

Inspection report on compliance with HTA licensing standards
Inspection dates: **9 and 10 December 2025**



LeMaitre Vascular Ltd
HTA licensing number 22696

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

Licisable 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, Valves; Pulmonary Patches				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, two minor shortfalls were found against standards for Governance and Quality.

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

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
GQ2 There is a documented system of quality management and audit.		
a) There is a quality management system which ensures continuous and systematic improvement.	<p>A power outage occurred at the premises in September 2025, lasting approximately six hours. While contingency measures were implemented to maintain appropriate storage temperatures, these actions were not defined in a written procedure.</p> <p>Additionally, the outage was not recorded as an incident. As a result, the establishment did not:</p> <ul style="list-style-type: none">• document that raw data had been lost;• record whether any corrective action, such as data recovery or risk assessment and procedure updates, were required; and• review the effectiveness of the contingency arrangements.	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.	Discrepancies were identified in staff training records for two members of staff. These included incomplete documentation of training on tissue return, ethical principles of the work being undertaken, and confirmation that individuals had read and understood the procedure for which they were being trained.	Minor
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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.	GQ4b	The DI may wish to consider removing criteria that are not relevant from the “Allograft Distribution Form”, as two out of the three forms reviewed during the inspection were not consistently completed in accordance with the establishment’s requirements.
2.	PFE1a	Additional security measures have been implemented at the premises. The DI is advised to ensure that these control measures are reflected in the premises risk assessment.

3.	PFE1b	The DI is advised to consider implementing the Fire Service's recommendation on the use of personal oxygen monitoring alarms in addition to existing wall-mounted monitoring systems. The DI is further advised to assess the risks to workers and others when items are removed from liquid nitrogen and when heavy equipment is moved, for example, determining whether suitable safety shoes are required.
4.	PFE3b	The inspection team were told that the tissue freezer's alarm activates at -150°C, and the system triggers an "annotation" at -130°C. However, a job sheet from 2024 indicated that the alarm threshold was -140°C. The DI is advised to review the alarm settings to ensure they are correctly understood, aligned with the current procedure(s), and to clarify whether these settings apply to both the internal and remote monitoring systems.
5.	PFE5a	Two of the tanks storing tissue had rust on their wheels. The DI is advised to consider increasing the frequency of tank inspections, including the wheels, to provide additional assurance regarding their continued suitability.
6.	PFE5d	Although the establishment ensures that new and serviced equipment is validated before being put into use, the DI may find it helpful to implement a procedure and controlled form(s) to cover this process. Doing so would provide additional assurance that equipment has been correctly installed, is fully operational, and will perform in accordance with establishment requirements before being put into or returned to routine use. The freezer storing tissue was serviced shortly before the inspection. The inspection certificate indicates that corrective actions are required, including reducing the holding tank pressure, and notes that a safety relief valve could not be located or rated. The DI should ensure that all identified remedial actions are completed.

Background

The establishment imports cardiovascular tissue from its parent company, which is the establishment's third country supplier (3CS), in the USA. The 3CS is responsible for reviewing tissue suitability in accordance with UK requirements and recording which tissues are suitable within the company's tissue database. The establishment orders tissue from the available list. It is then shipped to the establishment's premises in liquid nitrogen shippers.

Upon receipt, tissue is held in quarantine until all receipt checks are completed. Once verified, the tissue is stored in the establishment's liquid nitrogen storage tanks until distribution to end-users in the UK, within 48 hours of the scheduled operation. Establishment representatives attend hospital theatres at the point of end-use and help to ensure traceability records are completed and returned to the establishment for retention.

The establishment has been licensed by the HTA since January 2022. This was the establishment's second inspection; the last inspection took place in November 2023.

Since the last inspection, the establishment has added an additional tissue type (pulmonary patches) to the licence. Additionally, the CLH contact has changed.

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 procedures relevant to the establishment's licence, a selection of temperature records and the most recent probe calibration certificate for the freezer storing tissue. The agreement between the establishment and its 3CS was reviewed, along with a sample of training records for establishment staff. A couple of incidents were discussed, as well as the establishment's reporting procedure.

Further discussions were held about the processes for managing and charging shippers for tissue distribution, as well as the alarm monitoring system for the storage units. An audit of one of the 3CS' sub-contractors, on-boarded since the last inspection, was reviewed during a virtual meeting with the 3CS. A sample of the 3CS' procedural documents was also reviewed, including the process for managing "non-conforming contaminants", and training records for two of its tissue processing operators.

Visual inspection

An inspection was carried out of the area where tissue is received, quarantined, receipted, stored and transferred to shippers for distribution.

Audit of records

The inspection team reviewed records for three pre-selected imported tissue products (two pulmonary patches and one ascending aortic valve). This included documentation relating to consent, donor selection and serology testing results, processing, suitability assessment for UK import, receipt at the establishment, storage, and distribution to end-users.

Meetings with establishment staff

Discussions were held in person with various members of staff, including the DI and the CLH who is the Vice President Northern Europe, as well staff responsible for tissue ordering, receipt, and distribution. A virtual meeting was also conducted with colleagues from the establishment's 3CS team who are responsible for quality and regulatory affairs.

Report sent to DI for factual accuracy: 16 January 2026

Report returned from DI: No factual accuracy or request for redaction comments were made by the DI

Final report issued: 22 January 2026

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.
- 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.