

## **Directions given under the Human Tissue Act 2004 implementing the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended)**

**Directions relating to licences granted under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended)**

**Ref 002/2018**

**These Directions are**

General Directions

**Sections of the Human Tissue Act 2004 providing for these Directions**

Sections 23 and Schedule 3  
paragraph 2 (5)

**Regulations under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended)**

Regulation 16 and Schedule 2 paragraph 1

**These Directions come into force on:**

1 April 2018

**These Directions remain in force:**

Until revoked or superseded

1. These Directions are given in relation to Human Tissue Authority (HTA) licences issued to establishments storing and importing tissues and/or cells for human application under Regulations 7(1) and 7(1A) of the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended) and licences and / or third party agreements authorising the carrying out of procurement, testing, processing, distribution, import or export of tissues and/ or cells for human application under Regulation 7(2) of the Regulations.
2. The Directions are made for the purpose of securing adherence to the standards required under the European Tissues and Cells Directive (2004/23/EC) and the technical Directives 2006/17/EC (as amended by 2012/39/EU), 2006/86/EC (as amended by (EU) 2015/565) and (EU) 2015/566.

### **Implementation of the Guide for Quality and Safety Assurance for Human Tissues and Cells for Patient Treatments**

3. These Directions implement the HTA consolidated requirements for human application licences and third party agreements. The requirements are set out in version 2 of the "Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment" which forms the Annex to these Directions. The Guide will be the primary reference for establishments and will be subject to periodic updates.

### **Revocation of HTA Directions 003/2010**

4. Version 2 of the Guide replaces a version issued previously under HTA Directions for the sector. Directions 003/2010 are therefore no longer required and are revoked.

Dated 1 April 2018

Signed:

*Christophe Birkett*

**Director of Regulation**

