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 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)) arising from the withdrawal of the United Kingdom from the European Union.

These Regulations make amendments to legislation concerning human tissue and cells intended for use in human application, including stem cells and cell lines grown outside the body. These Regulations do not apply to reproductive cells, embryos grown outside the human body, organs and blood. In particular, they amend legislation relating to technical requirements for the storage, procurement, testing, processing or distribution of tissues and cells into, and their export from, the United Kingdom. Part 2 amends primary legislation. Part 3 amends subordinate legislation and Part 4 makes transitional provision.

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

Changes to legislation:
There are currently no known outstanding effects for the The Human Tissue (Quality and Safety for Human Application) (Amendment) (EU Exit) Regulations 2019.