Dated: 14 November 2022

DIRECTIONS TO LICENSED ESTABLISHMENTS IN THE ORGAN DONATION AND TRANSPLANTATION SECTOR, GIVEN UNDER THE QUALITY AND SAFETY OF ORGANS INTENDED FOR TRANSPLANTATION REGULATIONS 2012 (S.I. 2012 NO.1501) AS AMENDED

Ref: 002/2022

This Directions are:	General Directions
Regulations providing for these directions:	Issued under sections 23(1) and 37(6) of the Human Tissue Act 2004 and Regulations 6 and 11 of the Quality and Safety of Organs Intended for Transplantation Regulations 2012
These Directions come into force on:	14 November 2022
These Directions remain in force until:	Directions are revoked by the HTA

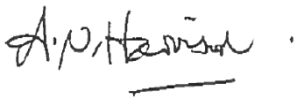
1. These Directions are given in relation to all licences in the Organ Donation and Transplantation sector under Regulation 5 of the Quality and Safety of Organs Intended for Transplantation Regulations 2012 (S.I.2012 NO.1501) as amended.

2. The Directions require that that where an organ is sent to an establishment for assessment or recovery purposes and a mechanical perfusion device is used, the establishment under whose licence this activity takes place must record and store any organ characterisation and traceability data generated by the establishment, for a period of 30 years.

3. The requirements are set out in version 16 of the “The Quality and Safety of Organs Intended for Transplantation: A Documentary Framework.” The Framework will be the primary reference for establishments and will be subject to periodic updates.

4. These Directions are made by the Human Tissue Authority.

Dated: 14 November 2022



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