
EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations are made in exercise of the powers conferred by section 8(1) of , paragraph 7(2) of Schedule 4 and paragraph 21 of Schedule 7 to the European Union (Withdrawal) Act 2018 (c. 16) (“the Withdrawal Act”) in order to address failures of retained EU law to operate effectively and other deficiencies (in particular under section 8(2)(a) of the Withdrawal Act) arising from the withdrawal of the UK from the European Union

These Regulations make amendments to legislation in the field of medical devices.

Part 1 amends the existing Medical Devices Regulations 2002 (“the 2002 Regulations”) which implemented three European Union Directives which aimed to ensure the safety and quality of general medical devices, active implantable medical devices and in vitro diagnostic medical devices (“the three Directives”). Part I also makes certain transitional and savings provisions which seek to mirror the transitional and savings provisions which exist as part of current EU law in the two EU Regulations (see below). Part 1 also amends EU tertiary legislation which relates to the regime implemented by the 2002 Regulations and revokes certain tertiary legislation along with the two EU Regulations insofar as they are retained EU law.

Parts 2 and 3 restate (by inserting restated new provisions into the 2002 Regulations) the provisions of two EU Regulations: Regulation (EU) 2017/745 of the European Parliament and of the Council of 5th April 2017 on medical devices and Regulation (EU) 2017/746 of the European Parliament and of the Council of 5th April 2017 on in vitro diagnostic medical devices (the two EU Regulations). Rights, powers, liabilities, obligations restrictions, remedies and procedures contained in the two Regulations were retained by virtue Section 4 of the Withdrawal Act and limited provisions were retained by virtue of section 3 of that Act.

Part 4 inserts new Schedules into the 2002 Regulations which reproduce the procedures in the Annexes to the two EU Regulations.

An explanatory memorandum is published alongside this instrument on www.legislation.gov.uk.

An impact assessment of the effect that this instrument will have on the costs to business, the voluntary sector and the public sector is available from the Medicines and Healthcare Products Regulatory Agency, 10 South Colonnade, Canary Wharf, London, E14 4PU and is published alongside this instrument www.legislation.gov.uk.