for "Section 3 of Part A of Annex I" substitute "Sections 9.1(a), 9.1(b) and 9.3 of Annex I to Regulation (EU) 2017/746 (as modified by, and as it has effect under, Parts 1 and 2 of Schedule 2C);";

(c) after sub-paragraph (e) insert—

"(f) in relation to Class B devices, evidence of QMS certification relevant to the device to ISO 13485, from a UKAS accredited body, or an International Accreditation Forum accredited body of a country that is party to the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP);".

(6) After paragraph (6) insert—

"(6A) In paragraph (2)—

(a) reference to a "UDI issuing entity" is to a person who operates a system for the assignment of UDIs to devices and is registered in accordance with Part 2 of Schedule 8;

(b) reference to an "established place of business" is to a place in the UK which is either the person's—

(i) registered address shown in the public registers held by Companies House, or

(ii) permanent principal business address,

DRAFT

at which place the person is physically located in the UK and from which the person carries out the activities from which the relevant device is being placed on the market."

(7) In paragraph (7), in sub-paragraph (a), for "Annexes III to VIII" substitute "regulation 33B(3)".

New regulation 33B - technical documentation requirements for *in vitro* diagnostic medical devices

43. After regulation 33A insert—

"Technical documentation requirements for *in vitro* diagnostic medical devices

33B.—(1) The manufacturer of a relevant device must draw up and keep up to date technical documentation for that device.

(2) The technical documentation in paragraph (1) must—

(a) be drawn up in a manner which allows the conformity of the device with the requirements of this Part to be assessed, and

(b) be in English and presented in a readily searchable manner.

(3) For the purposes of this regulation, "technical documentation" is—

(a) the documentation listed in Annex II to Regulation 2017/746 (as modified by Part 3 of Schedule 2C),

(b) documentation relating to the device that the manufacturer is required to retain under regulation 44ZQ (retention of post-market surveillance documentation), and

(c) in the case of devices that are software, the PCCP relating to the device where the manufacturer has chosen to have one under regulation 44ZBB.

(4) The manufacturer of a relevant device and the UK responsible person (if there is one) must retain the following for the period specified in paragraph (5)—

(a) the technical documentation,

(b) the declaration of conformity of the device, and

(c) certificates in respect of the device, including any amendments and supplements where one is required.

(5) The period—

(a) begins with the date of the last manufacture of the device by the manufacturer, and

(b) ends with the later of—

(i) the lifetime of the device, and

(ii) 10 years.

(6) A manufacturer who is based outside the UK must ensure the UK responsible person keeps available the documentation referred to in paragraph (4) for the required periods."

New regulation 33C - inspection of *in vitro* diagnostic medical device technical documentation by the Secretary of State

44. After the new regulation 33B, insert—

DRAFT

"Inspection of *in vitro* diagnostic medical device technical documentation by the Secretary of State

33C.—(1) A manufacturer and the UK responsible person (if there is one) must keep available a copy of the documentation retained under regulation 33B(4) for inspection by the Secretary of State.

(2) A manufacturer or the UK responsible person (if there is one) must make the documentation referred to in regulation 33B(4) available to the Secretary of State upon request.

(3) The Secretary of State may request that such documentation is provided in summary form.

(4) A request made by the Secretary of State under paragraph (2) must be complied with before the end of—

(a) the period of three working days beginning with the day on which the Secretary of State makes the request, or

(b) such longer period as may be agreed by the Secretary of State in a particular case.

(5) The requirements of this regulation cease to have effect in relation to a device at the end of the period specified in regulation 33B(5)."

Amendments to regulation 34 - essential requirements for *in vitro* diagnostic medical devices

45.—(1) Regulation 34 is amended as follows.

(2) In paragraph (1), after "Annex I" insert "to Regulation (EU) 2017/746 (as modified by, and as it has effect under, Parts 1 and 2 of Schedule 2C)".

(3) In paragraph (2), in sub-paragraph (b), after "Annex I" insert "to Regulation (EU) 2017/746 (as modified by, and as it has effect under, Parts 1 and 2 of Schedule 2C)".

Revocation of provision relating to approval of coronavirus test devices

46. Omit regulations 34A to 34D(**a**) and their headings.

Amendments to regulation 35 - determining compliance of *in vitro* diagnostic medical devices with relevant essential requirements

47.—(1) Regulation 35(**b**) is amended as follows.

(2) In paragraph (2), for "Section 8 of Part B of Annex I" substitute "Section 20 of Annex I to Regulation (EU) 2017/746 (as modified by, and as it has effect under, Parts 1 and 2 of Schedule 2C)".

(3) In paragraph (3), after "designated standard" insert "unless there are reasonable grounds for suspecting that the device does not comply with those requirements".

(4) In paragraph (4), for "common technical specification" substitute "common specification".

(**a**) Regulation 34A was inserted by S.I. 2021/910 and amended by S.I. 2024/221. Regulations 34B to D were inserted by S.I. 2024/221.

(**b**) Amended by S.I.s 2019/791 and 2020/1478.

DRAFT

Revocation of further provision relating to approval of coronavirus test devices

48. Omit regulations 38A to 38C(**a**) and 39A(**b**) and their headings.

Amendments to regulation 40 - procedures for affixing a UK marking to *in vitro* diagnostic medical devices

49.—(1) Regulation 40(**c**) is amended as follows.

(2) In paragraph (1), for "relevant device other than a device referred to in the lists in Annex II or a device for self-testing" substitute "Class A relevant device".

(3) After paragraph (1) insert—

"(1A) A Class B relevant device may bear a UK marking only if the manufacturer of the device or the UK responsible person (if there is one)—

(a) fulfils the applicable obligations imposed by Section 1 to 5 of Annex III,

(b) declares, in accordance with the declaration of conformity procedure set out in that Annex, that the device meets the provisions of this Part which apply to it,

(c) ensures that the device meets the provisions of this Part which apply to it, and

(d) obtains from a UKAS accredited body, or an International Accreditation Forum accredited body of a country that is party to the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP), evidence of QMS certification relevant to the device, to ISO 13485.

(1B) A Class B relevant device which is also a sterile device may bear a UK marking only if the manufacturer or the UK responsible person (if there is one), also provides a statement that—

(a) an approved body has assessed that the aspects of manufacture concerned with securing and manufacturing sterile conditions have met the requirements in Annex I to Regulation (EU) 2017/746 (as modified by, and as it has effect under, Parts 1 and 2 of Schedule 2C), and

(b) the sterility assessment procedures set out in Annexes IV-VII of Directive 98/79 (as modified by, and as it has effect under Part 3 of Schedule 2A) have been applied.

(1C) For the purposes of the declaration in paragraph (1)(b), in relation to a relevant device that is software, where—

(a) a manufacturer has chosen to have a PCCP under regulation 44ZBB, and

(b) where applicable, that PCCP has been approved by an approved body under regulation 42(3A)(a) or (b),

the manufacturer must include in the declaration of conformity a reference to the PCCP and, where applicable, the approved PCCP."

(4) Omit paragraph (2). After the omitted paragraph (2) insert—

"(2A) For the purposes of the declaration in paragraph 1A(b), in relation to a relevant device that is software, where—

(a) a manufacturer has chosen to have a PCCP under regulation 44ZBB, and

(**a**) Regulations 38A to 38C were inserted by S.I. 2021/910.
(**b**) Inserted by S.I. 2021/910.
(**c**) Amended by S.I. 2019/791.

DRAFT

(b) that PCCP has been approved by an approved body under regulation 42(3A)(a) or (b),

the manufacturer must ensure that any certificate issued by the approved body in connection with the conformity procedure set out in the Annexes referred to in paragraph 1A(a) includes a reference to the approved PCCP."

(5) In paragraph (3), for "relevant device referred to in List A in Annex II" substitute "Class D relevant device".

(6) After paragraph (3) insert—

"(3A) For the purposes of the declaration in paragraph (3)(b), in relation to a relevant device that is software, where—

(a) manufacturer has chosen to have a PCCP under regulation 44ZBB, and

(b) that PCCP has been approved by an approved body under regulation 42(3A)(a) or (b),

the manufacturer must ensure that any certificate issued by the approved body in connection with the conformity procedure set out in the Annexes referred to in paragraph (3)(a) includes a reference to the approved PCCP."

(7) In paragraph (4), for "relevant device referred to in List B in Annex II" substitute "Class C relevant device".

(8) After paragraph (4) insert—

"(4A) For the purposes of the declaration in paragraph (4)(b), in relation to a relevant device that is software, where—

(a) a manufacturer has chosen to have a PCCP under regulation 44ZBB, and

(b) that PCCP has been approved by an approved body under regulation 42(3A)(a) or (b),

the manufacturer must ensure that any certificate issued by the approved body in connection with the conformity procedure set out in the Annexes referred to in paragraph (4)(a) includes a reference to the approved PCCP."

Amendments to regulation 41 - manufacturers etc. and conformity assessment procedures for *in vitro* diagnostic medical devices

50.—(1) Regulation 41(**a**) is amended as follows.

(2) In regulation 41(3)(a)—

(a) for "five" substitute "ten";

(b) after "the last product" insert "or ending with the expiry of the lifetime of the device, whichever is longer".

(3) In paragraph (1), at the start insert "Subject to paragraph (1A),".

(4) After paragraph (1) insert—

"(1A) The requirements in Sections 3.4 and 4.4 of Annex IV and Section 6.1 of Annex V, relating to notifying the approved body of substantial changes to the product range do not apply to changes to an in vitro diagnostic medical device which is software and—

(a) the change is set out in an approved PCCP,

(**a**) Amended by S.I.s 2019/791 and 2021/873.

DRAFT

(b) the change has been made in accordance with the approved PCCP, and

(c) the manufacturer has—

(i) notified the approved body within 10 working days beginning with the day of the change, and

(ii) confirmed that the requirements of sub-paragraphs (a) and (b) have been met."

(5) After paragraph (2) insert—

"(2A) A manufacturer of a relevant in vitro diagnostic medical device that is software who—

(a) is required to follow a conformity procedure set out in this Part which requires the involvement of an approved body, and,

(b) has chosen to have a PCCP under regulation 44ZBB,

must include the PCCP in the manufacturer's application to an approved body for the conformity procedure, for approval by the approved body.

(2B) If a manufacturer is unable to include a PCCP in the application under paragraph (3) at the time the application is made, it may be supplied at such later date as may be agreed."

Amendments to regulation 42 - approved bodies and the conformity assessment procedures for *in vitro* diagnostic medical devices

51.—(1) Regulation 42(**a**) is amended as follows.

(2) In paragraph (2), after "in accordance with" insert "paragraph (3A) or"

(3) After paragraph (3) insert—

"(3A) Where a manufacturer has submitted a PCCP to an approved body in accordance with regulation 41(2A), the approved body may—

(a) approve the PCCP with no conditions or restrictions, if the PCCP meets the requirements specified in regulation 44ZBB(2)(a),

(b) approve the PCCP subject to such conditions or restrictions that the approved body considers appropriate, with which the manufacturer must comply prior to implementing the proposed modifications described in the PCCP, or

(c) refuse to approve the PCCP, and the approved body must notify the manufacturer of its decision.

(3B) In the event of a dispute between a manufacturer and an approved body over the conditions or restrictions applied to the PCCP under paragraph (3A)(b), the matter must be referred for determination by the Secretary of State.

(3C) Where an approved body has approved a PCCP in accordance with paragraph (3A)(a) or (b), it must include a reference to the approved PCCP in the certificate issued in connection with the relevant conformity procedure carried out in accordance with regulation 40."

(**a**) Amended by S.I. 2019/791.

DRAFT

Amendments to regulation 44 - registration of persons placing *in vitro* diagnostic medical devices on the market or for performance evaluation

52.—(1) Regulation 44(**a**) is amended as follows.

(2) In paragraph (1)—

(a) in sub-paragraph (a), for "Annex II devices or devices for self-testing" substitute "Class C or Class D devices";

(b) in sub-paragraph (b), for "other than Annex II devices or devices for self-testing" substitute "that are Class A or Class B devices".

(3) In paragraph (7)—

(a) in sub-paragraph (d), for "devices in a list in Annex II and devices for self-testing" substitute "Class A, Class B, Class C, and Class D devices";

(b) in sub-paragraph (e), for "either to devices referred to in a list in Annex II or to devices for self-testing" substitute "Class A, Class B, Class C, or Class D devices".

(c) in sub-paragraph (d)(i) and (e), for "Section 3 of Part A of Annex I" substitute "section 9 of Annex I to Regulation (EU) 2017/746".

Amendment to regulation 44ZB - obligations in Part 4 which are met by complying with obligations in Regulation (EU) 2017/746

53. In regulation 44ZB(7)(b)(**b**), for "common technical specification" substitute "common specification".

New regulation 44ZBA - misleading or unsubstantiated claims about *in vitro* diagnostic medical devices

54. After regulation 44ZB insert—

"Misleading or unsubstantiated claims about *in vitro* diagnostic medical devices

44ZBA.—(1) A person who creates or modifies a relevant article relating to a relevant device, or who promotes a relevant device for financial or other material advantage, must not mislead the user or the patient with regard to the device's intended purpose, safety or performance by—

(a) suggesting through the article or promotion that the device has a function or property which it does not have or which cannot be established from available evidence,

(b) failing to inform the user or patient of any significant risk associated with the use of the device for its intended purpose,

(c) suggesting through the article or promotion uses for the device other than those stated to form part of the intended purpose for which the conformity assessment was carried out, including using the device in combination with other devices or equipment where that combination has not been conformity assessed, or

(**a**) Amended by S.I.s 2002/618, 2019/791, 2020/1478 and 2024/221.
(**b**) Inserted by S.I. 2019/791, substituted by S.I. 2020/1478 and amended by regulation 1ZA of S.I. 2002/618.

DRAFT

(d) in relation to devices for performance evaluation, suggesting through the article or promotion uses for the devices other than those stated to form part of the intended purpose which the performance evaluation is being carried out to verify.

(2) Where the Secretary of State is determining whether a person has complied with paragraph (1), the Secretary of State may, in particular—

(a) take into account whether the language or imagery used in the relevant article or promotion was liable to mislead the intended audience;

(b) have regard to suggestions made explicitly or implicitly, through language or imagery, or through a particular feature or combination of features of the relevant article or promotion.

(3) For the purposes of this regulation, "relevant article" includes instructions for use, labelling, packaging and any promotional or sales material relating to the relevant device."

New regulation 44ZBB - pre-determined change control plan option for software *in vitro* diagnostic medical devices

55. After the new regulation 44ZBA insert—

"Pre-determined change control plan option for software *in vitro* diagnostic medical devices

44ZBB.—(1) A manufacturer of a relevant *in vitro* diagnostic medical device that is software may choose to have a PCCP for that software.

(2) A manufacturer that chooses to have a PCCP must—

(a) include within that PCCP—

(i) a description of the proposed modifications to the software and a statement confirming that the proposed modifications fall within the device's intended purpose,

(ii) a modification protocol which describes the process to be followed by the manufacturer in implementing the proposed modifications, and

(iii) a review of the risk management system.

(b) include the PCCP in the device's technical documentation in accordance with regulation 33B, and

(c) subject to paragraph (4), report any substantial deviation from the PCCP to the approved body for that device.

(3) Subject to paragraph (4), a manufacturer may not implement the proposed modifications described in the PCCP unless—

(a) the PCCP has been reviewed and approved by the approved body in accordance with regulation 42(3A)(a), and

(b) the PCCP has been reviewed and approved by the approved body, and the manufacturer has complied with the conditions or restrictions applied to the PCCP in accordance with regulation 42(3A)(b).

(4) Paragraphs (2)(c) and (3) only apply to a relevant *in vitro* diagnostic medical device that is software if it falls within Class C or D."

DRAFT

PART 6

Amendments to Part 4A - post-market surveillance requirements

Amendment to regulation 44ZC - interpretation of Part 4A

56. In regulation 44ZC(**a**)—

(a) omit the definition of "lifetime of a device";

(b) in the definition of "relevant device", for "or 4" substitute ", 4 or 8";

(c) in the definition of "relevant essential requirements", after paragraph (h) insert—

"(i) in relation to a device otherwise placed on the market or put into service in accordance with Part 8 (International Reliance Pathway);".

Amendment to regulation 44ZD - scope of Part 4A

57. In regulation 44ZD(1)(**b**), for "or 4" substitute ", 4 or 8".

Amendment to regulation 44ZE - post-market surveillance system

58. In regulation 44ZE(4)(**c**), after sub-paragraph (b) insert—

"(c) for devices placed on the market or put into service in accordance with Part 8—

(i) the instructions for use and labelling of the device;

(ii) the required risk analysis;

(iii) any other technical documentation in accordance with Part 8."

Amendment to regulation 44ZF - post-market surveillance plan

59. In regulation 44ZF(3)(**d**)—

(a) in sub-paragraph (d)(ii), for "placed on the market or put into service in accordance with Part 4" substitute "that is a diagnostic medical device".

(b) in sub-paragraph (g)—

(i) for "a" substitute "any";

(ii) after "plan for" omit "any";

(iii) omit "required under Part 2 or 3".

Amendment to regulation 44ZG - preventive and corrective actions

60.—(1) Regulation 44ZG(**e**) is amended as follows.

(2) In paragraph (1)—

(a) after sub-paragraph (a) omit "or";

(b) after sub-paragraph (b) insert— "or"

(**a**) Inserted by S.I. 2024/1368.
(**b**) Inserted by S.I. 2024/1368.
(**c**) Inserted by S.I. 2024/1368.
(**d**) Inserted by S.I. 2024/1368.
(**e**) Inserted by S.I. 2024/1368.

DRAFT

"(c) in relation to devices under Part 8, otherwise has reason to believe that the device is no longer in compliance with the requirements in Part VIII,";"

(c) after "into conformity" insert "or, in relation to devices under Part 8, into compliance with the requirements in Part VIII".

(3) In paragraph (4), after "into conformity" insert "or, in relation to devices under Part 8, into compliance".

Amendments to regulation 44ZL - post-market surveillance report

61.—(1) Regulation 44ZL(**a**) is amended as follows.

(2) In paragraph (1)—

(a) in sub-paragraph (c), after "Part 2" insert "or 8";

(b) in sub-paragraph (e), for "that is not a device" to the end substitute "or 8 belonging to class A or class B under regulation 33ZA (classification of in vitro diagnostic medical devices);".

(3) In paragraph (2)—

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

(b) in sub-paragraph (b), at the end insert ", and";

(c) after sub-paragraph (b) insert—

"(c) for a device that is software, and where a manufacturer has chosen to have PCCP under regulation 19F(1) or 44ZBB(1), a summary of the PCCP modifications, including details of the changes and outcomes."

(4) For paragraph (4)(a), substitute—

"(a) the system or procedure pack incorporates a medical device which does not—

(i) bear a UK marking,

(ii) bear a CE marking, or

(iii) for devices under Part 8, comply with the requirements in this Part;".

(5) For paragraph (5)(b) substitute—

"(b) for devices under Part 8 with a certificate that was issued by an approved body in accordance with regulation 74, the action taken after that certificate was issued;

(c) for any other devices, the action was taken after the declaration of conformity was drawn up."

Amendments to regulation 44ZM - periodic safety update report

62.—(1) Regulation 44ZM(**b**) is amended as follows.

(2) In paragraph (3)—

(a) in sub-paragraph (d) omit "required under Part 2 or 3";

(b) after sub-paragraph (g) insert—

"; and

(**a**) Inserted by S.I. 2024/1368.
(**b**) Inserted by S.I. 2024/1368.

DRAFT

(h) for a device that is software, and where the manufacturer has chosen to have a PCCP under regulation 19F(1) or 44ZBB(1), a summary of the PCCP modifications, including details of the changes and outcomes."

(3) For paragraph (4)(a) substitute—

"(a) the system or procedure pack incorporates a medical device which does not—

(i) bear a UK marking,

(ii) bear a CE marking, or

(iii) for devices under Part 8, comply with the requirements in this Part;".

(4) In paragraph (7)(c), after "Part 2" insert "or Part 8".

(5) In paragraph (10), for "Regulations." substitute "Regulations, or, for devices under Part 8, when carrying out its surveillance activities for devices with a Certificate of International Reliance issued under regulation 74 in accordance with the requirements in this Part".

(6) In paragraph (12)—

(a) in sub-paragraph (a), after "Part 2" insert "or Part 8";

(b) in sub-paragraph (b)—

(i) after "Part 2" insert "or Part 8";

(ii) omit "under Directive 93/42";

(c) in sub-paragraph (c), after "Part 3" insert " or Part 8"

(d) in sub-paragraph (d), for "that is referred to" to the end substitute "or Part 8 and classified as belonging to Class D under regulation 33ZA (classification of in vitro diagnostic medical devices);".

Amendment to regulation 44ZN – trend reporting

63. In regulation 44ZN(3)(**a**), for "placed on the market or put into service in accordance with Part 4" substitute "that is a diagnostic medical device".

PART 7

Amendments to Part 5 - Approved Bodies (E, W & S), Notified Bodies (NI), Conformity Assessment Bodies and Marking of Products

Amendments to regulation 45 - designation of approved bodies

64.—(1) Regulation 45 is amended as follows.

(2) In paragraph (2)—

(a) at the end of sub-paragraph (c) delete "and"

(b) at the end of sub-paragraph (d) delete "." and insert ", and";

(c) after sub-paragraph (d) insert—

"(e) in so far as it is to be designated as a body which is to carry out tasks set out in Part 8, it—

(i) is designated under sub-paragraphs (a), (b) or (c), and

(ii) complies, in relation to those tasks, with the requirements set out in Annex 1 of Commission Implementing Regulations (EU) No 920/2013

(**a**) Inserted by S.I. 2024/1368.

DRAFT

in which "conformity assessment body" shall be read as "approved body" and "conformity assessment activities" shall be read as "activities related to international reliance"."

(3) In paragraph (5)—

(a) in sub-paragraphs (b) and (c), for "he considers" substitute "they consider";

(b) at the end of sub-paragraph (b), delete "or";

(c) at the end of sub-paragraph (c), delete "," and insert "; or";

(d) after sub-paragraph (c), insert—

"(d) they consider that the body is not capable of fulfilling the relevant requirements in Part 8,".

(4) In paragraph (7), after "Directive 98/79" insert "or Part 8 of these Regulations".

(5) In paragraph (8)(a), after "Directive 98/79" insert "or Part 8 of these Regulations ".

PART 8

Amendments to Part 6 - fees charged by the Secretary of State

Amendments to regulation 52 - interpretation of Part 6

65.—(1) Regulation 52(**a**) is amended as follows.

(2) In paragraph (1)—

(a) in the definitions of "clinical development", "quality development" and "safety development", for "paragraph 7.4" to the end substitute "Section 12.1 of Annex I to Regulation (EU) 2017/745 (as modified by, as has it has effect under, Parts 1 and 2 of Schedule 2B)";

(3) For paragraph (2) substitute—

"(2) For the purposes of this Part, medical devices are classified as being implantable or long term invasive medical devices in accordance with the definitions set out in regulation 2 and Schedule 9."

(4) After paragraph (2) insert—

"(3) In the event of a dispute over the classification of a device—

(a) the matter must be referred to the Secretary of State; and

(b) the Secretary of State must determine the classification of the device in accordance with the definitions set out in regulation 2 and Schedule 9."

Amendment to regulation 53 - fees in connection with the registration of devices and changes to registration details.

66. In regulation 53(**b**), for "or 44", in both places it occurs, substitute ", 44 or 77".

(**a**) Amended by S.I.s 2003/1697 and 2023/377.
(**b**) Amended by S.I.s 2019/791 and 2025/749.

DRAFT

Revocation of provision relating to fees in connection with the approval of coronavirus test devices

67. Omit regulation 56A(**a**) and its heading.

PART 9

Amendment to Part 7 - General, Enforcement and Miscellaneous

Amendments to regulation 59 - Interpretation of Part 7

68. In the definition of "relevant device", for "III or IV" substitute "III, IV or VIII".

Amendments to regulation 67 - Review

69. For regulation 67(**b**) substitute—

"Review

67.—(1) The Secretary of State must—

(a) from time to time carry out a review of these Regulations;

(b) set out the conclusions of the review in a report;

(c) publish the report.

(2) The report must, in particular—

(a) set out the objectives intended to be achieved by the regulatory provision made by these Regulations;

(b) assess the extent to which the objectives under sub-paragraph (a) are achieved;

(c) assess whether the objectives under sub-paragraph (a) remain appropriate, and, if so, the extent to which they could be achieved in another way which involves less onerous regulatory provision.

(3) The first report under this regulation must be published before 31st December 2034.

(4) Reports under this regulation are afterwards to be published at intervals not exceeding five years."

PART 10

New Part VIII - International Reliance Pathway

New Part VIII - international Reliance Pathway

70. After Part VII insert—

(**a**) Inserted by S.I. 2021/910.
(**b**) Inserted by S.I. 2013/2327 and amended by S.I. 2019/791.

DRAFT

"PART VIII

International Reliance Pathway

Interpretation of Part VIII

68.—(1) In this Part—

"510(k) regulation" means the United States Code of Federal Regulations (CFR), Title 21, part 807 subpart E (21 CFR 807.81-807.100);

"Canadian MDR" means the Canadian Medical Devices Regulations SOR/98-282;

"Common specification" means a technical specification set out in the Annexes to Commission Implementing Regulation (EU) 2022/1107 of 4 July 2022 laying down common specifications for certain Class D *in vitro* diagnostic medical devices as modified by Schedule 2D, and in accordance with regulation (EU) 2017/746 of the European Parliament and of the Council, as it had effect immediately before IP completion day and as modified by Schedule 2C;

"companion diagnostic" means a device which is essential for the safe and effective use of the corresponding medicinal product, to identify, whether before and during treatment—

(a) patients who are most likely to benefit from the medicinal product, or

(b) patients who are likely to be at increased risk of serious adverse reaction as a result of treatment with the medicinal product;

"comparable regulator country" means Australia, Canada, or the United States of America;

"De Novo regulation" means the United States Code of Federal Regulations (CFR), Title 21, part 860 subpart D (21 CFR 860.200 - 860.260);

"Medicinal substance" means a substance which, if used separately from a device, may be considered to be a medicinal product as defined in regulation 2;

"PMA regulation" means the United States Code of Federal Regulations (CFR), Title 21, part 814 (21 CFR 814);

"Route 1 device" means—

(a) a Class I medical device, other than a device that is sterile, measuring or software, or

(b) a Class A *in vitro* diagnostic medical device that is non-sterile, which complies with applicable medical devices legislation in a comparable regulator country;

"Route 2 device" means—

(a) a sterile and/or measuring Class I medical device which is placed on the market or put into service in a comparable regulator country under De Novo regulation, 510(k) regulation, or Therapeutic Goods Regulations which is not a medical device that is software,

(b) a Class IIa or Class IIb medical device which is placed on the market or put into service in a comparable regulator country under De Novo regulation, PMA regulation, Therapeutic Goods Regulations, or requirements

DRAFT

in the Canadian MDR relating to Class III or IV medical devices as they are classified under those regulations, other than—

(i) a medical device that is software,

(ii) a medical device that incorporates an ancillary medicinal substance,

(c) a Class III medical device which is placed on the market or put into service in a comparable regulator country under PMA regulation, Therapeutic Goods Regulations, or requirements in the Canadian MDR relating to Class IV medical devices as they are classified under those regulations, other than—

(i) a medical device that is software,

(ii) a medical device that incorporates an ancillary medicinal substance,

(d) a sterile Class A *in vitro* diagnostic medical device which is placed on the market or put into service in a comparable regulator country under De Novo regulation, 510(k) regulation, or Therapeutic Goods Regulations, and;

(e) a Class B or Class C *in vitro* diagnostic medical device which is placed on the market or put into service in a comparable regulator country under De Novo regulation, 510(k) regulation, PMA regulation, Therapeutic Goods Regulations, or requirements in the Canadian MDR relating to Class III or IV medical devices as they are classified under those regulations;

"Route 3 device" means—

(a) a Class IIa, Class IIb, or Class III medical device that is placed on the market or put into service in the United States of America under 510(k) regulation;

(b) a Class III medical device that incorporates an ancillary medicinal substance that is placed on the market or put into service in a comparable regulator country under De Novo regulation, 510(k) regulation, PMA regulation or Therapeutic Goods Regulations;

(c) a Class III medical device that incorporates an ancillary medicinal substance that is placed on the market or put into service in Canada under the requirements in the Canadian MDR for Class IV medical devices;

(d) a Class D *in vitro* diagnostic medical device that is placed on the market or put into service in a comparable regulator country under De Novo regulation, 510(k) regulation, PMA regulation, Therapeutic Goods Regulations, or requirements in the Canadian MDR relating to Class III or IV medical devices as they are classified under those regulation;

(e) a measuring Class I medical device, Class IIa, Class IIb or Class III medical device that is software that is placed on the market or put into service in a comparable regulator country under De Novo regulation, 510(k) regulation, PMA regulation, Therapeutic Goods Regulations, or requirements in the Canadian MDR relating to Class III or IV medical devices as they are classified under those regulations;

DRAFT

"Therapeutic Goods Regulations" means the Australian Therapeutic Goods (Medical Devices) Regulations 2002(**a**).

(2) References in this Part to the classification of medical devices refer to their classification under these Regulations, and not to their classification in a comparable regulator country, unless specified otherwise.

Scope of Part VIII

69. This Part applies to a Route 1 device, Route 2 device and Route 3 device, other than a device which is—

(a) a device that has a certification of inclusion in the Australian register of Therapeutic Goods;

(b) a device that contains non-viable cells or tissues of human origin;

(c) a device which is manufactured utilising animal tissue or derivatives, other than an *in vitro* diagnostic medical device;

(d) co-packaged with a medicinal product; or

(e) a companion diagnostic.

In this Part, references to "medical devices" and "in vitro diagnostic medical devices" are to be construed as including accessories to such devices.

Applicable provisions

70.—(1) Subject to paragraph (3), where a manufacturer places on the market or puts into service a Route 1, Route 2 or Route 3 device which complies with the requirements of this Part, the provisions of these Regulations, other than those specified in paragraph (2), do not apply to that manufacturer in respect of that device.

(2) The provisions are—

(a) regulation 1 (citation and commencement),

(b) regulation 2 (interpretation),

(c) regulation 3 (scope of these Regulations),

(d) regulation 5 (interpretation of Part II),

(e) regulation 7 (classification of general medical devices),

(f) regulation 7A (registration of persons placing general medical devices on the market), other than sub-paragraphs 3(a), 3(b), and 3(c),

(g) regulation 19D (misleading or unsubstantiated claims about general medical devices),

(h) regulation 19E (information about implantable devices),

(i) regulation 21A (registration of persons placing active implantable medical devices on the market), other than sub-paragraphs 3(a), 3(b), and 3(c),

(j) regulation 21ZA (classification of active implantable medical devices),

(k) regulation 31A (misleading or unsubstantiated claims about active implantable devices),

(l) regulation 31B (information about active implantable medical devices),

(**a**) Statutory Rules No. 236, 2002.

DRAFT

(m) regulation 33A (registration etc of persons placing *in vitro* diagnostic medical devices on the market), other than sub-paragraphs 3(a), 3(b), and 3(c),

(n) regulation 33ZA (classification of *in vitro* diagnostic medical devices and accessories),

(o) regulation 44ZBA (misleading or unsubstantiated claims about *in vitro* diagnostic medical devices),

(p) Part 4A (post-market surveillance requirements),

(q) regulation 45 (designation etc of approved bodies),

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

(s) regulation 56C (fees payable in connection with a consultation or further consultation on the safety, quality and usefulness of a medicinal substance incorporated in a device),

(t) Part VII (general, enforcement and miscellaneous), and

(u) Schedule 8 (UDI issuing entities, UDIs and registration requirements), unless the device carries a UDI that is in accordance with the requirements in the comparable regulator country and has been issued according to the rules of the UDI issuing entity that is registered with the Secretary of State in accordance with Part 2 of Schedule 8.

(3) The non-application in regulation (1) does not apply to a device—

(a) for which the authorisation for use in the comparable regulator country has been suspended or cancelled,

(b) which the manufacturer has withdrawn from use in the comparable regulatory country.

Application for Certificate of International Reliance - Route 2 and 3 devices

71.—(1) An application for a Certificate of International Reliance must be submitted by a manufacturer to an approved body designated under regulation 45 (designation etc of approved bodies).

(2) The application must include—

(a) the name and address of the manufacturer,

(b) a description of the device,

(c) the intended purpose of the device,

(d) the name of the comparable regulator country where the device has been authorised, evidence of that authorisation, and a statement that the use of the device is not suspended in the comparable regulator country,

(e) the classification of the device under these Regulations and an accompanying rationale,

(f) a statement of the Route that applies to the device and an accompanying rationale,

(g) the following evidence of a certified quality management system related to the device—

(i) for a device for which the comparable regulator country is Australia, the conformity assessment certificate issued by the Australian Therapeutic Goods Administration;

DRAFT

(ii) for a device for which the comparable regulator country is Canada, the Medical Device Single Audit Program certificate;

(iii) for a device for which the comparable regulator country is the United States of America, the Medical Device Single Audit Program certificate or ISO 13485 certificate issued by a certification body accredited by the International Accreditation Forum.

(h) the label for the device which complies with regulation 80 where applicable,

(i) where applicable, the instructions for use,

(j) the UDI-DI for the device as defined in Part 1 of Schedule 8,

(k) where applicable, the implant card and patient information leaflet,

(l) a list of part numbers,

(m) an explanation of what other United Kingdom product safety or health and safety legislation applies to the device,

(n) where applicable, information demonstrating compliance with regulation 78,

(o) a post-market surveillance plan,

(p) post-market surveillance data covering the most recent period during which the device has been made available inside and outside Great Britain, up to five years, including any ongoing field safety corrective actions and information regarding any significant increase in the frequency or severity of incidents involving the device,

(q) information stating whether the device has marketing authorisation in more than one comparable regulator country,

(r) where applicable, evidence of an agreement between the manufacturer and the UK responsible person relating to the device,

(s) for Route 2 and 3 devices that are connected to or equipped with an energy source, technical reports demonstrating that the device is designed and manufactured in such a way as to reduce as far as possible the risks of creating electromagnetic interference which could impair the operation of the device in question or other devices or equipment in the intended environment, and

(t) for Route 2 and 3 devices that are connected to or equipped with an energy source, technical reports demonstrating that the device is designed and manufactured in such a way as to provide a level of intrinsic immunity to electromagnetic interference such that is adequate to enable them to operate as intended.

(3) Where the application is for a Route 3 medical device, it must also include—

(a) for devices that comply with 510(k) regulation, the rationale for equivalence to the predicate device that was submitted during the 510(k) submission process in the United States of America,

(b) where applicable, information regarding the usefulness of incorporating the ancillary medicinal substance into the device,

(c) for Class D *in vitro* diagnostic medical devices—

(i) results of batch verification tests that demonstrate that the device complies with the performance characteristics set by the manufacturer and, where applicable, common specifications, and

(ii) a plan for regular independent batch verification testing that, taking into account the intended purpose of the device, will enable the manufacturer to

DRAFT

ensure that the device continues to meet the performance characteristics set by the manufacturer and, where applicable, common specifications.

(d) in the case of a device that is software, a comparison of any differences between the intended population, user and use environment in the comparable regulator country and Great Britain, and information that demonstrates that the differences will not adversely impact on the safety or performance of the device,

(e) where applicable, a Predetermined Change Control Plan that complies with regulation 19F(2)(a) or 44ZBB(2)(a).

Approved body review - Route 2 and 3 devices

72.—(1) For a Route 2 device and Route 3 device, the approved body must confirm that—

(a) the device has been authorised for use in the relevant comparable regulator country,

(b) the device has been classified correctly under these Regulations,

(c) the post-market surveillance plan meets the requirements in Part 4A,

(d) the available post-market information for the subject device does not show any emerging serious risks,

(e) where applicable, the implant card and patient leaflet meet the requirements set out in regulations 19E and 31B, as applicable, and

(f) the instructions for use provided with a reusable device contain information on the appropriate processes to allow reuse including—

(i) cleaning,

(ii) disinfection,

(iii) packaging,

(iv) where appropriate, the method of sterilisation, and

(v) any restriction on the number of reuses.

(2) For a Route 3 device, the approved body must also confirm that—

(a) for a device that is subject to 510(k) regulation, the rationale for equivalence to the predicate device meets the requirements in regulation 9A for general medical devices or 23A for active implantable medical devices,

(b) for a device with an ancillary medicinal substance that complies with devices legislation in a comparable regulator country, the approved body must request an opinion from the Secretary of State on the quality and safety of the substance, including the clinical benefit and risk profile of the incorporation of the substance into the device, and the Secretary of State must provide that opinion, and

(c) for a device that is software, where a manufacturer has submitted a predetermined change control plan to an approved body as part of this application, that the plan has been accepted in the comparable regulator country.

Approved body review - safety concerns

73. If, in reviewing the information provided under regulation 71(2)(p), the approved body identifies a serious risk or serious safety concern, it must request that the manufacturer provide information demonstrating that the serious risk or serious safety concern has been addressed.

DRAFT

Certificate of International Reliance

74. If an approved body determines that the applicable requirements in regulations 71 and 72 are met and a manufacturer has provided any information required under regulation 73, it must issue a Certificate of International Reliance to the manufacturer that contains—

(a) a description of the device,

(b) the name and address of the manufacturer and the UK responsible person (if there is one),

(c) the name, address and identification number of the approved body,

(d) a unique number associated with the Certificate,

(e) the date the Certificate was issued,

(f) the date the Certificate expires in accordance with regulation 76(1),

(g) a reference to the regulatory scheme under which the device was authorised in the comparable regulator country,

(h) where applicable, a reference to the predetermined change control plan that has been accepted in the comparable regulator country

(i) a statement that the requirements in regulations 71, 72 and 73, where applicable, have been met, and

(j) the signature of an employee of the approved body.

Refusal to issue a Certificate of International Reliance

75.—(1) If an approved body determines that the requirements in regulations 71, 72 and 73 have not been met, it must refuse to issue a Certificate of International Reliance.

(2) If an approved body refuses to issue a Certificate of International Reliance, it must provide the manufacturer with the reason for the refusal.

Expiry of Certificate of International Reliance

76.—(1) A Certificate of International Reliance expires—

(a) for a device for which the comparable regulator country is Australia, on the expiry date of the conformity assessment certificate for the device issued under the Therapeutic Goods Regulations;

(b) for a device for which the comparable regulator country is Canada, on the expiry date of the quality management system certificate referred to in regulation 71(2)(g);

(c) for a device for which the comparable regulator country is the United States of America, on the expiry date of the quality management system certificate referred to in regulation 71(2)(g).

(2) If, prior to the expiry date referred to in 74(f), the manufacturer provides the information set out in paragraph (3) then the Certificate of International Reliance will not expire, and the approved body must amend the expiry date in accordance with the expiry date associated with the information.

(3) The information is—

(a) for a device for which the comparable regulator country is Australia, a new conformity assessment certificate for the device issued under the Therapeutic Goods Regulations;

(b) for a device for which the comparable regulator country is Canada, a new Medical Device Single Audit Program certificate.

DRAFT

(c) for a device for which the comparable regulator country is the United States of America, a new Medical Device Single Audit Program certificate or ISO 13485 certificate issued by a certification body accredited by the International Accreditation Forum.

Registration

77.—(1) After a Certificate of International Reliance, where applicable, is issued for a device, and before a manufacturer places the device on the market, the manufacturer or the UK responsible person (if there is one) must register the device with the Secretary of State.

(2) The registration must include—

(a) for a Route 1 device—

(i) the information required in Part 5 of Schedule 8, other than basic UDI-DI;

(ii) a declaration that the device complies with an appropriate quality management system (such as ISO 13485);

(b) for a Route 2 device and Route 3 device—

(i) the information required in Part 5 of Schedule 8, other than basic UDI-DI;

(ii) a copy of the Certificate of International Reliance.

(3) The requirement in paragraph (1) applies to systems and procedure packs that contain devices that are subject to this Part.

(4) The registration of systems and procedure packs must include the declarations referred to in regulation 84(1)(c) and regulation 84(3)(b).

Devices with a measuring function

78. For a Route 1 device, Route 2 device and Route 3 device with a measuring function, the measurements made by the device must be expressed in authorised units conforming to the Units of Measurement Regulations 1986(**a**).

Labelling and instructions for use

79.—(1) In addition to any labelling requirements in this Part, a Route 1 device, Route 2 device and Route 3 device must be packaged and labelled in accordance with the applicable requirements in the comparable regulator country.

(2) The requirements referred to in paragraph (1) include any of those related to information provided to users, including instructions for use, warnings, and risk statements.

(3) The information in paragraphs (1) and (2) must be provided in English, but may in addition be provided in another language that is legally required in the comparable regulator country.

(4) The name and address of the UK responsible person (if there is one), must be included on the product labelling, the outer packaging, or the instructions for use.

Labelling requirements relating to specific substances

80.—(1) In addition to the requirements in regulation 79, a Route 1 device, Route 2 device and Route 3 device, which is not an *in vitro* diagnostic device, must be labelled in

(**a**) S.I. 1986/1082.

DRAFT

accordance with the provisions of Section 10.4.5 of Annex I to the Regulation (EU) 2017/745.

(2) For the purposes of paragraph (1), a reference in Section 10.4.5 of Annex I to the Regulation (EU) 2017/745 to Section 10.4.1 of that Annex is to Section 10.4.1 modified as follows—

(a) in point (a), for "Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council" substitute "the GB mandatory classification and labelling list (maintained by the Health and Safety Executive under Article 38A of Regulation (EC) No 1272/2008)";

(b) in point (b), from "once a delegated act" to the end substitute "Commission Delegated Regulation (EU) 2017/2100 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council."

(3) The instructions for use for a Route 1 device, Route 2 device and Route 3 device must include—

(a) where the device contains or consists of—

(i) substances which are carcinogenic, mutagenic or toxic to reproduction, or

(ii) endocrine-disrupting substances,

precautions relating to materials incorporated into the device;

(b) where materials incorporated into the device could result in sensitisation or an allergic reaction by the patient or user—

(i) a list of the materials, and

(ii) precautionary statements relating to them.

Modifications to medical devices

81.—(1) If a change is made to a Route 1 medical device that has been issued a certificate, other than a change that has been made in the comparable regulator country or a change that is required under this Part, the the non-application of these Regulations in regulation 70(1) (applicable provisions) do not apply.

(2) If a change set out in paragraph (3) is made to a Route 2 device or a Route 3 device that has been issued a certificate, other than a change that is required under this Part, the non-application of these Regulations in regulation 70(1) (applicable provisions) do not apply unless—

(a) the manufacturer submits a new application under regulation 71 (application for Certificate of International Reliance - Route 2 and 3 devices), and

(b) an approved body issues a new Certificate of International Reliance for the device.

(3) The changes are those that require—

(a) for a device for which the comparable regulator country is Australia, an updated version of the existing conformity assessment certificate,

(b) for a device for which the comparable regulator country is Canada, an amendment to their medical device licence,

(c) for a device for which the comparable regulator country is the United States of America, a new 510(k) or PMA supplement.

(4) The manufacturer must document any change made to a Route 1, Route 2 or Route 3 device and keep this information available for inspection by the Secretary of State.

DRAFT

Document retention

82.—(1) For a Route 1 device, the manufacturer and the UK responsible person (if there is one) must keep the following documents for the later of either the lifetime of the device, or 10 years from the date of the last manufacture of the device by the manufacture—

(a) the declaration referred to in regulation 77(2)(a)(ii) (registration), and

(b) any associated documentation relevant to the device design, safety and performance.

(2) For a Route 2 or a Route 3 device, the manufacturer and the UK responsible person (if there is one) must keep a copy of the following documents for the period referred to in paragraph (3)—

(a) the Certificate of International Reliance,

(b) the information listed in regulation 71 (application for Certificate of International Reliance - Route 2 and 3 devices), and

(c) any associated documentation relevant to the device design, safety and performance.

(3) The period referred to in paragraph (2) is the later of—

(a) the lifetime of the device,

(b) in the case of an implantable device, 15 years from the date of the last manufacture of the device by the manufacturer, and

(c) in the case of any device that is not an implantable device, 10 years from the date of the last manufacture of the device by the manufacturer.

Inspection of documentation by the Secretary of State

83.—(1) A manufacturer and the UK responsible person (if there is one) must keep available for inspection the documentation referred to in regulation 82 to the Secretary of State upon request.

(2) The Secretary of State may request that the documentation be provided in summary form.

(3) The manufacturer and the UK responsible person (if there is one) must comply with a request by the Secretary of State under paragraph (1) or (2) before the end of—

(a) the period of three working days beginning with the day on which the Secretary of State makes the request, or

(b) such longer period as may be agreed by the Secretary of State in a particular case.

Systems and procedure packs

84.—(1) No person shall supply a system or procedure pack consisting of devices that are subject to this Part (if that supply is also a placing on the market, or if that supply is of a system or procedure pack that has been placed on the market) unless—

(a) the medical devices in that system or procedure pack comply with the requirements of this Part;

(b) the medical devices in that system or procedure pack are for use within their intended purpose and within the limits of use specified by their manufacturer;

(c) the person who places or has placed it on the market has drawn up a declaration that—

DRAFT

(i) they have verified the mutual compatibility of the medical devices in that system or procedure pack in accordance with the manufacturers' instructions, and they have carried out their operations in accordance with these instructions,

(ii) they have packaged the system or procedure pack and supplied relevant information to users incorporating relevant instructions from the manufacturers,

(iii) their production of the system or procedure pack is subjected to appropriate methods of internal control and inspection,

and that declaration is true at the time it is made and continues to be true.

(2) No person shall supply (if that supply is also a placing on the market, or if that supply is of a device that has been placed on the market)—

(a) a system or procedure pack which was sterilised before being placed on the market; or

(b) a system or procedure pack which is designed by its manufacturer to be sterilised before use,

unless the person who places, or who has placed, the device on the market satisfies the conditions set out in paragraph (3).

(3) The conditions referred to in paragraph (2) are that the person shall—

(a) follow the procedures referred to in either Annex II or V to Council Directive 93/42/EEC that relate to obtaining sterility; and

(b) if the device has been sterilised, make a written declaration that sterilisation has been carried out in accordance with the manufacturer's instructions.

(4) The application of Annex II or V and the intervention of the approved body are limited to the aspects of the procedure relating to the obtaining of sterility until the sterile package is opened or damaged.

(5) The declarations referred to in sub-paragraphs (1)(c) and (3)(b) shall be kept available for the Secretary of State by the person responsible for placing the product on the market for a period of five years.

UDI for systems and procedure packs

85.—(1) Prior to a system or procedure pack being placed on the market, the person referred to in regulations 7A(1) (registration of persons placing general medical devices on the market) and 21A(1) (registration of persons placing active implantable medical devices on the market) must ensure the following UDI requirements are met respect of systems and procedure packs that are subject to this Part—

(a) a UDI (including a UDI-DI and UDI-PI) has been assigned to the system or procedure pack;

(b) each medical device contained within a system or procedure pack has its own UDI;

(c) the UDI is affixed to the outside of the packaging, and

(d) the UDI is readable, or in the case of AIDC is scannable, whether placed on the outside of the packaging or inside transparent packaging.

(2) Devices which are exempt under these regulations from bearing a UDI on the device or packaging are not required to have a UDI when included within a system or procedure pack.

DRAFT

(3) In this regulation "AIDC", "UDI-DI" and "UDI-PI" have the same meaning as in Part 1 of Schedule 8.

On-market batch verification

86.—(1) The manufacturer of a Class D *in vitro* diagnostic medical device for which a certificate has been issued must carry out the plan referred to in regulation 71(3)(c)(ii) and must provide the test results to the approved body.

(2) The approved body must assess whether the test results meet the requirement in regulation 71(3)(c).

(3) The approved body may request samples of the device or batches of devices from the manufacturer if they have reasonable grounds to believe that the requirements in regulation 71(3)(c) have not been met.

(4) The approved body may arrange for independent batch verification testing of any devices if they have reasonable grounds to believe that the requirements in regulation 71(3)(c) have not been met.

Electromagnetic compatibility

87. Before placing on the market a Route 1, Route 2 or Route 3 device that is connected to or equipped with an energy source, the manufacturer must ensure that it is designed and manufactured in such a way as to—

(a) reduce as far as possible the risks of creating electromagnetic interference which could impair the operation of the device in question or other devices or equipment in the intended environment, and

(b) provide a level of intrinsic immunity to electromagnetic interference such that is adequate to enable the device to operate as intended.

On-market requirements for manufacturers

88. The manufacturer and their UK responsible person (if there is one) for which a certificate has been issued must notify the Secretary of State if—

(a) the authorisation for use in the comparable regulator country has been suspended or cancelled, or

(b) the manufacturer has withdrawn the device from use in the comparable regulatory country.

On-market requirements for approved bodies

89. If, in reviewing information provided under regulation 44ZG or 44ZM, the approved body identifies a serious risk or serious safety concern regarding the safety or performance of the device then the approved body must notify the Secretary of State."

DRAFT

PART 11

Amendments to the Schedules

Amendments to Schedule 2A - modifications of Annexes to Directives 90/385, 93/42, 98/79

71.—(1) Schedule 2A(**a**) is amended as follows.

(2) In paragraph 1(1), for "paragraphs 2" substitute "paragraphs 3".

(3) Omit paragraph 2(**b**).

(4) In paragraph 3(**c**)—

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

"(ii) in point (c)—

(aa) in the first indent for "Article 5" substitute "regulation 3A of the Regulations";

(bb) in the third indent for "Section 10 of Annex 1" substitute "section 12.1 of Annex I to Regulation (EU) 2017/745 (as modified by, and as it has effect under, Parts 1 and 2 of Schedule 2B)";";

(b) for sub-paragraph (j) substitute—

"(j) in Section 4.2—

(aa) in the second indent for "Article 5" substitute "regulation 3A of the Regulations";

(bb) in the third indent for "section 10 of Annex 1" substitute "section 12.1 of Annex I to Regulation (EU) 2017/745 (as modified by, and as it has effect under, Parts 1 and 2 of Schedule 2B)";";

(c) in sub-paragraph (k), in the substituted Section 4.3—

(i) for "Annex 1, Section 10, second paragraph" substitute "paragraph (b) of section 12.1 of Annex I to Regulation (EU) 2017/745 (as modified by, and as it has effect under, Parts 1 and 2 of Schedule 2B)";

(ii) for "Annex 1, Section 10, third paragraph" substitute "paragraph (c) of section 12.1 of Annex I to Regulation (EU) 2017/745 (as modified by, and as it has effect under, Parts 1 and 2 of Schedule 2B)".

(5) In paragraph 4—

(a) for sub-paragraph (g) substitute—

"(g) in Section 3—

(i) for "Article 5", substitute "regulation 3A of the Regulations";

(ii) for "section 10 of Annex 1", substitute "section 12.1 of Annex I to Regulation (EU) 2017/745 (as modified by, and as it has effect under, Parts 1 and 2 of Schedule 2B)";";

(b) in sub-paragraph (h), in the substituted Section 5—

(**a**) Inserted by S.I. 2019/791.
(**b**) Amended by S.I. 2021/873.
(**c**) Amended by S.I. 2021/873.

DRAFT

(i) for "Annex 1, Section 10, second paragraph" substitute "paragraph (b) of section 12.1 of Annex I to Regulation (EU) 2017/745 (as modified by, and as it has effect under, Parts 1 and 2 of Schedule 2B)";

(ii) for "Annex 1, Section 10, third paragraph" substitute "paragraph (c) of section 12.1 of Annex I to Regulation (EU) 2017/745 (as modified by, and as it has effect under, Parts 1 and 2 of Schedule 2B)".

(6) In paragraph 7(**a**)—

(a) after sub-paragraph (a) insert—

"(aa) in Section 2.1, in the sixth indent, for "Annex 1" substitute "Annex I to Regulation (EU) 2017/745 (as modified by, and as it has effect under, Parts 1 and 2 of Schedule 2B)";

(ab) in Section 2.2, in the sixth indent, for "section 10 of Annex 1" substitute "section 12.1 of Annex I to Regulation (EU) 2017/745 (as modified by, and as it has effect under, Parts 1 and 2 of Schedule 2B)";";

(b) for sub-paragraph (d) substitute—

"(d) in Section 3.2—

(i) for the fourth indent substitute—

"— the results of the risk analysis and a list of the designated standards provided for in regulation 3A of the Regulations, applied in full or in part, and a description of the solutions adopted to satisfy the essential requirements where the standards in regulation 3A of the Regulations have not been applied,";

(ii) in the fifth indent, for "Section 10 of Annex 1" substitute "section 12.1 of Annex I to Regulation (EU) 2017/745 (as modified by, and as it has effect under, Parts 1 and 2 of Schedule 2B)";";

(c) after sub-paragraph (d) insert—

"(da) for Section 4 substitute—

"4. The documentation referred to in Section 3 must be kept for a period that begins with the end of the clinical investigation and ends with the later of:

— the lifetime of the device;

— 15 years.

In the event that the device is placed on the market after the clinical investigation has concluded, this documentation must be kept for a period that begins with the date of the last manufacture of the device by the manufacturer and ends with the later of:

— the lifetime of the device;

— 15 years.";".

(7) In paragraph 8(**b**)—

(a) for sub-paragraph (a) substitute—

"(a) in Section 1.1—

(**a**) Amended by S.I. 2024/1368.
(**b**) Substituted by S.I. 2021/873.

DRAFT

(i) for "Sections 1 and 2 of Annex 1" substitute "section 1 of Annex I to Regulation (EU) 2017/745 (as modified by, and as it has effect under, Parts 1 and 2 of Schedule 2B)";

(ii) for "Section 5 of Annex 1" substitute "section 2 of Annex I to Regulation (EU) 2017/745 (as modified by, and as it has effect under, Parts 1 and 2 of Schedule 2B)";

(iii) for "harmonised" substitute "designated";";

(b) after sub-paragraph (a) insert—

"(aa) in Section 2.1, for "section 2 of Annex 1" substitute "section 1 of Annex I to Regulation (EU) 2017/745 (as modified by, and as it has effect under, Parts 1 and 2 of Schedule 2B)";".

(8) In paragraph 11, in sub-paragraph (1), for "paragraphs 12" substitute "paragraphs 13".

(9) Omit paragraph 12.

(10) In paragraph 13(**a**)—

(a) in sub-paragraph (e)—

(i) after paragraph (aa) insert—

"(aza) for "section 7.4 of Annex I" substitute "section 12.1 of Annex I to Regulation (EU) 2017/745 (as modified by, and as it has effect under, Parts 1 and 2 of Schedule 2B)";";

(ii) after paragraph (bb) insert—

"(cc) for "Annex I, Chapter I, Section 2" substitute "section 4 of Annex I to Regulation (EU) 2017/745 (as modified by, and as it has effect under, Parts 1 and 2 of Schedule 2B)";";

(b) in sub-paragraph (i), in the substituted Section 4.3—

(i) for "Annex 1, Section 7.4, second paragraph" substitute "paragraph (b) of section 12.1 of Annex I to Regulation (EU) 2017/745 (as modified by, and as it has effect under, Parts 1 and 2 of Schedule 2B)";

(ii) for "Annex 1, Section 7.4, third paragraph" substitute "paragraph (c) of section 12.1 of Annex I to Regulation (EU) 2017/745 (as modified by, and as it has effect under, Parts 1 and 2 of Schedule 2B)";

(c) after sub-paragraph (j) insert—

"(ja) in Section 5.2, for "Annex I, Chapter I, Section 2" substitute "section 4 of Annex I to Regulation (EU) 2017/745 (as modified by, and as it has effect under, Parts 1 and 2 of Schedule 2B)";";

(d) for sub-paragraph (k) substitute—

"(k) for Section 6.1 substitute—

"6.1 The manufacturer and the UK responsible person (if there is one) must, for the period specified in this section, keep at the disposal of the Secretary of State:

— the declaration of conformity,

(**a**) Amended by S.I.s 2021/873 and 2024/1368.

DRAFT

— the documentation referred to in the fourth indent of Section 3.1 and in particular the documentation, data and records referred to in the second paragraph of Section 3.2,

— the changes referred to in Section 3.4,

— the documentation referred to in Section 4.2, and

— the decisions and reports from the approved body as referred to in Sections 3.3, 4.3, 4.4, 5.3 and 5.4.

The period for the purposes of this section begins with the date of the last manufacture of the device by the manufacturer and ends with the later of:

— the lifetime of the device;

— 15 years in the case of an implantable device, or 10 years in the case of any other device.”.”

(11) In paragraph 14—

(a) in sub-paragraph (d)—

(i) after paragraph (i) insert—

“(ia) for “Section 7.4 of Annex I” substitute “section 12.1 of Annex I to Regulation (EU) 2017/745 (as modified by, and as it has effect under, Parts 1 and 2 of Schedule 2B)”;”;

(ii) after paragraph (ii) insert—

“(iii) for “Annex I, Chapter I, Section 2” substitute “section 4 of Annex I to Regulation (EU) 2017/745 (as modified by, and as it has effect under, Parts 1 and 2 of Schedule 2B)”;”;

(b) in sub-paragraph (e), in the substituted Section 5—

(i) for “Annex 1, Section 7.4, second paragraph” substitute “paragraph (b) of section 12.1 of Annex I to Regulation (EU) 2017/745 (as modified by, and as it has effect under, Parts 1 and 2 of Schedule 2B)”;

(ii) for “Annex 1, Section 7.4, third paragraph” substitute “paragraph (c) of section 12.1 of Annex I to Regulation (EU) 2017/745 (as modified by, and as it has effect under, Parts 1 and 2 of Schedule 2B)”;

(c) for sub-paragraph (h) substitute—

“(h) for Section 7.3 substitute—

“7.3 The manufacturer and the UK responsible person (if there is one) must keep with the technical documentation copies of type-examination certificates and their additions for a period that begins with the date of the last manufacture of the device by the manufacturer and ends with the later of:

— the lifetime of the device;

— 15 years in the case of an implantable device, or 10 years in the case of any other device.”.”

(12) For paragraph 15(h)(**a**), substitute—

(**a**) Amended by S.I. 2021/873.

"(h) for Section 7 substitute—

"7. Administrative provisions

The manufacturer and the UK responsible person (if there is one) must, for the period specified in this section, make available to the Secretary of State:

— the declaration of conformity,

— the documentation referred to in Section 2,

— the certificates referred to in Sections 5.2 and 6.4,

— where appropriate, the type-examination certificate referred to in Annex III.

The period for the purposes of this section begins with the date of the last manufacture of the device by the manufacturer and ends with the later of:

— the lifetime of the device;

— 15 years in the case of an implantable device, or 10 years in the case of any other device.";".

(13) For paragraph 16(h) substitute—

"(h) for Section 5.1 substitute—

"5.1 The manufacturer and the UK responsible person (if there is one) must, for the period specified in this section, make available to the Secretary of State:

— the declaration of conformity,

— the documentation referred to in the fourth indent of Section 3.1,

— the documentation referred to in the seventh indent of Section 3.1,

— the changes referred to in Section 3.4,

— the decisions and reports from the approved body as referred to in Sections 4.3 and 4.4,

— where appropriate, the type-examination certificate referred to in Annex III.

The period for the purposes of this section begins with the date of the last manufacture of the device by the manufacturer and ends with the later of:

— the lifetime of the device;

— 15 years in the case of an implantable device, or 10 years in the case of any other device.";".

(14) For paragraph 17(h)(**a**) substitute—

"(h) for Section 5.1 substitute—

(**a**) Amended by S.I. 2021/873.

DRAFT

"5.1 The manufacturer and the UK responsible person (if there is one) must, for the period specified in this section, make available to the Secretary of State:

— the declaration of conformity,

— the documentation referred to in the seventh indent of Section 3.1,

— the changes referred to in Section 3.4,

— the decisions and reports from the approved body as referred to in the final indent of Section 3.4 and in Sections 4.3 and 4.4,

— where appropriate, the certificates referred to in Annex III.

The period for the purposes of this section begins with the date of the last manufacture of the device by the manufacturer and ends with the later of:

— the lifetime of the device;

— 15 years in the case of an implantable device, or 10 years in the case of any other device.";".

(15) In paragraph 18(**a**)—

(a) for sub-paragraph (c) substitute—

"(c) for Section 2 substitute—

"2. The manufacturer must draw up the technical documentation described in Section 3. The manufacturer and the UK responsible person (if there is one) must make this documentation, including the declaration of conformity, available to the Secretary of State for inspection purposes for a period that begins with the date of the last manufacture of the device by the manufacturer and ends with the later of:

— the lifetime of the device;

— 15 years in the case of an implantable device, or 10 years in the case of any other device.";";

(b) in sub-paragraph (d)—

(i) in paragraph (ii), in sub-paragraph (bb), after "Annex I" insert "to Regulation (EU) 2017/745 (as modified by, and as it has effect under, Parts 1 and 2 of Schedule 2B)";

(ii) after paragraph (ii) insert—

"(iii) in the seventh indent, for "Annex I, Chapter I, Section 2" substitute "section 4 of Annex I to Regulation (EU) 2017/745 (as modified by, and as it has effect under, Parts 1 and 2 of Schedule 2B)";".

(16) In paragraph 19(**b**)—

(a) after sub-paragraph (a) insert—

"(aa) in Section 2.1, in the sixth indent, for "Annex I" substitute "Annex I to Regulation (EU) 2017/745 (as modified by, and as it has effect under, Parts 1 and 2 of Schedule 2B)";";

(**a**) Amended by S.I. 2024/1368.
(**b**) Amended by S.I. 2024/1368.

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(b) for sub-paragraph (b) substitute—

"(b) in Section 2.2—

(i) in the sixth indent, for "Section 7.4 of Annex I" substitute "section 12.1 of Annex I to Regulation (EU) 2017/745 (as modified by, and as it has effect under, Parts 1 and 2 of Schedule 2B)";

(ii) in the seventh indent, for "Directive 2003/32/EC" substitute "Regulation (EU) No 722/2012";";

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

"(ia) in the fifth indent, for "Section 7.4 of Annex I" substitute "section 12.1 of Annex I to Regulation (EU) 2017/745 (as modified by, and as it has effect under, Parts 1 and 2 of Schedule 2B)";";

(d) after sub-paragraph (e) insert—

"(ea) for Section 4 substitute—

"4. The documentation referred to in Section 3 must be kept for a period that begins with the end of the clinical investigation and ends with the later of:

— the lifetime of the device;

— 15 years in the case of an implantable device, or 10 years in the case of any other device.

In the event that the device is subsequently placed on the market, this documentation must be kept for a period that begins with the date of the last manufacture of the device by the manufacturer and ends with the later of:

— the lifetime of the device;

— 15 years in the case of an implantable device, or 10 years in the case of any other device.";".

(17) In paragraph 21—

(a) for sub-paragraph (a) substitute—

"(a) in Section 1.1—

(i) for "Sections 1 and 3 of Annex I" substitute "sections 1 and 5 of Annex I to Regulation (EU) 2017/745 (as modified by, and as it has effect under, Parts 1 and 2 of Schedule 2B)";

(ii) for "Section 6 of Annex I" substitute "section 8 of Annex I to Regulation (EU) 2017/745 (as modified by, and as it has effect under, Parts 1 and 2 of Schedule 2B)";

(iii) for "harmonised standards" substitute "designated standards";";

(b) after sub-paragraph (a) insert—

"(aa) in Section 2.1, for "Section 3 of Annex I" substitute "section 1 of Annex I to Regulation (EU) 2017/745 (as modified by, and as it has effect under, Parts 1 and 2 of Schedule 2B)";".

(18) For paragraph 22(e) substitute—

"(e) in Section 3—

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(i) for “this Directive” substitute “the Regulations”;

(ii) for “Annex I” substitute “Annex I to Regulation (EU) 2017/745 (as modified by, and as it has effect under, Parts 1 and 2 of Schedule 2B)”;”.

(19) In paragraph 24(1), for “paragraphs 25” substitute “paragraphs 26”.

(20) Omit paragraph 25.

(21) After paragraph 26(b)(iii)(**a**) insert—

“(iv) omit “and additionally, in the case of devices for self-testing, the obligations imposed by section 6, ensures and declares that the products concerned meet the provisions of this Directive which apply to them;"”.

(22) After paragraph 27(b)(**b**) insert—

“(ba) for “Annex II, List A”, wherever occurring, substitute “Class D”;”.

(23) After paragraph 30(f) insert—

“(fa) in Sections 5 and 5.1, for “Annex II, List A”, wherever occurring, substitute “Class D”;”.

(24) For paragraph 31(c) substitute—

“(c) for Section 3 substitute—

“3. The manufacturer shall also undertake to keep available for the Secretary of State the documentation allowing an understanding of the design, manufacture and performances of the product, including the expected performances, so as to allow assessment of conformity with the requirements of the Regulations. This documentation must be kept for a period that begins with the end of the performance evaluation and ends with the later of:

— the lifetime of the device;

— 10 years.

In the event that the device is subsequently placed on the market, this documentation must be kept for a period that begins with the date of the last manufacture of the device by the manufacturer and ends with the later of:

— the lifetime of the device;

— 10 years.

The manufacturer shall take all the measures necessary for the manufacturing process to ensure that the products manufactured conform to the documentation mentioned in the first paragraph.”.”

(25) Before paragraph 32(e)(i) insert—

“(ai) for “Annex I” substitute “Annex I to Regulation (EU) 2017/746 (as modified by, and as it has effect under, Parts 1 and 2 of Schedule 2C)”;”.

New Schedule 2B - modification of Regulation (EU) 2017/745

72. After Schedule 2A insert—

(**a**) Amended by S.I. 2024/1368.
(**b**) Amended by S.I. 2024/1368.

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"SCHEDULE 2B

Regulation 4O

Modification of Annexes to Regulation (EU) 2017/745

PART 1

Modifications relating to Annexes I and II to Regulation (EU) 2017/745 (general provisions)

1. For the purposes of these Regulations, in Annexes I and II to Regulation (EU) 2017/745—

(a) for "this Regulation", wherever occurring, substitute "the Medical Devices Regulations 2002";

(b) for "general safety and performance", wherever occurring, substitute "essential".

PART 2

Modifications relating to Annex I to Regulation (EU) 2017/745 (general safety and performance requirements)

2. For the purposes of these Regulations, Annex I to Regulation (EU) 2017/745 has effect as follows—

(a) where the Annex refers to an EU instrument or a provision of an EU instrument, the reference is to the assimilated direct legislation (as defined in the European Union (Withdrawal) Act 2018, Schedule 2, paragraph 8(9)(a)) unless (for a particular reference) this Schedule provides otherwise;

(b) where the Annex is modified by this Schedule to include a reference to an EU instrument or a provision of an EU instrument, the reference is to the assimilated direct legislation.

3. Annex I is modified as follows.

4. In Chapter 1 (general requirements), after paragraph 8 insert—

"8a. Demonstration of conformity with the essential requirements must include a clinical evaluation in accordance with Annex X to Directive 93/42 for general medical devices and Annex 7 to Directive 90/385 for active implantable medical devices."

5. Omit paragraph 9.

6.—(1) In Chapter 2 (requirements regarding design and manufacture)—

(a) in Section 10.4.1—

(i) in point (a), for "Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council", substitute "the GB mandatory classification and labelling list (maintained by the Health and Safety Executive under Article 38A of Regulation (EC) No 1272/2008)";

(ii) in point (b), for "once a delegated act" to the end substitute "Commission Delegated Regulation (EU) 2017/2100 setting out scientific criteria for the

DRAFT

determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council.";

(b) in Section 10.4.2, in point (d), for "in accordance with Sections 10.4.3 and 10.4.4" substitute "relating to the risks and benefits (including the availability of alternative substances, materials, designs or treatments) of CMR products, endocrine-disrupting substances, and phthalates";

(c) omit Section 10.4.3;

(d) omit Section 10.4.4;

(e) for Section 12.1 substitute—

(a)

Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product as defined in regulation 2 of the Human Medicines Regulations 2012, and which is liable to act upon the body with action ancillary to that of the device, the quality, safety and usefulness of the substance must be verified, by the approved body, by analogy with the methods specified in Annex I to Directive 2001/83/EC as modified by the Human Medicines Regulations 2012.

(b) For the substances referred to in paragraph (a), the approved body shall, having verified the usefulness of the substance as part of the medical device and taking account of the intended purpose of the device, seek a scientific opinion from the Secretary of State on the quality and safety of the substance including the clinical benefit/risk profile of the incorporation of the substance into the device. When issuing an opinion, the Secretary of State shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the approved body.

(c) Where a device incorporates, as an integral part, a human blood derivative, the approved body shall, having verified the usefulness of the substance as part of the medical device and taking into account the intended purpose of the device, seek a scientific opinion from the Secretary of State on the quality and safety of the substance including the clinical benefit/risk profile of the incorporation of the human blood derivative into the device. When issuing the opinion, the Secretary of State shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the approved body.

(d) Where a manufacturer makes changes to an ancillary substance incorporated in a device, in particular related to its manufacturing process, the manufacturer must inform the approved body of the changes and the approved body must consult the Secretary of State in order to confirm that the quality and safety of the ancillary substance are maintained. The Secretary of State must take account of the data related to the usefulness of incorporation of the substance into the device as determined by the approved body, in order to ensure that the changes have no negative impact on the established benefit/risk profile of the addition of the substance in the medical device.

(e) Where the Secretary of State has obtained information on an ancillary substance, which could have an impact on the established benefit/risk

DRAFT

profile of the addition of the substance to the device, the Secretary of State must provide the approved body with advice on whether this information has any impact on the established benefit/risk profile of the addition of the substance in the medical device or not. The approved body must take the updated scientific opinion into account in reconsidering its assessment of the conformity assessment procedure.";

(f) omit Section 12.2;

(g) omit Section 13.1;

(h) in Section 13.3, for "Sections 13.1 and" substitute "Section";

(i) in Section 15.2, for "in legal units conforming to the provisions of Council Directive 80/181/EEC", substitute "in authorised units conforming to the provisions of the Units of Measurement Regulations 1986(**a**)";

(j) in Section 16.4, in point (a), after "Directive 2013/59/Euratom" insert "as it has effect under the law of the United Kingdom".

(2) In Chapter 3 (requirements regarding the information supplied with the device)—

(a) in Section 23.1—

(i) in point (c), after "bar codes" insert "for the purpose of electronically conveying relevant information including UDIs";

(ii) in point (f), for "Regulation (EU) No 207/2012" to the end, substitute "Schedule 8A (electronic instructions for use) to the Medical Devices Regulations 2002.";

(iii) in point (h)—

(aa) for "harmonised standards or CS" substitute "designated standards";

(bb) for "no harmonised standards or CS exist" substitute "there are no designated standards";

(b) in Section 23.2—

(i) in point (c), for "registered place" substitute "established place";

(ii) in point (d)—

(aa) for "registered place", wherever occurring, substitute "established place";

(bb) for "Union" substitute "United Kingdom";

(cc) for "authorised representative", wherever occurring, substitute "UK responsible person";

(iii) in point (e), omit the second indent containing "tissues or cells, or their derivatives, of human origin, or";

(iv) in point (h), for "Article 27(4) and Part C of Annex VI" substitute "Schedule 8 (UDI issuing entities, UDIs and registration requirements) to these Regulations";

(v) in point (n), omit ". A manufacturer's indication of single use shall be consistent across the Union";

(vi) in point (o)—

(aa) for "reprocessed" substitute "re-manufactured";

(**a**) S.I. 1986/1082.

DRAFT

(bb) for "reprocessing", wherever occurring, substitute "re-manufacturing";

(vii) for point (s) substitute—

"(s) on the lowest level of packaging of implantable devices—

(i) a UDI-DI marked or identified using AIDC, and

(ii) a UDI-PI marked or identified using AIDC that contains the serial number in the case of active implantable medical devices,

(iii) the serial number in the case of active implantable medical devices, and

(iv) the serial number or lot number in the case of non-active implantable medical devices."

(c) in Section 23.4—

(i) omit point (d);

(ii) in point (n), omit "appropriate to the Member State or Member States in which the device has been placed on the market";

(iii) in point (s)—

(aa) in the fifth limb, omit "and";

(bb) in the sixth limb, omit ", or that could result in the sensitisation or an allergic reaction by the patient or user" and after the semi-colon add "and";

(cc) after the sixth limb, insert—

"- a list of materials incorporated into the device that could result in sensitisation or an allergic reaction by the patient or user, and precautionary statements relating to them;";

(vi) omit point (x);

(vii) in point (z), for "competent authority of the Member State in which the user and/or patient is established" substitute "Secretary of State";

(viii) in point (aa), for "Article 18" substitute "regulation 19E of the Medical Devices Regulations 2002 for implantable devices, and regulation 31B of the Medical Devices Regulations 2002 for active implantable medical devices".

PART 3

Modifications relating to Annex II to Regulation (EU) 2017/745 (Technical Documentation)

7. For the purposes of regulation 8A and regulation 22A, Annex II to Regulation (EU) 2017/745 has effect—

(a) as if any reference to relevant essential requirements in Annex I to Regulation (EU) 2017/745 were to that provision as modified by Part 1 and Part 2 of this Schedule;

(b) as if it were also subject to the modifications listed in this Part of this Schedule;

(c) as if any reference to "this Regulation" were to "the Medical Devices Regulations 2002".

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8. Annex II is modified as follows.

9.—(1) In Section 1.1—

(a) in point (b)—

(i) for "Part C of Annex VI" substitute "Part 1 of Schedule 8 (UDI issuing entities, UDIs and registration requirements) to the Medical Devices Regulations 2002";

(ii) for "as soon as identification of this device becomes based on a UDI system", substitute "under regulation 7A and regulation 21A of the Regulations";

(b) for point (f) substitute—

"(f) a statement of the device's classification under the Regulations;".

(2) In Section 1.2, in point (b), for "Union" substitute "United Kingdom".

10. In Section 2, omit "in the languages accepted in the Member States where the device is envisaged to be sold", wherever occurring.

11. In Section 4—

(a) after "Annex I" insert "(as modified by, and as it has effect under, Parts 1 and 2 of Schedule 2B)";

(b) for point (c) substitute—

"(c) the designated standards applied; and";

(c) in point (d), for "harmonised standard, CS or other method" substitute "designated standard".

12.—(1) In Section 6.1—

(a) in point (b), for "Directive 2004/10/EC of the European Parliament and of the Council" substitute "the Good Laboratory Practice Regulations 1999 (S.I. 1999/3106)";

(b) for point (c) substitute—

"(c) the written reports prepared in accordance with Annex X to Directive 93/42 for general medical devices and Annex 7 to Directive 90/385 for active implantable medical devices;";

(c) for point (d) substitute—

"(d) any plan for post-market clinical follow-up and the conclusions of any post-market clinical follow-up."

(2) In Section 6.2—

(a) in point (a)—

(i) for "point 2 of Article 1 of Directive 2001/83/EC" substitute "regulation 2(1) (medicinal products) of the Human Medicines Regulations 2012 (S.I. 2012/1916)";

(ii) omit "as referred to in the first sub-paragraph of Article 1(8)";

(b) in point (b)—

(i) omit "human or" in both places;

(ii) omit "in accordance with points (f) and (g) of Article 1(6, and where a device incorporates, as an integral part, tissues or cells of human origin or their

DRAFT

derivatives that have an action ancillary to that of the device and is covered by this Regulation in accordance with the first subparagraph of Article 1(10)";

(iii) for "Sections 13.1. or 13.2., respectively," substitute "Section 13.2."."

New Schedule 2C - modification of Regulation (EU) 2017/746

73. After Schedule 2B insert—

"SCHEDULE 2C

Regulation 4P

Modification of Annexes to Regulation (EU) 2017/746

PART 1

Modifications relating to Annexes I and II to Regulation (EU) 2017/746 (general provisions)

1. For the purposes of these Regulations, in Annexes I and II to Regulation (EU) 2017/746—

(a) for "this Regulation", wherever occurring, substitute "the Medical Devices Regulations 2002";

(b) for "general safety and performance", wherever occurring, substitute "essential".

PART 2

Modifications relating to Annex I to Regulation (EU) 2017/746 (general safety and performance requirements)

2. For the purposes of these Regulations, Annex I to Regulation (EU) 2017/746 has effect as follows—

(a) where the Annex refers to an EU instrument or a provision of an EU instrument, the reference is to the assimilated direct legislation unless this Schedule provides otherwise;

(b) where the Annex is modified by this Schedule to include a reference to an EU instrument or a provision of an EU instrument, the reference is to the assimilated direct legislation.

3. Annex I is modified as follows.

4. In Chapter II (requirements regarding performance, design and manufacture)—

(a) in Section 9.1, for "point (2) of Article 2" substitute "the definition of "*in vitro* diagnostic medical device" in regulation 2 of the Medical Devices Regulations 2002";

(b) in Section 10.3, for "Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council", substitute "the GB mandatory classification and labelling list (maintained by the Health and Safety Executive under Article 38A of Regulation (EC) No 1272/2008)";

DRAFT

(c) in Section 14.1, after "Annex I" insert "as modified by Schedule 2C to the Medical Devices Regulations 2002";

(d) in Section 14.2, for "in legal units conforming to the provisions of Council Directive 80/181/EEC", substitute "in authorised units conforming to the provisions of the Units of Measurement Regulations 1986(**a**)".

5. In Chapter III (requirements regarding the information supplied with the device)—

(a) in Section 20.1—

(i) in point (c), after "bar codes" insert "for the purpose of electronically conveying relevant information including UDIs";

(ii) in point (h)—

(aa) for "harmonised standards or CS" substitute "designated standards, common specifications or other solutions applied";

(bb) for "no harmonised standards or CS exist" substitute "there are no designated standards, common specifications or other solutions applied";

(iii) in point (i), after "Regulation (EC) No. 1271/2008", wherever occurring, insert "and the Classification, Labelling and Packaging of Substances and Mixtures (Amendment and Consequential Provision) Regulations 2023";

(b) in Section 20.2—

(i) in point (c), for "registered place" substitute "established place";

(ii) in point (d)—

(aa) for "registered place", wherever occurring, substitute "established place";

(bb) for "Union" substitute "United Kingdom";

(cc) for "authorised representative", wherever occurring, substitute "UK responsible person";

(iii) in point (g), for "Article 24 and Part C of Annex VI" substitute "Schedule 8 (UDI issuing entities, UDIs and registration requirements) to these Regulations";

(iv) in point (p), omit ". A manufacturer's indication of single use shall be consistent across the Union";

(c) in Section 20.4.1—

(i) in point (n), in indent (v), omit ". A manufacturer's indication of single use shall be consistent across the Union";

(ii) in point (ad)—

(aa) for "registered place" substitute "established place";

(bb) omit "and/or fax number";

(iii) in point (af), for "competent authority of the Member State in which the user and/or patient is established" substitute "Secretary of State";

(d) in Section 20.4.2, in point (f), omit "specific to the Member State(s) where the device is placed on the market".

(**a**) S.I. 1986/1082.

PART 3

Modifications relating to Annex II to Regulation (EU) 2017/746 (technical documentation)

6. For the purposes of regulation 33B, Annex II to Regulation (EU) 2017/746 has effect—

(a) as if any reference to the relevant essential requirements in Annex I to Regulation (EU) 2017/746 were to that provision as modified by Part 1 and Part 2 of this Schedule;

(b) as if were also subject to the modifications listed in this Part of the Schedule.

(c) as if any reference to "this Regulation" were to "the Medical Devices Regulations 2002".

7. Annex II is modified as follows.

8.—(1) In Section 1.1—

(a) in point (b)—

(i) for "Part C of Annex VI" substitute "Part 1 of Schedule 8 to the Medical Devices Regulations 2002";

(ii) for "as soon as identification of this device becomes based on a UDI system" substitute "under regulation 33A of the Medical Devices Regulations 2002";

(b) for point (f), substitute—

"(f) a statement of the device's classification under the Medical Devices Regulations 2002;"

(2) In Section 1.2(b), for "Union" substitute "United Kingdom".

9. In Section 2, omit "in the languages accepted in the Member States where the device is envisaged to be sold", wherever occurring.

10. In Section 4—

(a) after "Annex 1" insert "(as modified by Schedule 2C to the Medical Devices Regulations 2002)";

(c) in point (c), for "harmonised standards, CS" substitute "designated standards, common specifications";

(d) in point (d), for "harmonised standard, CS" substitute "designated standard, common specification".

11. In Section 6—

(a) omit Section 6.1.3;

(b) omit Section 6.2."

New Schedule 2D - modification of Commission Implementing Regulation (EU) 2022/1107

74. After Schedule 2C insert—

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“SCHEDULE 2D Regulation 4P

Modification of Commission Implementing Regulation (EU) 2022/1107

1. Commission Implementing Regulation (EU) 2022/1107 is modified as follows.

2. Omit the preamble.

3. In Article 1, a reference to Annex I to Regulation (EU) 2017/746 is a reference to that Annex as modified by Schedule 2C to the Medical Devices Regulations 2002.

4. Omit Article 3 and Article 4.

5. In Annex I, Part I, a reference to Annex I to Regulation (EU) 2017/746 is a reference to that Annex as modified by Schedule 2C to the Medical Devices Regulations 2002.

6. In the Annexes, for “CE marking”, wherever occurring, substitute “UK marking, as defined in section 2 (interpretation) of the Medical Devices Regulations 2002”.

7. In the Annexes, for “CE marked”, wherever occurring, substitute “UK marked, as defined in section 2 (interpretation) of the Medical Devices Regulations 2002”.

8. In the Annexes, for “CE-marked”, wherever occurring, substitute “UK marked, as defined in section 2 (interpretation) of the Medical Devices Regulations 2002”.”

New Schedule 8 - UDI issuing entities, UDIs and registration requirements

75. At the appropriate place(**a**) insert—

“SCHEDULE 8 Regulations 7A, 21A and 33A

UDI issuing entities, UDIs and registration requirements

PART 1

Interpretation

1. In this Schedule—

“AIDC” means automatic identification and data capture technology, including bar codes, smart cards, biometrics and RFID;

“application programming interface” is software that enables different software applications to communicate, exchange data, and share functionalities between them;

“Basic UDI-DI”means the identifier for a group of products with the same intended purpose, risk class and essential design and manufacturing characteristics, which is referred to in relevant certificates or declarations of conformity;

(**a**) Original Schedule 8 was inserted by S.I. 2019/791 and repealed by S.I. 2020/1478.

DRAFT

"clinical size" means a device's physical attributes (for example, length or width) which are relevant for clinical use;

"contraindications"means specific situations, conditions or patient characteristics (for example pregnancy or allergies) that make use of the device potentially harmful or unsafe;

"critical warnings" means safety information to alert users to significant risks, hazards or precautions associated with the device;

"HRI" means the human readable interpretation of the data characters encoded in the UDI;

"level of packaging" means a level of packaging containing one or more of the same device, where the lowest level is the level containing the individual device and where higher levels of packaging contain one or more levels of packaging;

"Registration system" means the electronic system operated by the Secretary of State in respect of the registration of data and UDIs;

"remanufactured single-use device"means a device with a certificate issued by an approved body or notified body for the remanufacturing of single-use devices;

"RFID" means the radio frequency identification technology which uses communication through the use of radio waves for the purpose of identification;

"software identification" is a method to identify a device that is software, which can include identifying the software version number;

"UDI carrier" is the means of conveying the UDI by using AIDC and, if applicable, its HRI;

"UDI-DI" means the UDI-Device Identifier which is the UDI specific to a manufacturer and a model of medical device;

"UDI-PI" means the UDI-Product Identifier which is the UDI for the unit of medical device production and, if applicable, the packaged medical devices;

"Unit of Use UDI-DI" means the identifier assigned to an individual medical device, which is assigned in instances when a UDI is not labelled at the level of the device unit of use.

PART 2

Registration of UDI issuing entities

2.—(1) A person other than an individual or unincorporated body may register with the Secretary of State as a UDI issuing entity provided that person—

(a) meets the criteria for registration in paragraph 2,

(b) grants the Secretary of State access to its system which is for the assignment of UDIs and any UDIs assigned under its system, and

(c) makes available to the Secretary of State such other information as the Secretary of State may require about its system for the assignment of UDIs and any UDIs assigned under its system.

(2) The criteria for registration of UDI issuing entities are—

DRAFT

(a) the UDI issuing entity's system for the assignment of UDIs conforms to the relevant designated standard in accordance with regulation 3A,

(b) the UDI issuing entity's system for the assignment of UDIs permits the identification of a device throughout its distribution and use, and

(c) the UDI issuing entity operates its system for the assignment of UDIs in respect of any interested user in accordance with a set of consistent and transparent terms and conditions.

(3) The Secretary of State may remove a person from the register where that person no longer complies with the terms of registration in paragraph 1.

PART 3

General UDI requirements

3. The following requirements apply to the manufacturer except where otherwise provided for—

(a) the UDI must use the coding standards provided by the UDI issuing entity, including the HRI;

(b) the manufacturer or the UK responsible person (if there is one) must use the UDI for reporting serious incidents and field safety corrective actions in accordance with regulations 44ZH, 44ZI and 44ZJ;

(c) the Basic UDI-DI, must appear on the declaration of conformity referred to in Annexes II, III, IV, V, VI, VI or VII for Part II, and Annexes II, III or IV, V, VI, or VII for Part VII, and Annexes 2, 3 or 4 for part III, and Annexes III, IV, V, VI or VII for Part IV;

(d) where applicable for devices that are the subject of a conformity assessment procedure, the assignment of the Basic UDI-DI in sub-paragraph (c) must be completed before applying to an approved body for that assessment;

(e) for the devices referred to in sub-paragraph (d)—

(i) the approved body must include a reference to the Basic UDI-DI on the certificate issued in accordance with that conformity assessment procedure, and

(ii) after the issuing of the relevant certificate and before placing the device on the market, the manufacturer or the UK responsible person (if there is one) must provide the Basic UDI-DI to the Registration system;

(f) a list of all UDIs that has been assigned must be kept up-to-date and include reference to the UDI in the device's technical documentation;

(g) the manufacturer, the UK responsible person (if there is one) or the other person placing the device on the market (if there is one) must store, by electronic means or otherwise, the UDI of the devices which they have supplied or with which they have been supplied; and

(h) where a person repackages or relabels a device, or remanufacturers a single use device, such that the person becomes a manufacturer of the device, that person must, in addition to complying with the requirements of regulation 7A, regulation 21A or regulation 33A, also retain a record of the device's original UDI.

4. The following requirements apply to the manufacturer in respect of the representation and labelling of UDIs —

DRAFT

(a) the UDI must be represented in a form of a UDI carrier;

(b) subject to sub-paragraph (c) and (h) and except where the device is within a container used solely in the shipment or transportation of devices, a UDI must be placed on the device, or the label, and on all higher levels of its packaging;

(c) where the device or its packaging is too small to accommodate all labelling and marking requirements—

(i) if the device is intended to be used in a home environment or by a person other than a healthcare professional, the HRI format must take priority over other information on the device and its packaging,

(ii) otherwise the AIDC must take priority over other information on the device and its packaging;

(d) in respect of the UDI-PI—

(i) if a lot number, serial number, software identification or expiry date appears on the label of the device, that information must be part of the UDI-PI;

(ii) where there is only a manufacturing date on the label, that date must be used as the UDI-PI;

(e) when a device carries an AIDC in addition to the UDI, the UDI must be clearly distinguishable from that AIDC;

(f) linear bar codes used in implantable medical devices must be concatenated and not separated in two or more bar codes, and all parts and elements of the linear bar code must be distinguishable and identifiable;

(g) if the UDI is represented using RFID technology, the label must also include a linear or 2D bar code set out in accordance with the standard used by the UDI issuing entity;

(h) the UDI must be readable during normal use and throughout the intended lifetime of the device;

(i) if the UDI is readable or, in the case of AIDC, scannable, through the device's packaging, the UDI does not need to be placed on that higher level of packaging;

(j) in the case of single finished devices made up of multiple parts which are assembled before the device is first used, the UDI must be placed on at least one of these parts; and

(k) the UDI must be placed in a manner such that the AIDC can be accessed during normal operation or storage of the device;

PART 4

Additional UDI requirements in relation to certain devices and other changes to devices

5. The manufacturer must assign a new UDI-DI to the device when any changes in the following are made to the device—

(a) trade name or brand name;

(b) device version or model;

(c) clinical size, including volume, length, gauge and diameter;

(d) labelling indicating the device is a single use device;

(e) labelling indicating the device is sterile;

DRAFT

(f) whether or not the device needs to be sterilised before use;

(g) quantity of devices in a package;

(h) critical warnings or contraindications; and

(i) remanufacturing of a single use device.

6. For reusable devices that require cleaning, disinfection, sterilisation or refurbishing between uses—

(a) the UDI must be placed on the device and be permanent and readable throughout the intended lifetime of the device, and

(b) the UDI-PI characteristics, in particular the lot or serial number, must be assigned to the device by the manufacturer except where—

(i) the UDI would interfere with the safety or performance of the device, or

(ii) the device cannot be directly marked because it is not technologically feasible to do so.

7. The following requirements apply in respect of implantable devices—

(a) implantable devices must be marked using AIDC with a UDI-DI and UDI-PI on the level of packaging closest to the device;

(b) the UDI-PI must contain the serial number for active implantable medical devices or, for other implantable devices, must contain the serial number or lot number; and

(c) the UDI must be identifiable prior to implantation.

8. The following requirements apply in respect of a system or procedure pack—

(a) the manufacturer is responsible for marking the system or procedure pack with a UDI-DI and UDI-PI;

(b) each medical device contained within a system or procedure pack must have its own UDI;

(c) the UDI must be affixed to the outside of the packaging; and

(d) the UDI must be readable or, in the case of AIDC, scannable, whether placed on the outside of the packaging of the system or procedure pack or inside transparent packaging.

9. The following requirements apply in respect of devices which consist of components which can be assembled in more than one configuration ("configurable devices") —

(a) a single UDI must be assigned to a configurable device in its entirety;

(b) the UDI-DI must be assigned to groups of configurations, not each configuration within a group, in accordance with the technical documentation;

(c) a UDI-PI must be assigned to each configurable device;

(d) the UDI must be placed on the assembly that is most unlikely to be exchanged during the lifetime of the system and must be marked as the UDI of the configurable device; and

(e) each component of a configurable device that is considered a device on its own must be assigned a separate UDI.

10. The following requirements apply in respect in respect of software—

(a) for software constitutes a device in itself, a UDI must be assigned at the system level of the software;

DRAFT

(b) the software identification must be displayed in the UDI-PI;

(c) where the manufacturer has chosen to have a PCCP under regulation 19F or 44ZBB—

(i) a new UDI-DI is required whenever there is a modification to the software that changes the intended use of the software, the safety of the software or changes any aspects outside of the limits of the PCCP;

(ii) a new UDI-PI is required for all other modifications to the software;

(d) where the manufacturer has chosen not to have a PCCP under regulation 19F or 44ZBB—

(i) a new UDI-DI is required whenever there is a modification to the software that changes the original performance of the software, the safety or the intended use of the software or the interpretation of data;

(ii) a new UDI-PI is required for all other modifications to the software;

(e) where the software is supplied on a physical medium such as a CD or DVD, each level of packaging must bear the HRI and AIDC representation of the complete UDI, which must be the same as the UDI assigned to the system level software;

(f) the UDI must be provided on a readily accessible screen for the user in an easily readable plain-text format or included on the start-up screen;

(g) software lacking a user interface, must be capable of transmitting the UDI through an application programming interface; and

(h) the HRI element of the UDI must be displayed on the screen;

PART 5

Registration requirements in respect of data and UDIs

11. The following requirements apply in respect of registration of data and UDIs—

(a) manufacturers or the UK responsible person (if there is one), must periodically, and at least annually, verify the correctness of all of the data relevant to devices they have placed on the market, except for devices that are no longer placed on the market;

(b) manufacturers or the UK responsible person (if there is one), must ensure the registration of their data and UDIs are complete, correct and up-to-date and, where appropriate and within 30 days, must submit corrections or updates to the Registration system; and

(c) data relating to devices that are no longer placed on the market must be retained in the Registration system.

12. In respect of general medical devices and active implantable medical devices the manufacturer, or the UK responsible person (if there is one), must submit the following information to the Secretary of State and ensure that the information on their devices is complete, correct and up-to-date—

(a) the name, address and contact details of the manufacturer and UK responsible person (if there is one);

(b) the name and address of the original device manufacturer, if different from above;

(c) the Unique Registration Number;

(d) basic UDI-DI and UDI-DI;

DRAFT

(e) declaration or certificate, including type, number and expiry date issued by an approved body and the name or identification number of that approved body;

(f) risk classification of the device;

(g) whether the device is active;

(h) whether the device is implantable;

(i) whether the device is intended to introduce, or to remove, medicinal products, bodily fluids or other substances into, or from, the body;

(j) the Global Medical Device Nomenclature;

(k) trade name or brand name;

(l) device model, version, reference, or catalogue number, as applicable;

(m) the manner in which production of the device is controlled, including in particular the expiry date or manufacturing date, lot number and serial number;

(n) whether the device is labelled as a single-use device and, if so, the maximum number of reuses;

(o) whether the device is labelled sterile and, if so, the method of sterilisation;

(p) whether there is a need for sterilisation before use and, if so, the method of sterilisation;

(q) whether the device contains natural rubber latex or dry natural rubber latex;

(r) whether the device is a remanufactured single-use medical device;

(s) in the case of Class III or implantable devices, whether an Annex X summary of clinical evaluation is available;

(t) whether a substance is present which, if used separately, may be considered to be a medicinal product and, if so, the name of that substance;

(u) whether a substance is present which, if used separately, may be considered to be a medicinal product derived from human blood or human plasma and, if so, the name of that substance;

(v) whether tissues or cells of human origin, or their derivatives, are present;

(w) whether tissues or cells of animal origin, or their derivatives, are present;

(x) whether endocrine disruptors are present;

(y) whether substances which are carcinogenic, mutagenic or toxic to reproduction are present;

(z) whether nanomaterials are present;

(aa) whether the device contains an Artificial Intelligence component or element;

(bb) quantity per package configuration; and

(cc) the status of the device, in particular whether it is on the market or no longer on the market.

13. Additionally, in respect of general medical devices and active implantable medical devices, the following data elements must be submitted to the Secretary of State, if applicable—

(a) clinical size, including in particular the volume, length, gauge and diameter;

(b) additional product description;

(c) where a UDI is not labelled on the device at the level of its unit of use, the unit of use UDI-DI;

DRAFT

(d) secondary or additional UDI-DI;

(e) storage and any handling conditions, as indicated on the label or in the instructions for use;

(f) critical warnings or contraindications;

(g) MRI safety information;

(h) the identification number of any clinical investigation conducted in relation to the device and where applicable, a summary of the clinical investigation; and

(i) URL for additional information, such as electronic instructions for use.

14. In respect of *in vitro* diagnostic medical devices the manufacturer, or the UK responsible person (if there is one), must submit the following information to the Secretary of State and ensure that the information on their devices is complete, correct and up-to-date—

(a) the name, address and contact details of the manufacturer and UK responsible person (if there is one);

(b) the name and address of the original device manufacturer, if different from above;

(c) the Unique Registration Number;

(d) Basic UDI-DI and UDI-DI;

(e) declaration or certificate including type, number and expiry date issued by an approved body and the name or identification number of that approved body;

(f) classification of the device;

(g) whether the device is undergoing a performance evaluation study;

(h) the Global Medical Device Nomenclature;

(i) trade name or brand name;

(j) device model, version, reference, or catalogue number, as applicable;

(k) the manner in which production of the device is controlled, including in particular the expiry date or manufacturing date, lot number and serial number;

(l) whether the device is labelled as a single-use device and, if not, the maximum number of reuses;

(m) whether the device is labelled sterile and, if so, the method of sterilisation;

(n) whether there is a need for sterilisation before use and, if so, the method of sterilisation before use;

(o) whether tissues or cells of human origin, or their derivatives, are present;

(p) whether tissues or cells of animal origin, or their derivatives, are present;

(q) whether cells or substances of microbial origin are present;

(r) whether the device contains an Artificial Intelligence component or element;

(s) quantity per package configuration;

(t) the status of the device, in particular whether it is on the market or no longer on the market;

(u) whether the device is a new relevant device;

(v) whether the device is intended for self-testing, near-patient testing or point of care testing; and

(w) in the case of Class C or D devices, whether a summary of performance evaluation is available.

DRAFT

15. Additionally, in respect of *in vitro* diagnostic medical devices, the following data elements must be submitted to the Secretary of State, if applicable—

(a) additional product description;

(b) where a UDI is not labelled on the device at the level of its unit of use, the unit of use UDI-DI;

(c) secondary or additional UDI-DI;

(d) storage and any handling conditions, as indicated on the label or in the instructions for use;

(e) critical warnings or contraindications; and

(f) URL for additional information, such as electronic instructions for use.

16. The information entered into the Registration system, including the name and address of the manufacturer and the UK responsible person (if there is one), as well as all the other information in respect of their devices except for commercially sensitive information or information which, if disclosed, would contravene data protection legislation, will be made publicly available."

New Schedule 8A - electronic instructions for use

76. At the appropriate place(**a**) insert—

"SCHEDULE 8A

Regulation 1A

Electronic instructions for use

Scope and interpretation

1. This Schedule applies to devices, other than *in vitro* diagnostic medical devices, which are—

(a) active implantable medical devices;

(b) implantable devices;

(c) fixed installed medical devices;

(d) other devices that have a built-in system to visually display the instructions for use; or

(e) software.

2. In this Schedule, "fixed installed medical device" means a device—

(a) which is intended to be installed, fastened or otherwise secured at a specific location in an entity providing healthcare so it cannot be moved from this location or detached without using tools or apparatus, and

(b) which is not specifically intended to be used within a mobile entity providing healthcare.

3. For the purposes of this Schedule, instructions for use of a device are provided "in electronic form" where they are—

(a) displayed in electronic form by the device,

(**a**) Original Schedule 8 was inserted by S.I. 2019/791 and repealed by S.I. 2020/1478.

DRAFT

(b) contained in portable electronic storage media supplied with the device by its manufacturer, or

(c) made available by the manufacturer through software or through a website.

4. In this Schedule, a reference to a device includes an accessory to that device.

Provision of instructions in electronic form

5. A manufacturer of a device may provide instructions for use of a device in electronic form (instead of in paper form) for the devices listed in paragraph 1(a) to (d) if the device is intended for use only by a healthcare professional in the course of that profession and use of the device by any other person is not reasonably foreseeable.

6. A manufacturer of a device may provide instructions for use in electronic form for the devices listed in paragraph 1(a) to (e) if—

(a) the manufacturer has carried out a documented risk assessment, covering the matters set out in paragraph 8, in relation to the provision of instructions in electronic form, and

(b) the risk assessment demonstrates that the safety of the device is not compromised by the instructions being provided in electronic form instead of in paper form.

7. Where instructions in electronic form are provided instead of in paper form, the manufacturer must comply with the conditions set out in paragraphs 10 to 27.

Risk assessments

8. The risk assessment mentioned in paragraph 6(a) must, in particular, cover the following matters in relation to the provision of instructions in electronic form—

(a) how familiar intended users are expected to be with—

(i) the device,

(ii) user needs, and

(iii) the hardware and software needed to display the instructions;

(b) the characteristics of the environment in which the device will be used;

(c) how easily users will be able to access the electronic resources needed to display the instructions;

(d) the effectiveness of safeguards for ensuring that the content of the instructions is protected from tampering;

(e) safety and back-up mechanisms in the event of a hardware or software fault;

(f) any reasonably foreseeable medical emergency situations in which having instructions available in a paper form would be required;

(g) the impact of users being—

(i) temporarily unable to access the website through which the instructions are available;

(ii) temporarily unable to access the internet;

(h) safety measures to address the impacts mentioned in sub-paragraph (g);

(i) the period within which the instructions for use must be provided to users in paper form upon request;

DRAFT

(j) where the instructions are displayed on a website, an assessment of the website's compatibility with different devices that may be used to access the website;

(k) how revisions and updates to the instructions will be managed.

9. The risk assessment must be kept up to date, and in particular must be updated as a result of information collected in the course of post-market surveillance carried out under Part 4A.

Conditions: instructions in electronic form

10. The manufacturer must clearly indicate to users—

(a) that the instructions are being provided in electronic form instead of instructions in paper form, and

(b) how to access the instructions.

11. The information mentioned in paragraph 10 must be provided—

(a) where the device is software, at the location where access to the software is granted;

(b) for any other device, on the packaging for the device or where appropriate, on the sales packaging.

12. Where it is not practicable to provide the information mentioned in paragraph 10(b) in accordance with paragraph 11, this information may instead be provided in a paper document provided with the device.

13. Where the device is a fixed installed medical device, the information mentioned in paragraph 10 must also be provided on the device itself.

14. The instructions—

(a) must be available in text form in English (which may contain symbols and graphics), and

(b) must contain at least the information that they would be required to contain if they were provided in paper form.

15. The manufacturer must ensure that the electronic IFUs are functional and verify that they can be easily accessed by the end user.

16. Information on how to access the instructions must contain—

(a) any information needed to view the instructions;

(b) the Basic UDI and/or the UDI-DI of the device, and any additional information needed to identify the device, in particular its name and model;

(c) contact details for the manufacturer and the UK responsible person (if there is one);

(d) details of—

(i) how to request free of charge a copy of the instructions in paper form, and

(ii) the period within which the copy will be provided, which must be no later than the end of the period of seven calendar days beginning with the day on which the request is received, or where the request is made when the device is ordered, no later than the time when the device is delivered.

DRAFT

17. Where a device is fitted with a built-in system that displays the instructions, the manufacturer must ensure that displaying those instructions does not impede the safe use of the device, in particular any life-monitoring or life-supporting functions of the device.

18. The instructions must be available for users for a period which—

(a) begins with the date of the last manufacture of the device by the manufacturer, and

(b) ends with the later of—

(i) the lifetime of the device,

(ii) in the case of an implantable device, 15 years, and

(iii) in the case of any other device, 10 years.

19. The manufacturer must have arrangements in place for—

(a) indicating when the instructions have been revised and informing users if the revision was necessary for safety reasons,

(b) informing users of updates or corrective actions in relation to the instructions, where the instructions have been downloaded from a website, and

(c) making all historical versions of the instructions available on the manufacturer's website, along with their dates of publication.

20. If the instructions are—

(a) displayed in electronic form by the device, or

(b) contained in portable electronic storage media supplied with the device by its manufacturer,

then the manufacturer must also make the instructions available through a website.

21. In a case where the instructions are made available through a website—

(a) they must be available in a commonly used format that can be read with software that is available free of charge,

(b) the manufacturer must ensure that there are safeguards to protect the website against unauthorised access or tampering of content,

(c) the website address must be accessible for the whole of the period during which the instructions must be available to users under paragraph 18, and

(d) the manufacturer must take steps to ensure that periods for which the server is unavailable are minimised and display errors are reduced as far as possible.

Conditions: certain information to be provided in paper form or on the device

22. The manufacturer must have arrangements in place for ensuring that instructions for use can also be provided upon request free of charge in paper form to the user within the period set out in the risk assessment (see paragraph 8(i)).

23. The manufacturer must provide information on any software and hardware requirements for displaying the instructions in electronic form in their catalogue or other supporting documentation.

24. Where, in the case of an implantable device, part of the instructions is intended to be provided to the patient, the manufacturer must provide that part in paper form.

DRAFT

25. Where a device is fitted with a built-in system that displays the instructions, the manufacturer must provide information on how to start the device on the device itself or in an accompanying leaflet.

26. The manufacturer must provide information on reasonably foreseeable medical emergency situations that may occur when using the device on the device itself or in an accompanying leaflet.

Provision of instructions in electronic form as well as in paper form

27. A manufacturer may provide instructions in electronic form as well as in paper form if—

(a) the content of the instructions in electronic form is consistent with the content of the instructions in paper form, and

(b) where the instructions in electronic form are made available through a website, the manufacturer ensures that the conditions in paragraph 19(c) and paragraph 21(b) and (c) are complied with in relation to that website."

New Schedule 9 - classification rules for general medical devices and active implantable medical devices

77. At the appropriate place(**a**) insert—

"SCHEDULE 9 Regulation 21ZA

Classification rules for general medical devices and active implantable medical devices

PART 1

Introductory

Interpretation

1.—(1) In this Schedule—

"accessory" means an article which, whilst not being a medical device, is intended specifically by its manufacturer to be used together with a medical device to enable it to be used in accordance with the use of the medical device intended by its manufacturer.

"active device" means—

(a) a device—

(i) the operation of which depends on a source of electrical energy or any source of power other than that generated by the human body or by gravity, and

(ii) which acts by changing the density of, or converting, that energy,

(**a**) Original Schedule 9 was inserted by S.I. 2019/791 and repealed by S.I. 2020/1478.

DRAFT

but does not include a device intended to transmit energy, substances or other elements between an active device and a patient without any significant change, or

(b) a device that is software;

"active device intended for diagnosis and monitoring" means an active device, whether used alone or in combination with other devices, intended to supply information for—

(a) detecting,

(b) diagnosing,

(c) monitoring,

(d) treating, or

(e) providing a prediction or prognosis for,

states of health, physiological or pathological conditions;

"active therapeutic device" means an active device, whether used alone or in combination with other devices, intended to—

(a) support,

(b) modify,

(c) replace, or

(d) restore,

biological functions or structures with a view to treatment or alleviation of an illness, injury or disability;

"body orifice" means—

(a) any natural opening in the body,

(b) any permanent artificial opening in the body including a stoma, or

(c) the external surface of the eyeball;

"central circulatory system" means the following blood vessels—

(a) arteriae pulmonales,

(b) aorta ascendens,

(c) arcus aortae,

(d) aorta descendens to the bifurcatio aortae,

(e) arteriae coronariae,

(f) arteria carotis communis,

(g) arteria carotis externa,

(h) arteria carotis interna,

(i) arteriae cerebrales,

(j) truncus brachiocephalicus,

(k) venae cordis,

(l) venae pulmonales,

(m) vena cava superior, and

(n) vena cava inferior;

"central nervous system" means the brain, meninges and spinal cord;

DRAFT

"device" means—

(a) a medical device, or

(b) an accessory;

"invasive device" means any device which, in whole or in part, penetrates inside the body through—

(a) a body orifice, or

(b) the surface of the body;

"reusable surgical instrument" means an instrument—

(a) intended for surgical use by cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar procedures; and

(b) which is—

(i) not connected to an active device; and

(ii) intended by the manufacturer to be reused after appropriate procedures have been carried out such as cleaning, disinfection and sterilisation;

"surgically invasive device" means—

(a) an invasive device which penetrates inside the body through the surface of the body, including through the mucous membrane of a body orifice, with the aid of, or in the context of, a surgical operation, or

(b) a device that produces penetration other than through a body orifice.

(2) In relation to the intended use of a device—

"long term" means intended for continuous use for a period of more than 30 days;

"short term" means intended for continuous use for a period lasting between 60 minutes and 30 days inclusive;

"transient" means intended for continuous use for less than 60 minutes;

(3) In calculating the period of continuous use for the purposes of sub-paragraph (2)—

(a) continuous use means an uninterrupted use of the device for the intended purpose; and

(b) the use of a device must be treated as continuous where use is stopped for the device to be replaced immediately by the same or an identical device.

General implementation rules

2.—(1) The rules in this Schedule must be applied in relation to a device by reference to the intended purpose of the device.

(2) Each device must be classified individually, including where the device is—

(a) an accessory; or

(b) is intended to be used in combination with another medical device.

(3) Subject to sub-paragraph (5), software intended to—

(a) drive a device; or

(b) influence the use of a device,

must be classified in the same class as that device.

(4) If a device is not intended to be used solely or principally in a specific part of the body, it must be classified on the basis of the most critical specified use.

DRAFT

(5) If more than one rule applies to a device, the device must be classified in the higher class.

(6) The classes, ranked from lowest to highest, are as follows—

(a) Class I;

(b) Class IIa;

(c) Class IIb;

(d) Class III.

PART 2

Non-invasive devices

Rule 1

3. All non-invasive devices are classified as Class I, unless one of the rules set out in this part applies.

Rule 2

4.—(1) Non-invasive devices intended for channelling or storing blood, other bodily fluids, body tissues or cells, liquids or gases for the purpose of eventual infusion, administration or introduction into the body, are classified as Class IIa if they—

(a) may be connected to a Class IIa, Class IIb or Class III active device, or

(b) are intended for channelling or storing blood, or other bodily fluids, or body tissues or cells including organs or parts of organs.

(2) Blood bags are classified as Class IIb.

Rule 3

5.—(1) Non-invasive devices intended for modifying the biological or chemical composition of blood, or other bodily fluids, intended for infusion into the body are classified as—

(a) Class IIa where the treatment for which the device is used consists of filtration, centrifugation or exchanges of gas or heat;

(b) Class IIb in all other cases.

(2) Devices that are composed of substances that are intended to be used *in vitro* in direct contact with human embryos before their implantation or administration into the body are classified as Class III.

Rule 4

6.—(1) Non-invasive devices intended to come into contact with injured skin or mucous membrane are classified as—

(a) Class I if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates;

(b) Class IIb if they are intended to be used principally for injuries to skin which have breached the dermis or mucous membrane and can only heal by secondary intent;

DRAFT

(c) Class IIa in all other cases.

(2) In this paragraph, "injured skin or mucous membrane" means an area of skin, or an area of mucous membrane, presenting a pathological change or a change following disease or a wound.

PART 3

Invasive devices

Rule 5

7.—(1) Invasive devices with respect to body orifices, which are not intended for connection to an active device or which are intended for connection to a Class I active device, are classified as—

(a) Class I if they are intended for transient use;

(b) Class IIa if they are intended for short-term use, except if they are used in—

(i) the oral cavity as far as the pharynx,

(ii) an ear canal up to the ear drum, or

(iii) a nasal cavity,

in which case they are classified as Class I.

(c) Class IIb if they are intended for long-term use, except if they are used in—

(i) the oral cavity as far as the pharynx,

(ii) an ear canal up to the ear drum, or

(iii) a nasal cavity,

and are not liable to be absorbed by the mucous membrane, in which case they are classified as Class IIa.

(2) Invasive devices with respect to body orifices, which are, intended for connection to a Class IIa, Class IIb or Class III active device, are classified as Class IIa.

(3) This rule does not apply to surgically invasive devices.

Rule 6

8. Surgically invasive devices intended for transient use are classified as—

(a) Class I if they are reusable surgical instruments;

(b) Class IIb if they are intended to—

(i) supply energy in the form of ionising radiation,

(ii) have a biological effect or to be wholly or mainly absorbed,

(iii) administer medicinal products by means of a delivery system, in a manner that is hazardous taking account of the mode of application;

(c) Class III if they are intended specifically—

(i) to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, or

(ii) for use in direct contact with the heart, the central circulatory system or the central nervous system;

(d) Class IIa in all other cases.

DRAFT

Rule 7

9. Surgically invasive devices intended for short term use are classified as—

(a) Class IIb if they are intended to—

(i) undergo chemical change in the body, except devices intended to be placed in the teeth,

(ii) administer medicines, or

(iii) supply energy in the form of ionising radiation;

(b) Class III if they are intended—

(i) specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body,

(ii) to have a biological effect or to be wholly or mainly absorbed, or

(iii) specifically for use in direct contact with the heart, central circulatory system or central nervous system;

(c) Class IIa in all other cases.

Rule 8

10. Implantable devices, and surgically invasive devices intended for long term use, are classified as—

(a) Class IIa if they are intended to be placed in the teeth;

(b) Class III if they are—

(i) intended to be used in direct contact with the heart, the central circulatory system or the central nervous system,

(ii) intended to have a biological effect or to be wholly or mainly absorbed,

(iii) intended to undergo chemical change in the body, except for devices intended to be placed in the teeth,

(iv) devices intended to administer medicinal products,

(v) active implantable medical devices or their accessories,

(vi) breast implants or surgical meshes,

(vii) total or partial joint replacements, except for ancillary components such as screws, wedges, plates and instruments, or

(viii) spinal disc replacement implants or implantable devices that come into contact with the spinal column, except for components such as screws, wedges, plates and instruments;

(c) Class IIb in all other cases.

PART 4

Active devices

Rule 9

11.—(1) Active therapeutic devices intended to administer or exchange energy are classified as—

DRAFT

(a) Class IIb if they are able to—

(i) administer energy to, or

(ii) exchange energy with,

the human body in a hazardous way, taking into account the nature, density and the site of application of the energy;

(b) Class IIa in all other cases.

(2) All active devices intended to control or monitor the performance of active therapeutic class IIb devices or intended to directly influence the performance of such devices are classified as class IIb.

(3) Active devices intended to control or monitor the performance of active implantable medical devices or intended to directly influence the performance of such devices are classified as Class III.

Rule 10

12.—(1) Active devices intended for diagnosis and monitoring are classified as Class IIa if they are intended to—

(a) supply energy which will be absorbed by the human body, except for devices intended to illuminate the patient's body in the visible spectrum,

(b) image in vivo distribution of radiopharmaceuticals,

(c) allow direct diagnosis, or

(d) allow monitoring of vital physiological processes,

(2) Active devices are classified as Class IIb if they are intended for—

(a) monitoring of vital physiological parameters where the nature of variations is such that it could result in immediate danger to the patient, such as variations in cardiac performance, respiration or activity of the central nervous system, or

(b) diagnosis in clinical situations where the patient is in immediate danger.

(3) Active devices intended—

(a) to emit ionising radiation; and

(b) for diagnostic or therapeutic radiology, including interventional radiology devices,

including devices which control or monitor such devices, or which directly influence their performance, are classified as Class IIb.

Rule 11

13. Active devices intended to introduce medicinal products, bodily fluids or other substances into the body, or to remove them from the body are classified as—

(a) Class IIb if the manner of introduction or removal is hazardous, taking account of the nature of the substances involved, the part of the body concerned and the mode of application;

(b) Class IIa in all other cases.

Rule 12

14. Active devices which do not fall within rules 9 to 11 are classified as Class I.

DRAFT

PART 5

Special Rules

Rule 13

15. A device is classified as Class III if it incorporates, as an integral part—

(a) a substance which—

(i) if used separately, can be considered a medicinal product, and

(ii) is liable to act on the human body with an action ancillary to that of the device;

(b) a human blood derivative.

Rule 14

16. Devices intended to be used for contraception or for preventing the transmission of sexually transmitted diseases are classified as—

(a) Class III if they are—

(i) implantable devices, or

(ii) invasive devices intended for long term use;

(b) Class IIb in all other cases.

Rule 15

17.—(1) Devices intended to be used for disinfecting, sterilising, cleaning, rinsing or hydrating medical devices are classified as—

(a) Class IIa if they are specifically intended for disinfecting or sterilising devices;

(b) Class IIb if they are specifically intended for—

(i) disinfecting invasive devices; or

(ii) disinfecting, cleaning, rinsing or, when appropriate, hydrating contact lenses.

(2) This rule does not apply to devices that are intended to clean medical devices other than contact lenses by means of physical action only.

Rule 16

18. Devices intended to record diagnostic images generated by X-ray radiation are classified as Class IIa.

Rule 17

19.—(1) Devices manufactured utilising animal tissues or cells, or their derivatives, which are non-viable are classified as Class III.

(2) This rule does not apply to such devices intended to come into contact with intact skin only.

DRAFT

Rule 18

20.—(1) Devices incorporating or consisting of nanomaterial are classified as—

(a) Class IIa if they present a negligible potential for internal exposure;

(b) Class IIb if they present a low but not negligible potential for internal exposure;

(c) Class III in all other cases.

(2) "nanomaterial" means a natural, incidental or manufactured material—

(a) consisting of particles that are present, either on their own or as identifiable constituent particles in aggregates or agglomerates, and

(b) where 50% or more of these particles in the number-based size distribution fulfil at least one of the following conditions—

(i) one or more external dimensions of the particle are in the size range 1nm to 100nm;

(ii) the particle has an elongated shape, such as a rod, fibre or tube, where two external dimensions are smaller than 1nm and the other dimension is larger than 100nm;

(iii) the particle has a plate-like shape, where one external dimension is smaller than 1 nm and the other dimensions are larger than 100 nm;

(3) For the purposes of determining the particle number-based size distribution, particles with at least two orthogonal external dimensions larger than 100μm are not to be considered.

(4) In this paragraph—

"agglomerate" means a collection of weakly bound particles or aggregates where the resulting external surface area is similar to the sum of the surface areas of the individual components;

"aggregate" means a particle comprising of strongly bound or fused particles;

"particle" means a minute piece of matter with defined physical boundaries.

Rule 19

21. Invasive devices with respect to body orifices, which are not surgically invasive devices and which are intended to administer medicinal products by inhalation are classified as—

(a) Class IIb if—

(i) use of such devices is intended to have a significant impact on the efficacy or safety of the administered medicinal product, or

(ii) they are intended to treat life-threatening conditions;

(b) Class IIa in all other cases.

Rule 20

22.—(1) Sub-paragraph (2) applies to devices that are composed of substances intended to be introduced into the human body—

(a) through a body orifice; or

(b) by application to the skin,

and that are absorbed by, or locally dispersed in, the human body.

(2) The devices referred to in sub-paragraph (1) are classified as—

DRAFT

(a) Class III if—

(i) the substances, or their products of metabolism, are systemically absorbed by the human body in order to achieve the intended purpose, or

(ii) they achieve their intended purpose in the stomach or lower gastrointestinal tract and they, or their products of metabolism, are systemically absorbed by the human body;

(b) Class IIa if—

(i) they are applied to the skin or in the nasal or oral cavity as far as the pharynx, and

(ii) they achieve their intended purpose on those cavities;

(c) Class IIb in all other cases."

New Schedule 23 - classification rules for *in vitro* diagnostic medical devices

78. At the appropriate place(**a**) insert —

"SCHEDULE 23 Regulation 33ZA

Classification rules for *in vitro* diagnostic medical devices

PART 1

Introductory

Interpretation

1. In this Schedule—

"accessory" means an article intended specifically by its manufacturer to be used together with an in vitro diagnostic medical device to enable that device to be used in accordance with its intended purpose, which is not—

(a) itself an in vitro diagnostic medical device;

(b) an invasive sampling medical device; or

(c) a medical device which is directly applied to the human body for the purpose of obtaining a specimen;

"companion diagnostic" means a device which is essential for the safe and effective use of the corresponding medicinal product, to identify, whether before and during treatment—

(a) patients who are most likely to benefit from the medicinal product, or

(b) patients who are likely to be at increased risk of serious adverse reaction as a result of treatment with the medicinal product;

"device" means—

(a) an *in vitro* diagnostic medical device, or

(**a**) Original Schedule 23 was inserted by S.I. 2019/791 and repealed by S.I. 2020/1478.

DRAFT

(b) an accessory.

General implementation rules

2.—(1) The rules in this Schedule must be applied in relation to a device by reference to—

(a) the intended purpose of the device, and

(b) the intended user.

(2) Each device must be classified individually, including where the device is—

(a) an accessory to a medical device;

(b) intended to be used in combination with another medical device;

(c) software which is independent of any other device;

(d) a companion diagnostic.

(3) Subject to sub-paragraph (4), the following devices must be classified in the same class as the device with which they are intended to be used—

(a) software which is intended to drive a device, or is intended to influence the use of a device;

(b) a calibrator;

(c) control material with quantitative or qualitative assigned values intended for specific or multiple analytes;

(d) reference material with quantitative or qualitative assigned values intended for specific or multiple analytes.

(4) If more than one rule applies to a device, the device must be classified in the higher class.

(5) The classes, ranked from lowest to highest, are as follows—

(a) Class A;

(b) Class B;

(c) Class C;

(d) Class D.

(6) The rules in this Schedule do not apply to—

(a) internationally certified reference materials;

(b) materials used for external quality assessment schemes.

(7) Each of the rules in this Schedule, including the general implementation rules in Part 1 and the classification rules in Part 2, must be considered to establish the classification of a device.

(8) In this paragraph—

"calibrator" means a measurement standard used in the calibration of an *in vitro* diagnostic test, instrument, or system;

"control material" means a substance, material or article intended by its manufacturer to be used to verify the performance characteristics of a device.

DRAFT

PART 2

Classification Rules

Rule 1

3. Devices with the following intended purpose are classified as Class D—

(a) detecting the presence of, or exposure to, a transmissible agent in blood, blood components, cells, tissues or organs, or in any of their derivatives, in order to assess their suitability for transfusion, transplantation or cell administration;

(b) detecting the presence of, or exposure to, a transmissible agent that causes a life-threatening disease with a high or suspected high risk of propagation;

(c) determining the infectious load of a life-threatening disease where monitoring is critical in the process of patient management.

Rule 2

4.—(1) Devices are classified as Class C if they are intended to be used for—

(a) blood grouping,

(b) determining foeto-maternal blood group incompatibility, or

(c) tissue typing,

to ensure the immunological compatibility for transfusion or transplantation, of blood, blood grouping for cell administration, blood components, cells, tissues or organs.

(2) Devices are classified as Class D if they are intended to determine the presence of the antigen or antibody for any of the following markers—

(a) ABO system [A (ABO1), B (ABO2), AB (ABO3)];

(b) Rhesus system [RH1 (D), RH2 (C), RH3 (E), RH4 (c), RH5 (e) and weak or partial Rh(D)];

(c) Kell system [Kel 1 (K)];

(d) Kidd system [JK1 (Jka), JK2 (Jkb)];

(e) Duffy system [FY1 (Fya), FY2 (Fyb)].

Rule 3

5. Devices with the following intended purpose are classified as Class C—

(a) detecting the presence of, or exposure to, a sexually transmitted agent;

(b) detecting the presence in cerebrospinal fluid or blood of an infectious agent with a risk of limited propagation;

(c) detecting the presence of an infectious agent, if there is a significant risk that an erroneous result would cause death or severe disability to an individual, foetus or embryo being tested or to the individual's offspring;

(d) pre-natal screening of women to determine their immune status towards transmissible agents;

(e) determining infective disease status or immune status, where there is a risk that an erroneous result will lead to a patient management decision resulting in an

DRAFT

imminent life-threatening situation or severe disability for the patient or for the patient's offspring;

(f) screening for selection of patients for selective therapy and management as companion diagnostics;

(g) screening, diagnosing, or staging of cancer;

(h) human genetic testing;

(i) monitoring levels of medicinal products, substance or biological components, where there is a risk that an erroneous result will lead to a patient management decision resulting in an immediate life-threatening situation for the patient or for the patient's offspring;

(j) managing patients suffering from a life-threatening disease or condition;

(k) screening for congenital disorders in an embryo or foetus;

(l) screening for congenital disorders in new-born babies where failure to detect and treat such disorders could lead to life-threatening situations or severe disabilities;

(m) screening, detecting or diagnosing neurodegenerative disease;

(n) screening, detecting or diagnosing cardiovascular diseases.

Rule 4

6.—(1) Devices for self-testing and devices for near-patient testing are classified as Class B if they are devices from which the result of the self-testing or near-patient testing does not determine a critical situation, and Class C in all other cases.

(2) In this paragraph—

"critical situation" means a situation or condition where accurate or timely diagnosis or treatment action is vital to avoid death, long-term disability or other serious deterioration of health of an individual patient or to mitigating impact to public health;

"device for near-patient testing" means a device that is intended to be used but does not include a device for self-testing—

(a) at the side of, or otherwise near to, a patient, and

(b) by a health professional,

"device for self-testing" means an *in vitro* diagnostic medical device intended for use by a lay user who is responsible for collecting the data or specimen, by themselves and on themselves, relying solely on the instructions provided by the manufacturer. This use can also include performing the test and interpreting the results by themselves and on themselves.

Rule 5

7.—(1) The following devices are classified as Class A—

(a) reagents or other articles, which possess no critical characteristics intended by the manufacturer to make them suitable for *in vitro* diagnostic procedures relating to a specific examination;

(b) instruments intended by the manufacturer specifically to be used for *in vitro* diagnostic procedures;

DRAFT

(c) specimen receptacles.

(2) In this paragraph "specimen receptacle" means an apparatus specifically intended by a manufacturer to obtain, contain and preserve a body fluid or tissue for *in vitro* diagnostic examination.

Rule 6

8. Devices which do not fall within paragraphs 3 to 7 are classified as Class B.

Rule 7

9. Devices which are controls without a quantitative or qualitative assigned value are classified as Class B."

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

[Name]
Parliamentary Under-secretary of State

Department for Health and Social Care
[Date]

We consent,

[Name]
[Name]
Two of the Lords Commissioners of Her Majesty's Treasury

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Medical Devices Regulations 2002 (S.I. 2002/618).

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