EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make amendments to the Medical Devices Regulations 2002 ("the 2002 Regulations"), the Blood Safety and Quality Regulations 2005 ("the 2005 Regulations") and the Medical Devices (Northern Ireland Protocol) Regulations 2021 ("the 2021 Regulations"). They also revoke and restate the Medical Devices (Consultation Requirements) (Fees) Regulations 1995 ("the 1995 Regulations").

The fee amounts specified in these Regulations are set in line with a consultation document issued by the Medicines and Healthcare products Regulatory Agency ("MHRA") on 13 August 2022. A summary of the consultation responses and the Government's response to the consultation are published on the MHRA's website (www.mhra.gov.uk).

Part 1 revokes the 1995 Regulations. Regulations 7 and 14 to 16 and regulation 23 restate, with amendments and fee increases, the 1995 Regulations in the 2002 and 2021 Regulations.

Part 2 amends the 2002 Regulations. Regulations 4 to 6 introduce new optional services provided by the Secretary of State in relation to intended clinical investigations of medical devices. Regulations 8 to 12 increase existing fees payable to the Secretary of State in connection with the registration of devices and the designation of approved bodies and conformity assessment bodies. Regulation 13 increases fees payable to the Secretary of State in connection with clinical investigations and inserts fees for the new services provided by regulations 5 and 6.

Part 3 amends the 2005 Regulations. Regulation 17 amends regulation 22 of the 2005 Regulations to increase the fees payable by blood establishments and hospital blood banks or facilities in relation to authorisation, operation, and haemovigilance.

Part 4 amends the 2021 Regulations. Regulations 19, 22 and 25 revise and increase existing fees in the 2021 Regulations payable to the Secretary of State in connection with the registration of custom-made devices and the designation of notified bodies. Regulations 20, 21 and 24 revise and increase the fees for clinical investigation applications and introduce new fees for advice provided by the Secretary of State in relation to an intended clinical investigation.

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