Medicines and Medical Devices Act 2021

2021 CHAPTER 3

PART 4

MEDICAL DEVICES

CHAPTER 5

INTERPRETATION OF PART 4

42 Interpretation of Part 4

(1) In this Part, apart from in sections 32, 33 and 34 (provisions relating to forfeiture or seizure of medical devices), references to a medical device include references to a type of medical device.

(2) In this Part—

the "appropriate appeals court" means—

(a) in England and Wales, the Crown Court;

(b) in Scotland, the Sheriff Appeal Court;

(c) in Northern Ireland, a county court;

the "appropriate lower court" means—

(a) in England and Wales, a magistrates' court;

(b) in Scotland, the sheriff;

(c) in Northern Ireland, a court of summary jurisdiction;

"compliance notice" has the meaning given by section 21(2);

"data protection legislation" has the meaning given by section 3(9) of the Data Protection Act 2018;

the "enforcement authority" means—

(a) in relation to medical devices which are ordinarily intended for private use or consumption—

(i) a local weights and measures authority in Great Britain or a district council in Northern Ireland, or

(ii) the Secretary of State, or

(b) in relation to other medical devices, the Secretary of State;

"EU Medical Devices Regulations" means—

(a) 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

(b) 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;

"forfeiture order" has the meaning given by section 32(1);

"information notice" has the meaning given by section 24(2);

"manufacture" includes assembly;

[[F1]"manufacturer" means any person who is a manufacturer for the purposes of any provision in—

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

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

"medical device" includes—

(a) medical devices to which the Medical Devices Regulations 2002 apply, and

(b) devices to which the EU Medical Devices Regulations apply;

[[F2]"medical devices provision"—

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

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

"relevant requirements" has the meaning given by section 16(1)(a);

"safety notice" has the meaning given by section 23(1);

"suspension notice" has the meaning given by section 22(2).

Textual Amendments

F1 Words in s. 42(2) substituted (27.7.2021) by The Medical Devices (Northern Ireland Protocol) Regulations 2021 (S.I. 2021/905), regs. 1(2), **28(6)(a)**

F2 Words in s. 42(2) substituted (27.7.2021) by The Medical Devices (Northern Ireland Protocol) Regulations 2021 (S.I. 2021/905), regs. 1(2), **28(6)(b)**

Changes to legislation:
There are currently no known outstanding effects for the Medicines and Medical Devices Act 2021, CHAPTER 5.