Commission Directive 2006/86/EC of 24 October 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells (Text with EEA relevance)

Article 4

Requirements for the accreditation, designation, authorisation, licensing of tissue and cell preparation processes

Preparation processes at the tissue establishments must comply with the requirements set out in Annex II.