Import licence variation form

Licence variation form for establishments in Great Britain importing tissues and cells for Human Application from suppliers based in the European Economic Area

# Who should use this form?

This form is intended to be used by establishments who are:

* licensed by the HTA in the Human Application sector;
* based in Great Britain (GB); and,
* receive, or intend to receive, tissues and cells for human application from suppliers based in the European Economic Area (EEA).

This form is to vary an existing licence to add import from suppliers based in the EEA only. If you undertake, or intend to undertake, any other activities with tissues or cells for human application (such as the storage of cellular products for more than 48 hours, onward distribution, export, procurement, testing or processing), and do not currently hold a licence for these activities, please get in touch as soon as possible via [licensing@hta.gov.uk](mailto:licensing@hta.gov.uk) to discuss your requirements.

# Links to further information

Please refer to the [HTA’s website](https://www.hta.gov.uk) for:

* [information about HTA licensing](https://www.hta.gov.uk/guidance-professionals/licensing/licensing-under-human-tissue-quality-and-safety-human-application);
* the [HTA Guide to Quality and Safety Assurance for Tissues and Cells for Patient Treatment](https://www.hta.gov.uk/guidance-professionals/regulated-sectors/human-application/hta-guide-quality-and-safety-assurance), which explains the regulatory requirements for establishments in the Human Application sector;
* [information on the role and responsibilities of Designated Individuals and Licence Holders](https://www.hta.gov.uk/guidance-professionals/licensing/designated-individuals-and-licence-holders-under-human-tissue) under the Human Tissue (Quality and Safety for Human Application) Regulations 2007, as amended (the Q&S Regulations); and,
* the [HTA’s latest UK Transition guidance](https://www.hta.gov.uk/guidance-professionals/uk-transition-guidance).

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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. the main site with remote satellite sites), a separate satellite licence will be needed for each additional site. | |
| **Name of the ITE** |  |
| **ITE licence number** |  |
| **Address of 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: |
| **Activity to be licensed at the hub site** | **Import of tissue and cell products from the EEA into GB only.**  If you intend to import cellular tissue and cells for human application and store them for more than 48 hours, and do not already hold a licence covering this activity, please contact us as soon as possible via [licensing@hta.gov.uk](mailto:licensing@hta.gov.uk) to discuss your application. |
| **Brief synopsis of proposed import activity** |  |

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| Part 2: [Site](http://www.hta.gov.uk/licensingandinspections/satellitepremises.cfm)(s) of reception of imports | |
| Will the establishment have other sites of reception for imports, in addition or instead of the hub site listed in Part 1? | Yes  No |
| If yes, please provide the information below for each site of reception of imports, including satellite sites. If there will be more than one additional site of reception, please copy and paste this part of the form onto a separate sheet: | |
| **Premises name** |  |
| **Address** |  |
| **Activity to be licensed at the satellite site** | **Import of tissue and cell products from the EEA into GB only.**  If you intend to import cellular tissue and cells for human application and store them for more than 48 hours, and do not already hold a licence covering this activity, please contact us as soon as possible via [licensing@hta.gov.uk](mailto:licensing@hta.gov.uk) to discuss your application. |

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| Part 3: Supplier information |
| **Please complete and return the following spreadsheet with your application:** |
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| Part 4: Confirmation of documentary requirements for import |

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| Please complete the following self-assessment against a subset of documentary requirements for import, as set out in the [HTA Guide to Quality and Safety Assurance for Tissues and Cells for Patient Treatment](https://www.hta.gov.uk/guidance-professionals/regulated-sectors/human-application/hta-guide-quality-and-safety-assurance). Information can be appended to the application if needed.  Full import licensing requirements can be found in the HTA Guide linked above.  Do not complete this section is you are undertaking one-off imports only. | |
| **Do you have:** | **Self-assessment:** |
| **A written agreement with any third country supplier for the import of tissues and cells that contains, as a minimum, the requirements set out in** [**paragraph 255 of the Guide**](https://www.hta.gov.uk/guidance-professionals/regulated-sectors/human-application/hta-guide-quality-and-safety-assurance)**?** | Yes  No  Please include a copy of the agreement with your application or [contact the HTA](mailto:licensing.enquiries@hta.gov.uk) to discuss. |
| **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  No  If no, provide details of information held by the ITE: |
| **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  No  If no, provide details of information held by the ITE: |
| **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 (for example, site visit or desk-based) and main conclusions** | Not applicable  Yes  No  If no, provide details of information held by the ITE: |
| **A summary of the most recent audit of the 3CS carried out by, or on behalf of, the importing tissue establishment (ITE)** | Not applicable  Yes  No  If no, provide details of information held by the ITE: |
| **Any relevant national or international accreditation held by the supplying organisation in the EEA** | Not applicable  Yes  No  If no, provide details of information held by the ITE: |
| **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  No  Please provide details of the environmental monitoring carried out during critical processing: |

\* 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 5: Information needed for one-off imports |

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| **Please complete this section if you intend to undertake one-off imports from suppliers based in the EEA.**    A one-off import is the import of any specific type of tissue or cell for the  personal use of an intended recipient, known to the importing tissue  establishment and the third country supplier before importation.  One-off imports should not as a general rule be carried out on a regular or  repeated basis for the same 3CS and should only be carried out once for any  given recipient unless the exemptions in paragraph 259 of the [HTA Guide to Quality and Safety Assurance for Tissues and Cells for Patient Treatment](https://www.hta.gov.uk/guidance-professionals/regulated-sectors/human-application/hta-guide-quality-and-safety-assurance) apply. | |
| **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 6: Supplementary Information | | |
| This section aims to gather further information about the receipt and use of tissue and cell products at your organisation. | | |
| **With regard to the receipt and use of human tissues and cells at your organisation, please indicate whether** | You have procedures in place for the receipt of these materials which include checks by trained staff to confirm that the quality and safety of the product are suitable. For example, that the correct material was received and the packaging is complete and undamaged. | Yes  No |
| You have procedures in place to ensure that these materials are stored in a clean, secure environment and in accordance with any guidance provided in the product packaging and by the supplying organisation.  If you intend to store **cellular** products for greater than 48 hours, please get in touch via [licensing@hta.gov.uk](mailto:licensing@hta.gov.uk) to discuss your requirements. | Yes  No |
| You have systems in place to report any serious adverse events and reactions to the HTA and to your EEA supplier. | Yes  No |
| You have systems in place to ensure tissues and cells are individually traceable from receipt to use in patient treatment (or disposal / return to the supplier). | Yes  No |
| The responses to the above questions also apply to any satellite sites (refer to Part 2 of this form). | Yes  No |

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| Part 7: Supporting documents | |
| The following documents all need to be included in support of your application. If any documents are not available, please indicate and provide a comment in the box provided.  **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. |
|  | A copy of the written agreement with the third country supplier(s) containing the minimum requirements described in paragraph 255 of the Guide. \* |
|  | A copy of the third country supplier's export authorisation certificate. This documentation shall also include the contact details of the third country competent authority or authorities. |
|  | 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. |
|  | A list of relevant SOPs relating to your proposed import activities including reception 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:**   1. Policy for importing on a one-off basis 2. 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 [tool for assessing equivalence](https://content.hta.gov.uk/sites/default/files/2021-06/GB%20Tool%20for%20assessing%20equivalent%20quality%20and%20safety%20of%20imported%20tissues.docx) may be helpful)    * how application to the intended recipient will be ensured 3. Copies of any agreements / contracts that will form part of the one-off import process |

**Comment of any mandatory documents which have not yet been included with this application and the reason for this:**

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**State the total number of documents included with your application:**

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| Part 8: Contact details for the application | |
| Please provide the details of the contact person for this application, **if this is not the DI**. | |
| **Name of contact person for the application** |  |
| **Job role of contact person** |  |
| **Telephone number** |  |
| **Email address** |  |

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| Part 9: Designated Individual Declaration | |
| The DI for the licence must complete this section | |
| **DI Name** |  |
| **DI job role** |  |
| **Telephone number** |  |
| **Email address** |  |
| **Declaration** | I, (*name of Designated Individual*), 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. |
| Signature: |
| Date: DD/MM/YYYY |

Please return this application form and associated documents by email to

[licensing@hta.gov.uk](mailto:licensing@hta.gov.uk)