Application form for establishments in the Human Application sector to add import as an activity to an existing licence or to vary the scope of an existing import authorisation

# Who should use this form?

This application form can be used by establishments that already hold a licence in the Human Application sector wishing to add the licensable activity of import, or to update their existing import licence.

Application forms for new licence applications are available on the [HTA website](https://www.hta.gov.uk/guidance-professionals/licensing/licensing-under-human-tissue-quality-and-safety-human-application).

If you are completing this application for:

* an establishment is based in Northern Ireland (NI) applying for a licence to receive tissues and cells for human application from a supplier based in Great Britain (GB); or
* an establishment is based in GB applying for a licence to import tissues and cells for human application from the European Economic Area (EEA).

please contact the HTA at licensing.enquiries@hta.gov.uk to ensure you are completing the correct application form.

# How to complete this application form

This application form consists of four parts covering establishment information, contact information, self assessment against regulatory requirements and supporting documentation to be included with the completed application form.

Sections to be completed:

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| **Import licence** | **Part 1** | **Part 2** | **Part 3** | **Part 4** |
| **Spread-sheet** | **a** | **b** |
| Fixed third country supplier (3CS) [[1]](#footnote-1) | ü | ü | ü | ü |  | ü |
| One-off | ü | ü | ü |  | ü | ü |

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| **Part 1: Importing Tissue Establishment (ITE) information** |
| A licence application must specify the premises where the activities are to take place; this should be the address of the main site. Where the licensed activity will take place at more than one premises (i.e. a main site with remote satellite sites), a separate satellite licence will be needed for each additional site. |
| **Name of the ITE** |  |
| **Licence Number** |  |
| **Address of the licensed premises** |  |
| **Are you currently, or have you previously been licensed for import under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended)** | Yes/No (delete as applicable)If yes, please provide further details |
| **Name of the site of reception for imports (if different to licensed establishment)** |  |
| **Address of the site of reception for imports (if different to licensed establishment)** |  |
| **Brief synopsis of proposed import activity** |  |

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| **Part 2: Contact details for the application** |
| **Name of contact person for the application** |  |
| **Job role of contact person** |  |
| **Telephone number** |  |
| **Email address** |  |
| **Name of Designated Individual (DI) (if not the contact person)\*** |  |
| **Telephone number** |  |
| **Email address** |  |
| **\*If the DI is not the contact person, please complete the following declaration:** | I, (*name of DI*), have assured myself of the suitability of the practices set out in this application and authorise the contact person named above to provide this information on my behalf.I am aware that under paragraph 7(2)(a) of Schedule 3 of the Human Tissue Act 2004, the Human Tissue Authority may revoke a licence if it is satisfied that any information given for the purposes of the application for a licence was in any material respect false and misleading. |
| DI Signature: |
| Date: DD/MM/YYYY |

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| **Part 3: Spreadsheet** |
| Complete the linked spreadsheet: |

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| Part 3a: Confirmation of documentary requirements for import from a fixed 3CSSelf-assessment against the documentary requirements set out below. To be completed by the applicant. Information can be appended to this application if needed.Do not complete this section if you are applying for one-off import only.**If you are based in GB and intend to import from suppliers in the European Economic Area (EEA) only, or you are based in NI and wish to import from suppliers based in GB, please contact us to discuss your application and confirm you are completing the correct form.** |
| **Documentation** | **Available to ITE** | **Verified against the requirements of Directions 001/2021**  |
| Detailed information on:the criteria used for donor identification and evaluationinformation provided to the donor or donor family* **how consent is obtained from the donor or donor family**
 | [ ]  Not applicable[ ]  Yes[ ]  NoIf no, provide details of information held by the ITE: | [ ]  Not applicable[ ]  Yes[ ]  No |
| For each tissue type product, will the donation be voluntary and unpaid? | [ ]  Yes[ ]  No[ ]  Don’t know |  |
| Detailed information on the testing centre(s) used by the 3CS and the tests performed, including documentation relating to the validation of the tests and timing of blood samples taken for donor serology testing | [ ]  Not applicable[ ]  Yes[ ]  NoIf no, provide details of information held by the ITE: | [ ]  Not applicable[ ]  Yes[ ]  No |
| Detailed information on the methods used during processing of the tissues / cells, including details of the validation work that has been performed | [ ]  Not applicable[ ]  Yes[ ]  NoIf no, provide details of information held by the ITE: | [ ]  Not applicable[ ]  Yes[ ]  No |
| **Where tissues and cells for human application are processed before receipt by the ITE without a subsequent validated microbial inactivation or terminal sterilisation process, do you have details of the environmental monitoring carried out during critical processing? \*** | [ ]  Not applicable[ ]  Yes[ ]  NoPlease provide details of the environmental monitoring carried out during critical processing: | [ ]  Not applicable[ ]  Yes[ ]  No |
| For each activity carried out prior to import, do you have:* **a detailed description of the facility in which the activity is carried out**
* **a list of all critical equipment used**
* **a list of all materials used**
 | [ ]  Not applicable[ ]  Yes[ ]  NoIf no for any requirement, provide details of information held by the ITE: | [ ]  Not applicable[ ]  Yes[ ]  No |
| **For each activity carried out prior to import, do you have a list of all relevant quality control criteria?** | [ ]  Yes[ ]  NoIf no, provide details of information held by the ITE: | [ ]  Yes[ ]  No |
| **For each activity carried out prior to import, will you have details of the conditions for release?** | [ ]  Yes[ ]  NoIf no, provide details of information held by the ITE: | [ ]  Yes[ ]  No |
| Do you have a summary of the most recent inspection of the 3CS by the third country competent authority or authorities, including the date of the inspection, type of inspection and main conclusions | [ ]  Not applicable[ ]  Yes[ ]  NoIf no, provide details of information held by the ITE: | [ ]  Not applicable[ ]  Yes[ ]  No |
| A summary of the most recent audit of the third country supplier carried out by, or on behalf of, the ITE | [ ]  Not applicable[ ]  Yes[ ]  NoIf no, provide details of information held by the ITE: | [ ]  Not applicable[ ]  Yes[ ]  No |
| Any relevant national or international accreditation | [ ]  Not applicable[ ]  Yes[ ]  NoIf no, provide details of information held by the ITE: | [ ]  Not applicable[ ]  Yes[ ]  No |
| **If you are responsible for arranging transportation during import:*** **an agreement with the courier undertaking this activity that reflects the requirements in paragraphs 238 and 239 of the HTA Guide; and,**
* **validation data to support the suitability of the transportation container and specified time and temperature during transport limits.**
 | [ ]  Not applicable[ ]  Yes[ ]  NoIf no, provide details of information held by the ITE: | [ ]  Not applicable[ ]  Yes[ ]  No |

\* For example, whenever tissues/cells are exposed to the environment during processing and the processing step is not followed by a validated microbial inactivation or validated terminal sterilisation process, are the following forms of environmental monitoring carried out for the full duration of critical processing:

1. the use of settle plates;

2. the use of finger dabs of the operator following processing; and

3. the use of non-viable particle monitoring during open processing.

Please also indicate whether these strategies are employed for the duration of each open processing event or on a scheduled basis.

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| **Part 3b: Information for the addition of one-off imports** |
| **Complete this section if you wish to add authorisation to undertake one-off imports to your licence.** |
| **What tissues / cells do you require one-off import authorisation for?** |  |
| **Will the tissues / cells be for autologous or allogeneic use?** |  |
| **Will the cells be used for immediate transplantation?** |  |
| **Will the imported tissues / cells be for a named recipient, known to the importer and 3CS before import?** |  |
| **Do you intend to use the same 3CS more than once?** |  |
| **Do you have an approved 3CS for this tissue type?** |  |
| **What activities will be carried out by the 3CS before import?** |  |
| **How will you select an appropriate 3CS for one-off import?** |  |
| **How will you ensure that imported tissues / cells have standards of quality and safety equivalent to those described in Directions 001/2021?** |  |
| **How will you ensure that traceability will be maintained?** |  |
| **How will you ensure that imported tissues / cells are not used in anyone other than their intended recipients?** |  |

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| **Part 4: Supporting documents** |
| **The following documents all need to be included in support of your application.****Items marked with \* do not apply to one-off imports** |
| [ ]  | A completed spreadsheet (see part 3) showing:1. details of tissues and cells to be imported and location of activities undertaken
2. details on third country suppliers
3. details of any sub-contractors used by the third country suppliers including the name, location and activity undertaken
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| [ ]  | A detailed description of the flow of imported tissues and cells from their procurement to their reception at the importing tissue establishment. |
| [ ]  | A copy of the written agreement with the third country supplier(s). \* |
| [ ]  | A copy of the third country supplier's export authorisation certificate or, where a specific export authorisation certificate is not issued, certification from the relevant third country competent authority or authorities authorising the third country supplier's activities in the tissue and cells sector including exports. This documentation shall also include the contact details of the third country competent authority or authorities. In third countries where such documentation is not available, alternative forms of documentation shall be provided such as reports of audits of the third country supplier. \* |
| [ ]  | A detailed description of the criteria used for donor identification and evaluation.\* |
| [ ]  | Detailed information on the testing centre(s) used by third country suppliers and the tests performed by such centres.\* |
| [ ]  | Where tissues and cells for human application are processed before receipt by the ITE without a subsequent validated microbial inactivation or terminal sterilisation process: information about the environmental monitoring that is performed during critical processing.  |
| [ ]  | Detailed information on the conditions for release of tissues and cells by the third country supplier or suppliers. \* |
| [ ]  | A copy of the primary label, repackage label, external package and transport container labels. \* |
| [ ]  | A list of relevant SOPs relating to your proposed import activities including SOPs on applying the Single European Code **(Northern Ireland ONLY)**, reception and storage of imported tissues and cells at the importing tissue establishment, management of serious adverse events and reactions, management of recalls and traceability from donor to recipient. |
| [ ]  | **For one-off imports only:*** Policy for importing on a one-off basis
* SOPs describing:
	+ how to select a supplier
	+ how to verify export authorisation certificate requirements
	+ how to ensure that the imported material has equivalent standards of quality and safety to those set out in HTA Directions 001/2021. The HTA’s tools for assessing equivalence on our website may be helpful:
		- [Establishments in Great Britain](https://content.hta.gov.uk/sites/default/files/2021-06/GB%20Tool%20for%20assessing%20equivalent%20quality%20and%20safety%20of%20imported%20tissues.docx)
		- [Establishments in Northern Ireland](https://content.hta.gov.uk/sites/default/files/2021-06/Northern%20Ireland%20Tool%20for%20assessing%20equivalent%20quality%20and%20safety%20of%20imported%20tissues.docx)
	+ how application to the intended recipient will be ensured
* Copies of any agreements / contracts that will form part of the one-off import process.
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State the total number of documents included with your application:

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Please return this application form by email to licensing.enquiries@hta.gov.uk

1. This is to be used where imports from a supplier in a third country will be taking placed on a regular or repeated basis. [↑](#footnote-ref-1)