Import licence application

Licence application 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 licence application form is intended to be used by establishments based in Great Britain (GB) receiving tissues and cells for human application from suppliers based in the European Economic Area (EEA).

Human application means using human tissues or cells on or in a human recipient, including use in extracorporeal applications. It excludes the use of an autologous graft within the same surgical procedure.

This form is for import applications 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 via [licensing@hta.gov.uk](mailto:licensing@hta.gov.uk) to discuss your requirements.

# Licensing requirement

Under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 as amended (the Q&S Regulations), the HTA licenses and inspects establishments that undertake the procurement, testing, processing, storage, distribution, import and export of tissues and cells for human application.

As set out in published GOV.UK [guidance on the quality and safety of human organs, tissues and cells](https://www.gov.uk/guidance/quality-and-safety-of-human-organs-tissues-and-cells-from-1-january-2021), suppliers of human tissues and cells for human application from outside the United Kingdom (UK) must be treated as third country suppliers (3CSs).

This means that if you receive tissues or cells from a supplier based in the EEA from 1 July 2021, you will need:

* an import licence from the HTA; and,
* an import agreement with the supplier in the EEA.

# Suppliers

Import of tissues and cells intended for use in human application into GB from a 3CS based in the EEA must only be carried out where:

* 1. the import is from a tissue establishment (TE) which is accredited, designated, authorised or licensed under the laws or other measures adopted and recognised in an EEA state to implement the European Tissues and Cells Directives (EUTCDs); or
  2. the import:
     1. is from a person who is approved to procure those tissues and cells under the laws or other measures adopted in an EEA state to implement the EUTCDs; and
     2. follows the procurement of those tissues and cells in conditions accredited, designated, authorised or licensed under the laws or measures adopted for the purposes of implementing the EUTCDs.

# 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).

Please contact us at [licensing@hta.gov.uk](mailto:licensing@hta.gov.uk) if you have any questions about your application.

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| Part 1: Establishment 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. | |
| **Premises name** |  |
| **Address** |  |
| **Type of organisation (e.g. hospital, commercial organisation, dental surgery)** |  |
| **Activity to be licensed at the main 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, 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: [Satellite sites](http://www.hta.gov.uk/licensingandinspections/satellitepremises.cfm) | |
| Will the establishment have any satellite sites that will be importing tissues or cells for human application? | Yes  No |
| If yes, please provide the information below for each satellite site. If you have more than one satellite, 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, 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: Application to be [Designated Individual](http://www.hta.gov.uk/licensingandinspections/peopleatlicensedestablishments/disandlicenceholdersundertheq&sregulations.cfm) (DI) | | | | |
| To be completed by the proposed DI.  Before completing, we recommend you read the information for DIs we have published on our website: [Useful information for DIs and Named Contacts](https://www.hta.gov.uk/guidance-professionals/licensing/designated-individuals-and-licence-holders-under-human-tissue) | | | | |
| **Title** |  | | | |
| **Forename(s)** |  | | | |
| **Surname** |  | | | |
| **If you have been known by another name, please provide details** |  | | | |
| **Correspondence address** |  | | | |
| **Email** |  | | | |
| **Telephone** |  | | | |
| **Job title** |  | | | |
| **Have you ever applied to be a DI for another establishment?** | Yes  No  If yes, please provide the establishment name and the application reference number. | | | |
| **Educational and/or professional qualifications** |  | | | |
| **Membership of relevant professional bodies and registration numbers where applicable** |  | | | |
| **Details of any other relevant experience, including practical experience in the fields of medicine, biological science, managerial experience and training** |  | | | |
| Declaration by proposed Designated Individual Any person making an application and submitting a compliance report should be 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 or misleading.  I understand the terms and conditions under which a licence will be granted under the Human Tissue Act 2004 and the Human Tissue (Quality and Safety for Human Application) Regulations 2007, particularly my duties under Section 18 of the Act and Regulation 12 of the Regulations and confirm: | | | | |
| a) I will follow the guidance set out in the Codes of Practice produced by the Human Tissue Authority and as amended from time to time. | | | | Yes  No |
| b) The licensed activity will be carried out under my supervision. | | | | Yes  No |
| c) I accept I am responsible for securing that the other persons to whom the licences apply are suitable persons to participate in the carrying out of the licensed activity. | | | | Yes  No |
| d) I accept that I am responsible for securing that suitable practices are used by the persons under my supervision in the course of carrying out the licensed activity. | | | | Yes  No |
| e) I accept I am responsible for compliance with the conditions of any licence(s) granted. | | | | Yes  No |
| f) I accept that I, the Licence Holder and the establishment must comply with any Directions issued by the Human Tissue Authority from time to time. | | | | Yes  No |
| g) I acknowledge that the requirements of any Directions issued by the Human Tissue Authority from time to time represent suitable practices in the course of carrying on the licensed activity. | | | | Yes  No |
| h) I accept that I am responsible for compliance with the conditions of any and all third-party agreements entered into by or on behalf of the Licence Holder in relation to the licensed activity authorised to be carried out under my supervision. | | | | Yes  No |
| i) I accept that I am responsible for securing compliance with the requirements of Regulation 13(1) of the Human Tissue (Quality and Safety for Human Application) Regulations 2007 regarding information and confidentiality. | | | | Yes  No |
| j) The information provided is true and accurate to the best of my knowledge. | | | | Yes  No |
| k) I consent to be the Designated Individual for the licence application made by the proposed Licence Holder and, where applicable, consent to be the Licence Holder. | | | | Yes  No |
| Signature: | | | Date: DD/MM/YYYY | |
| Part 5: Application to be Individual [Licence Holder](http://www.hta.gov.uk/licensingandinspections/peopleatlicensedestablishments/disandlicenceholdersundertheq&sregulations.cfm) (LH) | | | | |
| This section should be completed if an individual person is applying to be the LH. If a corporate body is applying to be the LH, please move on to the next section  If the proposed DI is to be the LH, please complete the declaration section only | | | | |
| **Title** |  | | | |
| **Forename(s)** |  | | | |
| **Surname** |  | | | |
| **If you have been known by another name, please provide details** |  | | | |
| **Email** |  | | | |
| **Telephone** |  | | | |
| **Correspondence address if different from licensed premises** |  | | | |
| **Job title** |  | | | |
| **Employing body or organisation** |  | | | |
| **Membership of relevant professional bodies and registration numbers where applicable** |  | | | |
| **Details of any other relevant experience, including managerial experience and training** |  | | | |
| Declaration by proposed Licence Holder Any person making an application and submitting a compliance report should be 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 or misleading.  I understand the terms and conditions under which a licence will be granted under the Human Tissue Act 2004 and the Human Tissue (Quality and Safety for Human Application) Regulations 2007 and confirm: | | | | |
| a) The information provided is true and accurate. | | Yes  No | | |
| b) The Designated Individual has consented to this application. | | Yes  No | | |
| c) I accept that the Licence Holder is responsible under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 for entering into third party agreements with any third parties that procure, test, process, distribute or export tissues and/or cells for human application on behalf of the establishment, or supply any goods or services which may affect the quality or safety of tissues and/or cells. | | Yes  No | | |
| d) I accept that I, the Designated Individual and the establishment must comply with any Directions issued by the Human Tissue Authority from time to time. | | Yes  No | | |
| e) I acknowledge that the requirements of any Directions issued by the Authority from time to time represent suitable practices in the course of carrying out the licensed activity. | | Yes  No | | |
| Signature: | | Date: DD/MM/YYYY | | |

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| Part 6: Application to be Corporate [Licence Holder](http://www.hta.gov.uk/licensingandinspections/peopleatlicensedestablishments/disandlicenceholdersundertheq&sregulations.cfm) (LH) | | |
| This section should be completed when a corporate body is applying to be the LH. If an individual person is applying to be the LH, please complete the previous section instead. | | |
| **Full name of body** |  | |
| **Trading name or business name if different from company name** |  | |
| **Type of corporate body and relevant details** | Limited company  Company registration number:  Sole proprietor  Name and address:  Public Limited Company  Company registration number:  Charity  Charity registration number:  Partnership  Names and addresses of partners:  NHS Organisation  Please describe:  Other public body  Please describe:  Higher Education Institution  Other  Please describe: | |
| **Name and registered office of parent company, if applicable** |  | |
| **If the body has been known by another name in the past five years, please provide details** |  | |
| **Name, job title and qualifications of person completing this application on behalf of the corporate body (and therefore authorised to sign on behalf of the corporate body)** | Name:  Job title:  Qualifications: | |
| **Correspondence address if different from the licensed premises** |  | |
| **Email** |  | |
| **Telephone** |  | |
| Declaration by proposed Corporate Licence Holder Any person making an application and submitting a compliance report should be 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 or misleading.  On behalf of the corporate body I accept the terms and conditions under which a licence will be granted under the Human Tissue Act 2004 and the Human Tissue (Quality and Safety for Human Application) Regulations 2007 and confirm: | | |
| a) The information provided is true and accurate. | | Yes  No |
| b) The Designated Individual has consented to this application. | | Yes  No |
| c) I have been authorised to make this application on behalf of the applicant corporate body. | | Yes  No |
| d) I accept that the Licence Holder is responsible under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 for entering into third party agreements with any third parties that procure, test, process, distribute or export tissues and/or cells for human application on behalf of the establishment, or supply any goods or services which may affect the quality or safety of tissues and/or cells. | | Yes  No |
| e) I accept that the Licence Holder, the Designated Individual and the establishment must comply with any Directions issued by the Human Tissue Authority from time to time. | | Yes  No |
| f) I, on behalf of the Licence Holder, acknowledge that the requirements of any Directions issued by the Human Tissue Authority from time to time represent suitable practices in the course of carrying on the licensed activity. | | Yes  No |
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| Signature: | | Date: DD/MM/YYYY |

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| Part 7: Confirmation of documentary requirements for import from a fixed 3CS |

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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  Please provide details of the donor serological tests carried out and the timing of donor blood sampling: |
| **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 8: 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 9: 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 10: 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 of 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 11: Contact details for the application | |
| Please provide the details of the contact person for this application, **if this is not the DI**. The DI must complete Part 3. | |
| **Name of contact person for the application** |  |
| **Job role of contact person** |  |
| **Telephone number** |  |
| **Email address** |  |

Please return this application form and associated documents by email to [licensing@hta.gov.uk](mailto:licensing@hta.gov.uk)