EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations are made in exercise of the powers in sections 8(1) and 8C of the European Union (Withdrawal) Act 2018 (c. 16) in order to address failures of retained EU law to operate effectively and other deficiencies (in particular under section 8(2)(a)) arising from the withdrawal of the United Kingdom from the European Union, and in order to give effect to the Protocol on Ireland/Northern Ireland in the withdrawal agreement, respectively.

Schedule 1 to these Regulations amends the Medical Devices Regulations 2002 (S.I. 2002/618) in relation to Northern Ireland. The provisions in that Schedule ensure that S.I. 2002/618 continues to operate effectively in light of the Ireland/Northern Ireland Protocol following IP completion day

Schedule 2 to these Regulations amends the Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791) and makes provision in respect of the regulatory regime applying to medical devices in Great Britain following IP completion day.

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

An impact assessment has not been produced for this instrument as no, or no significant, impact on the private, public or voluntary sector is foreseen.