STATUTORY INSTRUMENTS

# 2024 No. 221

# The Medical Devices (In Vitro Diagnostic Devices etc.) (Amendment) Regulations 2024

## PART 2

### Amendments to primary legislation

**Amendment to the Human Tissue Act 2004**

**3.** In section 1(**1**) of the Human Tissue Act 2004(**2**) (authorisation of activities for scheduled purposes), in subsection (12), for paragraph (a), substitute—

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

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

(ii) Regulation (EU) 2017/745(**3**) of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, or

(iii) Regulation (EU) 2017/746(**4**) of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU, or".

**Amendment to the Consumer Rights Act 2015**

**4.** In the Consumer Rights Act 2015(**5**), Schedule 5(**6**) (investigatory powers etc.) is amended as follows—

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

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

(b) in paragraph 19(7A)(a)—

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

(**1**) Section 1 was amended but none is relevant to these Regulations.
(**2**) 2004 c. 30.
(**3**) OJ No. L 117, 05.05.2017, p. 1, as amended OJ No. L 130, 24.04.2020, p.18; OJ No. L 70, 08.03.2023, p.1; and OJ No. L 80, 20.03.2023, p.24.
(**4**) OJ No. L 117, 05.05.2017, p.176, as amended by OJ No. L 19, 28.01.2022, p.3; OJ No. L 70, 08.03.2023, p.3; and OJ No. L 80, 20.03.2023, p.24.
(**5**) 2015 c. 15.
(**6**) Schedule 5 was amended by the Medicines and Medical Devices Act 2021, S.I. 2021/858 and S.I. 2021/905; there are other amending instruments but none is relevant.

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

"or

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

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

### Amendment to the Medicines and Medical Devices Act 2021

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

### Amendment to section 21 (compliance notices)

**6.** In section 21(**8**), in subsection (1A) for paragraph (d) substitute—

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

### Amendment to section 42 (interpretation of Part 4)

**7.** In section 42(**9**), in subsection (2), in the definition of "manufacturer", for paragraph (b) substitute—

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

(**7**) 2021 c. 3.
(**8**) Section 21 was amended by S.I. 2021/905.
(**9**) Section 42 was amended by S.I. 2021/905.