

## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations are made in exercise of the powers in section 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), (b), (c), (f) and (g) of that Act) 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.

They amend the Human Tissue (Quality and Safety for Human Application) (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/481) so as to enable the provision amended by those Regulations to continue to operate effectively in light of the Ireland/Northern Ireland Protocol following IP completion day.

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