
STATUTORY INSTRUMENTS

2020 No. 1305

**The Quality and Safety of Organs Intended for
Transplantation (Amendment) (EU Exit) Regulations 2020**

Substitution of regulation 2(2)

3. For regulation 2(2) (amendment of the Human Tissue Act 2004⁽¹⁾) substitute—

“(2) For subsection (3A) substitute—

“(3A) The Authority may not designate a person under subsection (3) if doing so would be incompatible with the principles set out in—

(a) Article 12 of [Directive 2004/23/EC](#) of the European Parliament and of the Council on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells, or

(b) Article 13 of [Directive 2010/53/EU](#) of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation,

and for the purposes of this subsection as it applies in relation to Great Britain, those Articles of those Directives are to be read subject to the modifications set out in subsections (3B) and (3C).””.

⁽¹⁾ 2004 c. 30. Section 32 was amended by [S.I. 2012/1501](#) and [2014/1459](#).