Inspection report on compliance with HTA licensing standards
Inspection dates: **06-07 and 15 November 2023**

LeMaitre Vascular Ltd

HTA licensing number 22696

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

Licensable activities carried out by the establishment

'E' = Establishment is licensed to carry out this activity and is currently carrying it out.

'E*' = Establishment is licensed to carry out this activity but is not currently carrying it out.

Site	Procurement	Processing	Testing	Storage	Distribution	Import	Export
LeMaitre Vascular Ltd				E	E	E	E*

Tissue types authorised for licensed activities

Authorised = Establishment is authorised to carry out this activity and is currently carrying it out.
Authorised* = Establishment is authorised to carry out this activity but is not currently carrying it out.

Tissue Category; Tissue Type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Cardiovascular, Valves; Heart Valves				Authorised	Authorised	Authorised	Authorised*
Cardiovascular, Vessels; Other Vessels				Authorised	Authorised	Authorised	Authorised*

Summary of inspection findings

The HTA found the Designated Individual (DI) and the Licence Holder (LH) to be suitable in accordance with the requirements of the legislation.

Although the HTA found that LeMaitre Vascular Ltd (the establishment) had met the majority of the HTA's standards that were assessed during the inspection, one major and eight minor shortfalls were found against standards for Governance and Quality and Premises, Facilities and Equipment.

The HTA has assessed the establishment as suitable to be licensed for the activities specified, subject to corrective and preventative actions being implemented to meet the shortfalls identified during the inspection.

Compliance with HTA standards

Major shortfalls

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.	During a review of records associated with tissue grafts that were imported and distributed under the establishment's licence, an example was identified where the form used to capture tissue eligibility for the UK market had not been completed until after the tissue had been distributed for end use. Prior to import, tissue is processed and cryopreserved at the establishment's parent company, which is the third country supplier (3CS). Tissue is subjected to a validated antibiotic treatment step, after which it is aseptically packaged prior to cryopreservation. The establishment has a system of routine and sessional environmental monitoring in place, but at present this does not include continuous non-viable particle monitoring during the aseptic processing steps that follow antibiotic treatment.	**Major**
n) The establishment ensures imports from third countries meet the standards of quality and safety set out in Directions 001/2021.		
PFE4 Systems are in place to protect the quality and integrity of tissues and / or cells during transport and delivery to its destination.		

a) There is a system to ensure tissue and / or cells are not distributed until they meet the standards laid down by Directions 001/2021.		

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.		
b) There are procedures for all licensable activities that ensure integrity of tissue and / or cells and minimise the risk of contamination.	The establishment's standard operating procedures (SOPs) and related controlled documents require review to ensure they reflect current practice, regulatory requirements, and include sufficient detail to support staff to undertake their tasks consistently. For example: • the SOP for the distribution of tissue for end use states that up to four items may be transported within each shipper. At present, establishment practice is that only one tissue is distributed per shipper; • documented procedures reference the possibility of directly supplying tissue from the establishment's third country supplier (3CS) to end users within the UK; however, establishment practice is to receive all imports at their premises prior to distribution.	**Minor**

	• the establishment's systems and expectations relating to following up with end users who have not yet returned tissue traceability information, and the responsibilities of the establishment's representatives, have not been captured in documented procedures; • at present, establishment representatives attend each end-use event. The applicable procedure indicates a representative may not always be present; • the establishment's approach to temperature monitoring and the requirement to review and store associated raw data records for 10 years from use or disposal of the tissue are not captured in a documented procedure; • documented procedures do not currently contain sufficient guidance to assist staff in the event there is a problem with received tissue or tissue that is returned from end users; and, • SOP 5010QUK requires updating to reflect that reports of issues relating to tissue imported by the establishment that could meet the definition of a HTA-reportable serious adverse event or reaction (SAEAR), could arise at any point in the tissue or donor testing pathway, and not only through reports from end users.	
d) There is a document control system to ensure that changes to documents are reviewed, approved, dated and documented by an authorised person	The establishment does not currently have a system in place to ensure that documented procedures are reviewed at least once every two years, in accordance with the requirements of Directions 001/2021.	**Minor**

and only current documents are in use.		
g) There are procedures to ensure that an authorised person verifies that tissues and / or cells received by the establishment meet required specifications.	The establishment has a SOP and associated controlled forms to document the checks undertaken at the point of tissue receipt. These documents require updating to ensure that staff reconfirm tissue suitability for UK distribution prior to release from quarantine, and that the items received were the items ordered.	**Minor**
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.		
e) Personnel are trained in all tasks relevant to their work and their competence is recorded.	Establishment representatives attend hospital sites at the point tissue is used in human application, and assist and train end users with tissue unpacking, checks prior to use, and paperwork completion. The training and competence of representatives in these tasks is not currently captured in documented training records.	**Minor**
GQ7 There are systems to ensure that all adverse events, reactions and/or incidents are investigated promptly.		
g) Establishments distributing tissue and / or cells provide information to end users on how to report a serious adverse event or reaction and have agreements with them specifying that they will report these events or reactions.	The establishment provides a dossier of information with each tissue that is distributed, which includes tissue-specific information and general guidance on the establishment's expectations of end users. The dossier requires updating to help ensure that: • end users are issued with clear guidance about the requirement to report potential serious adverse events or reactions (SAEARs) to the establishment within 24 hours of discovery or determination;	**Minor**

	• end users are reminded that tissue intended for human application must not be stored on unlicensed premises for more than 48 hours; and, • end users are instructed to place traceability stickers in the patient's notes and to retain these notes for 30 years from the operation date.	
PFE1 The premises are fit for purpose.		
a) A risk assessment has been carried out of the premises to ensure that they are fit for purpose.	The establishment has a detailed risk assessment following the tissue pathway from procurement to distribution for end use. The risk assessment requires updating to consider: • the security of traceability and raw data records held in paper form and electronically; • the security of tissue during delivery to the shared building entrance prior to transfer to the establishment's secure premises within the building; • whether any further mitigations are required to assure the health and safety of individuals within the multi-occupancy building in the event of a failure of liquid nitrogen storage tanks; and, • that sections relating to risks associated with fire and flood reflect the risks to tissue and records held at the establishment's premises, and the mitigations in place to address these risks.	**Minor**
b) There are procedures to review and maintain the safety of staff, visitors and patients.		

PFE4 Systems are in place to protect the quality and integrity of tissues and / or cells during transport and delivery to its destination.		
f) There are third party agreements with courier or transport companies to ensure that any specific transport conditions required are maintained.	At the time of the inspection, the establishment was not able to provide a copy of an agreement with their courier company that meets the requirements of Directions 001/2021, particularly with regard to the need to set out specific transportation requirements and responsibilities for the reporting of adverse events during transport.	**Minor**
j) Shipping packaging containing tissues and / or cells is labelled with the information required by Directions 001/2021.	The external labelling of the shippers used to distribute tissue to end users does not contain all the information required by Directions 001/2021, as detailed in the HTA's Guide to Quality and Safety Assurance for Tissues and Cells for Patient Treatment.	**Minor**

The HTA requires the DI to submit a completed corrective and preventative action (CAPA) plan setting out how the shortfalls will be addressed, within 14 days of receipt of the final report (refer to Appendix 2 for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

Advice

The HTA advises the DI to consider the following to further improve practice:

Number	Standard	Advice
1.	GQ1b	In addressing the shortfall against GQ1b, the DI is advised to ensure that documented procedures reflect that the direct supply of tissue from the 3CS to end users in the UK would be a change to the establishment's existing licence authorisations and must not be undertaken without prior authorisation

		from the HTA. The DI is advised to ensure staff are aware of this requirement and consider including guidance to this effect within documented procedures to help ensure awareness is maintained.
2.	GQ4b,c	During the inspection, a small number of data entry errors were identified. The DI is advised to introduce second-person independent checks of records such as receipt and distribution records. The DI is also advised to review existing forms with a view to supporting staff in completing fields correctly, for example, through including required operating ranges and checklists covering each step in a process.
3.	GQ4g	Records associated with tissue imported under the establishment's licence are held in a secure room, but at the time of the inspection a number of records were stacked outside of the filing cabinets present in the room. The DI is advised to review current storage arrangements to ensure records are secure and organised to allow for prompt retrieval when needed. The DI is further advised to expand current entries around data retention in the establishment's risk assessment to capture risks and mitigations relating to the security of paper and electronic records, and whether further potential mitigations, such as the scanning of paper-based records, may be justified.
4.	GQ4m	The establishment has contingency plans in place which include guidance that, in the event of termination of activities under the licence, records would be retained by the parent company in the USA. The DI is advised to update these plans to specify that traceability records, or copies thereof, must be retained at a premises within the UK in accordance with approval issued by the HTA during the revocation process.
5.	PFE1a,b	In addressing the shortfall against these standards, the DI is advised to seek the advice of the maintenance companies responsible for routine maintenance of the relevant tanks, storage equipment and alarm systems.

6.	PFE5c	The DI is advised to implement a system to capture confirmation that temperature and oxygen monitoring alarm systems are operating as required, for example, during routine maintenance undertaken by contracted maintenance companies.
7.	PFE4j	During the inspection examples were identified in which shipper addressee stickers were placed over the top of stickers used in previous distribution events. The DI is advised to update procedures to require staff to remove previous stickers before a new sticker is added.

Background

LeMaitre Vascular Ltd (the establishment) imports cardiovascular valves and vessels from its parent company, which is the establishment's third country supplier (3CS), in the USA. The 3CS is responsible for reviewing tissue suitability against UK requirements and indicating which tissues are suitable within the company's tissue database. The establishment orders tissue from the available list and it is then shipped to the establishment's premises in liquid nitrogen shippers. Upon receipt, tissue is held in quarantine until receipt checks are completed. Tissue is then stored in the establishment's liquid nitrogen storage tank until it is distributed to end users in the UK within 48 hours of the planned operation. Currently, establishment representatives attend theatres at the point of end use and help to ensure traceability records are returned to the establishment for retention.

The establishment has been licensed by the HTA since January 2022. This was the establishment's first routine inspection; the licence application assessment inspection took place in January 2022 and was a virtual regulatory assessment.

Since the licence was offered, the establishment applied for and was granted a variation adding authorisation for the activity of export to the licence, but reported that no export activity has been undertaken yet.

Description of inspection activities undertaken

The HTA's regulatory requirements are set out in Appendix 1. The following areas were covered during the inspection:

Review of governance documentation
The inspection included a review of policies and procedural documents relating to licensed activities, equipment calibration, validation and maintenance records, audits, risk assessments, reported incidents, temperature monitoring for the storage units, staff training records and records related to environmental monitoring and the efficacy of antibiotic treatment steps undertaken by the 3CS prior to import.

Visual inspection
The inspection included a visit to areas within the premises where tissue is received, held in quarantine, receipted, stored, and transferred to shippers at the point of distribution. The visit included reviews of the establishment's equipment monitoring systems, tissue databases and areas where paper records were stored.

Audit of records
The inspection included a review of two examples of tissue that was imported under the licence since it was first issued, and was assisted by virtual meetings with colleagues from the establishment's 3CS. The examples consisted of an aortic iliac graft and a saphenous vein. The tissue pathway was reviewed from consent, donor testing and assessment, procurement, transportation, processing, cryopreservation, assessment of suitability for import into the UK, receipt at the establishment, storage, distribution to end users and the information provided to end user establishments.

Meetings with establishment staff
The inspection included meetings with the DI, the CLHc, the Customer Services Manager, staff responsible for tissue ordering, receipt and distribution, and colleagues at the establishment's 3CS responsible for quality and regulatory affairs.

Report sent to DI for factual accuracy: 15 December 2023

Report returned from DI: 02 January 2024

Final report issued: 05 January 2024

Appendix 1: The HTA's regulatory requirements

The HTA must assure itself that the DI, Licence Holder, premises and practices are suitable.

The statutory duties of the DI are set down in Section 18 of the Human Tissue Act 2004. They are to secure that:

- the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity;
- suitable practices are used in the course of carrying on that activity; and
- the conditions of the licence are complied with.

The HTA developed its licensing standards with input from its stakeholders. They are designed to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. The HTA inspects the establishments it licences against four groups of standards:

- consent
- governance and quality systems
- premises facilities and equipment
- disposal.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that a standard is not met, the level of the shortfall is classified as 'Critical', 'Major' or 'Minor' (see Appendix 2: Classification of the level of shortfall). Where HTA standards are fully met, but the HTA has identified an area of practice that could be further improved, advice is given to the DI.

Reports of HTA inspections carried out from 1 November 2010 are published on the HTA's website.

Appendix 2: Classification of the level of shortfall

Where the HTA determines that a licensing standard is not met, the improvements required will be stated and the level of the shortfall will be classified as ‘Critical’, ‘Major’ or ‘Minor’. Where the HTA is not presented with evidence that an establishment meets the requirements of an expected standard, it works on the premise that a lack of evidence indicates a shortfall.

The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the Human Tissue Act 2004, Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended), or associated Directions.

1. **Critical shortfall:**

   A shortfall which poses a significant direct risk of causing harm to a recipient patient or to a living donor,

   or

   A number of ‘major’ shortfalls, none of which is critical on its own, but viewed cumulatively represent a systemic failure and therefore are considered ‘critical’.

   A critical shortfall may result in one or more of the following:

   - A notice of proposal being issued to revoke the licence
   - Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.
   - A notice of suspension of licensable activities
   - Additional conditions being proposed
   - Directions being issued requiring specific action to be taken straightaway

2. Major shortfall:

A non-critical shortfall.

A shortfall in the carrying out of licensable activities which poses an indirect risk to the safety of a donor or a recipient

or

A shortfall in the establishment's quality and safety procedures which poses an indirect risk to the safety of a donor or a recipient;

or

A shortfall which indicates a major deviation from the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended) or the HTA Directions;

or

A shortfall which indicates a failure to carry out satisfactory procedures for the release of tissues and cells or a failure on the part of the designated individual to fulfil his or her legal duties;

or

A combination of several 'minor' shortfalls, none of which is major on its own, but which, viewed cumulatively, could constitute a major shortfall by adversely affecting the quality and safety of the tissues and cells.

In response to a major shortfall, an establishment is expected to implement corrective and preventative actions within 1-2 months of the issue of the final inspection report. Major shortfalls pose a higher level of risk and therefore a shorter deadline is given, compared to minor shortfalls, to ensure the level of risk is reduced in an appropriate timeframe.

3. Minor shortfall:

A shortfall which cannot be classified as either critical or major and, which can be addressed by further development by the establishment.

This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by

the HTA either by desk-based review or at the time of the next on-site inspection.

In response to a minor shortfall, an establishment is expected to implement corrective and preventative actions within 3-4 months of the issue of the final inspection report.

Follow up actions

A template corrective and preventative action plan will be sent as a separate Word document with the final inspection report. Establishments must complete this template and return it to the HTA within 14 days of the issue of the final report.

Based on the level of the shortfall, the HTA will consider the most suitable type of follow-up of the completion of the corrective and preventative action plan. This may include a combination of

- a follow-up inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next routine inspection.

After an assessment of the proposed action plan establishments will be notified of the follow-up approach the HTA will take.

Appendix 3: HTA standards

The HTA standards applicable to this establishment are shown below; those not assessed during the inspection are shown in grey text. Individual standards which are not applicable to this establishment have been excluded.

Human Tissue (Quality and Safety for Human Application) Regulations 2007 Standards (as amended)

Governance and Quality

Standard
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.
a) There is an organisational chart clearly defining the lines of accountability and reporting relationships.
b) There are procedures for all licensable activities that ensure integrity of tissue and / or cells and minimise the risk of contamination.
c) There are regular governance meetings, for example health and safety, risk management and clinical governance committees, which are recorded by agendas and minutes.
d) There is a document control system to ensure that changes to documents are reviewed, approved, dated and documented by an authorised person and only current documents are in use.
g) There are procedures to ensure that an authorised person verifies that tissues and / or cells received by the establishment meet required specifications.
h) There are procedures for the management and quarantine of non-conforming consignments or those with incomplete test results, to ensure no risk of cross contamination.

i) There are procedures to ensure tissues and / or cells are not released from quarantine until verification has been completed and recorded.
j) There are procedures detailing the critical materials and reagents used and where applicable, materials and reagents meet the standards laid down by the Medical Devices Regulation 2002 (SI 2002 618, as amended) (UK MDR 2002) and United Kingdom Conformity Assessed (UKCA).
k) There is a procedure for handling returned products.
l) There are procedures to ensure that in the event of termination of activities for whatever reason, stored tissues and / or cells are transferred to another licensed establishment or establishments.
m) The criteria for allocating tissues and / or cells to patients and health care institutions are documented and made available to these parties on request.
n) The establishment ensures imports from third countries meet the standards of quality and safety set out in Directions 001/2021.
o) There is a complaints system in place.
p) There are written agreements with third parties whenever an activity takes place that has the potential to influence the quality and safety of human tissues and / or cells.
q) There is a record of agreements established with third parties.
r) Third party agreements specify the responsibilities of the third party and meet the requirements set out in Directions 001/2021.
s) Third party agreements specify that the third party will inform the establishment in the event of a serious adverse reaction or event.
t) There are procedures for the re-provision of service in an emergency.

GQ2 There is a documented system of quality management and audit.
a) There is a quality management system which ensures continuous and systematic improvement.
b) There is an internal audit system for all licensable activities.
c) An audit is conducted in an independent manner at least every two years to verify compliance with protocols and HTA standards, and any findings and corrective actions are documented.
d) Processes affecting the quality and safety of tissues and / or cells are validated and undergo regular evaluation to ensure they continue to achieve the intended results.
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.
a) There are clearly documented job descriptions for all staff.
b) There are orientation and induction programmes for new staff.
c) There are continuous professional development (CPD) plans for staff and attendance at training is recorded.
d) There is annual documented mandatory training (e.g. health and safety and fire).
e) Personnel are trained in all tasks relevant to their work and their competence is recorded.
f) There is a documented training programme that ensures that staff have adequate knowledge of the scientific and ethical principles relevant to their work, and the regulatory context.
g) There is a documented training programme that ensures that staff understand the organisational structure and the quality systems used within the establishment.
h) There is a system of staff appraisal.

j) There are training and reference manuals available.
k) The establishment is sufficiently staffed to carry out its activities.
GQ4 There is a systematic and planned approach to the management of records.
a) There are procedures for the creation, identification, maintenance, access, amendment, retention and destruction of records.
b) There is a system for the regular audit of records and their content to check for completeness, legibility and accuracy and to resolve any discrepancies found.
c) Written records are legible and indelible. Records kept in other formats such as computerised records are stored on a validated system.
d) There is a system for back-up / recovery in the event of loss of computerised records.
e) The establishment keeps a register of the types and quantities of tissues and / or cells that are procured, tested, preserved, processed, stored and distributed or otherwise disposed of, and on the origin and destination of tissues and cells intended for human application.
f) There are procedures to ensure that donor documentation, as specified by Directions 001/2021, is collected and maintained.
g) There is a system to ensure records are secure and that donor confidentiality is maintained in accordance with Directions 001/2021.
h) Raw data which are critical to the safety and quality of tissues and cells are kept for 10 years after the use, expiry date or disposal of tissues and / or cells.
i) The minimum data to ensure traceability from donor to recipient as required by Directions 001/2021 are kept for 30 years after the use, expiry or disposal of tissues and / or cells.
k) There are documented agreements with end users to ensure they record and store the data required by Directions 001/2021.

l) The establishment records the acceptance or rejection of tissue and / or cells that it receives and in the case of rejection why this rejection occurred.
m) In the event of termination of activities of the establishment a contingency plan is in place to ensure raw data and records of traceability are maintained for 10 or 30 years respectively, as required.
GQ6 A coding and records system facilitates traceability of tissues and / or cells, ensuring a robust audit trail.
a) There is a donor identification system which assigns a unique code to each donation and to each of the products associated with it.
b) An audit trail is maintained, which includes details of when the tissues and / or cells were acquired and from where, the uses to which the tissues and / or cells were put, when the tissues and / or cells were transferred elsewhere and to whom.
c) The establishment has procedures to ensure that tissues and / or cells imported, procured, processed, stored, distributed and exported are traceable from donor to recipient and vice versa.
GQ7 There are systems to ensure that all adverse events, reactions and/or incidents are investigated promptly.
a) There are procedures for the identification, reporting, investigation and recording of adverse events and reactions, including documentation of any corrective or preventative actions.
b) There is a system to receive and distribute national and local information (e.g. HTA regulatory alerts) and notify the HTA and other establishments as necessary of serious adverse events or reactions.
c) The responsibilities of personnel investigating adverse events and reactions are clearly defined.
d) There are procedures to identify and decide the fate of tissues and / or cells affected by an adverse event, reaction or deviation from the required quality and safety standards.
e) In the event of a recall, there are personnel authorised within the establishment to assess the need for a recall and if appropriate initiate and coordinate a recall.

f) There is an effective, documented recall procedure which includes a description of responsibilities and actions to be taken in the event of a recall including notification of the HTA and pre-defined times in which actions must be taken.
g) Establishments distributing tissue and / or cells provide information to end users on how to report a serious adverse event or reaction and have agreements with them specifying that they will report these events or reactions.
h) Establishments distributing tissues and / or cells have systems to receive notifications of serious adverse events and reactions from end users and notify the HTA.
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.
a) There are documented risk assessments for all practices and processes.
b) Risk assessments are reviewed regularly, as a minimum annually or when any changes are made that may affect the quality and safety of tissues and cells.
c) Staff can access risk assessments and are made aware of local hazards at training.
d) A documented risk assessment is carried out to decide the fate of any tissue and / or cells stored prior to the introduction of a new donor selection criteria or a new processing step, which enhances the quality and safety of tissue and / or cells.

Premises, Facilities and Equipment

Standard
PFE1 The premises are fit for purpose.
a) A risk assessment has been carried out of the premises to ensure that they are fit for purpose.
b) There are procedures to review and maintain the safety of staff, visitors and patients.

c) The premises have sufficient space for procedures to be carried out safely and efficiently.
e) There are procedures to ensure that the premises are secure, and confidentiality is maintained.
f) There is access to a nominated, registered medical practitioner and / or a scientific advisor to provide advice and oversee the establishment's medical and scientific activities.
PFE2 Environmental controls are in place to avoid potential contamination.
a) Tissues and / or cells stored in quarantine are stored separately from tissue and / or cells that have been released from quarantine.
c) There are procedures for cleaning and decontamination.
d) Staff are provided with appropriate protective clothing and equipment that minimise the risk of contamination of tissue and / or cells and the risk of infection to themselves.
PFE3 There are appropriate facilities for the storage of tissues and / or cells, consumables and records.
a) Tissues, cells, consumables and records are stored in secure environments and precautions are taken to minimise risk of damage, theft or contamination.
b) There are systems to deal with emergencies on a 24-hour basis.
c) Tissues and / or cells are stored in controlled, monitored and recorded conditions that maintain tissue and / or cell integrity.
d) There is a documented, specified maximum storage period for tissues and / or cells.

PFE4 Systems are in place to protect the quality and integrity of tissues and / or cells during transport and delivery to its destination.
a) There is a system to ensure tissue and / or cells are not distributed until they meet the standards laid down by Directions 001/2021.
b) There are procedures for the transport of tissues and / or cells which reflect identified risks associated with transport.
c) There is a system to ensure that traceability of tissues and / or cells is maintained during transport.
d) Records are kept of transportation and delivery.
e) Tissues and / or cells are packaged and transported in a manner and under conditions that minimise the risk of contamination and ensure their safety and quality.
f) There are third party agreements with courier or transport companies to ensure that any specific transport conditions required are maintained.
g) Critical transport conditions required to maintain the properties of tissue and / or cells are defined and documented.
h) Packaging and containers used for transportation are validated to ensure they are fit for purpose.
i) Primary packaging containing tissues and / or cells is labelled with the information required by Directions 001/2021.
j) Shipping packaging containing tissues and / or cells is labelled with the information required by Directions 001/2021.
PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored.
a) Critical equipment and technical devices are identified, validated, regularly inspected and records are maintained.
b) Critical equipment is maintained and serviced in accordance with the manufacturer’s instructions.

c) Equipment affecting critical processes and storage parameters is identified and monitored to detect malfunctions and defects and procedures are in place to take any corrective actions.
d) New and repaired equipment is validated before use and this is documented.
e) There are documented agreements with maintenance companies.
f) Cleaning, disinfection and sanitation of critical equipment is performed regularly, and this is recorded.
h) Users have access to instructions for equipment and receive training in the use of equipment and maintenance where appropriate.
i) Staff are aware of how to report an equipment problem.
j) For each critical process, the materials, equipment and personnel are identified and documented.
k) There are contingency plans for equipment failure.

Disposal

Standard
D1 There is a clear and sensitive policy for disposing of tissues and / or cells.
a) The disposal policy complies with HTA's Codes of Practice.
b) The disposal procedure complies with Health and Safety recommendations.
c) There is a documented procedure on disposal which ensures that there is no cross contamination.
D2 The reasons for disposal and the methods used are carefully documented.
a) There is a procedure for tracking the disposal of tissue and / or cells that details the method and reason for disposal.

b) Disposal arrangements reflect (where applicable) the consent given for disposal.