DRAFT STATUTORY INSTRUMENTS

2023 No.

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

PART 3

Amendments to secondary legislation

Amendment to the Medical Devices Regulations 2002

8. The Medical Devices Regulations 2002(**1**) are amended in accordance with regulations 9 to 19.

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

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

""Regulation (EU) 2022/1107" means Commission Implementing Regulation (EU) 2022/1107 of 4 July 2022 laying down common specifications for certain class D *in vitro* diagnostic medical devices in accordance with Regulation (EU) 2017/746 of the European Parliament and of the Council(**3**);".

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

10. In regulation 2(1)(**4**) after the definition of "Regulation (EU) 2017/745" insert—

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

"Regulation (EU) 2022/1107" means Commission Implementing Regulation (EU) 2022/1107 of 4 July 2022 laying down common specifications for certain class D *in vitro* diagnostic medical devices in accordance with Regulation (EU) 2017/746 of the European Parliament and of the Council(**6**);".

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

11. In regulation 2A(**7**)—

(a) in paragraph (1)—

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

(**1**) S.I. 2002/618.
(**2**) Relevant amending instruments are S.I. 2013/2327, 2021/873 and 2023/627.
(**3**) OJ No. L 178, 05.07.2022, p.3.
(**4**) Amended by S.I. 2021/905; there are other amending instruments but none is relevant.
(**5**) OJ No. L 117, 05.05.2017, p.176; amended by OJ No. L 19, 28.01.2022, p.3; OJ No. L 70, 08.03.2023, p.3; and OJ No. L 80, 20.03.2023, p.24.
(**6**) OJ No. L 178, 05.07.2022, p.3.
(**7**) Regulation 2A was inserted by S.I. 2019/791 and amended by S.I. 2021/905.

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

"(a) which meets the requirements of—

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

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

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

(b) after paragraph (1) insert—

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

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

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

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

12. In regulation 3ZA(**8**)—

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

(b) for paragraph (1) substitute—

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

(c) in paragraph (2)—

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

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

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

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

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

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

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

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

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

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

(d) in paragraph (3)—

(**8**) Regulation 3ZA was inserted by S.I. 2021/905.

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

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

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

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

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

13. In regulation 4T(**9**), omit paragraph (1).

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

14. Omit regulation 19B(**10**).

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

15. Omit regulation 21C(**11**).

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

16. In regulation 34A(**12**), in paragraphs (1) and (2), for "34B, 34C" substitute "34B to 34D".

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

17. After regulation 34C (transitional provisions for coronavirus test devices)(**13**) insert—

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

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

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

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

(**9**) Regulation 4T was inserted by S.I. 2019/791 and was amended by S.I. 2021/873.
(**10**) Regulation 19B was inserted by S.I. 2020/1478.
(**11**) Regulation 21C was inserted by S.I. 2020/1478.
(**12**) Regulation 34A was inserted by S.I. 2021/910.
(**13**) Regulation 34C was inserted by S.I. 2021/910.

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

18. In regulation 44(**14**)—

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

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

(c) omit paragraph (5);

(d) omit paragraph (6).

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

19. Omit regulation 44ZA(**15**).

Amendment to the Blood Safety and Quality Regulations 2005

20. In the Blood Safety and Quality Regulations 2005(**16**), in regulation 2(**17**) (designation of the competent authority for Northern Ireland and scope of the Regulations) for paragraph (3) substitute—

"(3) These Regulations apply without prejudice to—

(a) the Medical Devices Regulations 2002,

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

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

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

21. In the Human Tissue (Quality and Safety for Human Application) Regulations 2007(**18**), in regulation 2(**19**) (extent and application), paragraph (3) is amended as follows—

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

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

", or

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

(**14**) Regulation 44 was substituted by S.I. 2020/1478.
(**15**) Regulation 44ZA was inserted by S.I. 2020/1478. In that S.I. as originally printed it was inserted as regulation 44A. It was renumbered as regulation 44ZA by a correction slip (ISBN 978-0-34-821688-2).
(**16**) S.I. 2005/50.
(**17**) Regulation 2 was amended by S.I. 2019/4 and S.I. 2021/905.
(**18**) S.I. 2007/1523.
(**19**) Regulation 2 was amended by S.I. 2012/1916, 2018/335, 2019/481 and 2021/905.

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

22. In the Legislative and Regulatory Reform (Regulatory Functions) Order 2007(**20**), in Part 2 of the Schedule(**21**), in the section headed "Medicines", after "Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC" insert—

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

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

23.—(1) In the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012(**22**), regulation 2(**23**) (interpretation) is amended in accordance with this regulation.

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

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

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

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

Amendment to the Waste Electrical and Electronic Equipment Regulations 2013

24. In the Waste Electrical and Electronic Equipment Regulations 2013(**24**), in regulation 2(**25**) (interpretation), for the definition of "in vitro diagnostic medical device", substitute—

> ""in vitro diagnostic medical device" means an in vitro diagnostic device or accessory within the meaning of—
>
> (a) regulation 2(1) of the Medical Devices Regulations 2002 in relation to England and Wales and Scotland, and
>
> (b) Article 2 of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU in relation to Northern Ireland,
>
> which is EEE;.".

Amendment to the Economic Growth (Regulatory Functions) Order 2017

25. In the Economic Growth (Regulatory Functions) Order 2017(**26**), in Part 3 of the Schedule(**27**), under the cross-heading "Medicines", after "Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive

(**20**) S.I. 2007/3544.
(**21**) Part 2 was amended by S.I. 2021/905; there are other amending instruments but none is relevant.
(**22**) S.I. 2012/3032.
(**23**) Regulation 2 was amended but none is relevant to these Regulations.
(**24**) S.I. 2013/3113.
(**25**) Regulation 2 was amended by S.I. 2019/188; there are other amending instruments but none is relevant.
(**26**) S.I. 2017/267.
(**27**) Part 3 was amended by S.I. 2021/905; there are other amending instruments but none is relevant.

2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC" insert—

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

Amendment to the Market Surveillance (Northern Ireland) Regulations 2021

26. In the Market Surveillance (Northern Ireland) Regulations 2021(**28**), Schedule 1(**29**) (investigatory powers) is amended as follows—

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

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

(b) in paragraph 16—

(i) for sub-paragraph (2) substitute—

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

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

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

(**28**) S.I. 2021/858.
(**29**) Schedule 1 was amended by S.I. 2021/905.