Application for Transfer of a Tissue Establishment Authorisation

|  |
| --- |
| 1. Details of CURRENT authorisation holder

Name of tissue establishment:      Authorisation number:       Legally registered address of authorisation holder:      Eircode:      Site address of premises subject to the authorisation:      Eircode:      Companies Registration Office number:      Contact person:      Contact telephone:      Email address:       |
| 1. Details of Proposed authorisation holder

Name of proposed tissue establishment:      Legally registered address of proposed authorisation holder:      Eircode:      Site address of premises subject to the proposed authorisation:      Eircode:      Companies Registration Office number:      Contact person:      Contact telephone:      Email address:       |
| 1. BaCKGROUND

Please give a brief background explanation for the proposed transfer of the authorisation:       |
| 1. DECLARATION - CURRENT HOLDER OF THE AUTHORISATION

I hereby confirm that on transfer **<insert name of current holder>** will furnish to **<insert name of the proposed holder>**:* all records and documentation related to and in accordance with the principles and guidelines specified by Commission Directive 2004/23/EC (as implemented by Commission Directives 2006/17/EC and 2006/86/EC), and with the Quality and Safety of Human Tissues and Cells Regulations 2006, Human Tissues and Cells Traceability Requirements, Notification of Serious Adverse Reactions and Events and Certain Technical Requirements Regulations 2007; and
* all items of whatsoever nature required to be held by the holder of authorisation **<insert authorisation number>**.

I declare that all information supplied and supporting documentation is correct and I am authorised to make this declaration on behalf of the applicant.Signed: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:      Print name:      Capacity in which this declaration is made by or on behalf of the applicant:      Telephone no:      Email:      Witnessed by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:      Print name and address of witness:       |
| 1. DECLARATION - PROPOSED HOLDER OF AUTHORISATION

I hereby make application for the authorisation **<insert authorisation number>** granted to **<insert name of current holder>** in accordance with the requirements of Commission Directive 2004/23/EC and with Quality and Safety of Human Tissues and Cells Regulations 2006, to be transferred to **<insert name of the proposed holder>**.From time of transfer of the authorisation by the Health Products Regulatory Authority to **<insert name of the proposed holder>** I hereby undertake to ensure fulfilment by **<insert name of the proposed holder>** of the obligations arising from the authorisation.I hereby confirm that:* the quality management system in accordance with the principles and guidelines specified by Commission Directive 2004/23/EC and with the Quality and Safety of Human Tissues and Cells Regulations 2006 , which has been operated by **<insert name of current holder>** to time of transfer will continue to be implemented by **<insert name of the proposed holder>** from time of transfer;
* from time of transfer **<insert name of the proposed holder>** will have the sole responsibility for the activities authorised/under the authorisation including obtaining approval as required from the Health Products Regulatory Authority for any changes to the authorisation;
* **<insert name of the proposed holder>** has procedures in place to permit the recall of any human tissue and/or cell for human application released from the authorised premises subsequent to the transfer and a copy of the procedure is attached to this application;
* the transfer will not adversely affect the quality or safety of any human tissue and/or cell for human application issued from the authorised premises.

I declare that all information supplied and supporting documentation is correct and I am authorised to make this declaration on behalf of the applicant.Signed: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:      Print name:      Capacity in which this declaration is made by or on behalf of the applicant:      Telephone no:      Email:      Witnessed by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:      Print name and address of witness:       |
| 1. fees

An application fee must be submitted with each request for a transfer of an authorisation.Please refer to the ‘Guide to Fees for Human Products’ on [www.hpra.ie](http://www.hpra.ie) and complete the fee application form. |
| 1. CHECKLIST OF supporting items

The following must be submitted with the application (except where not applicable).Please tick the checkboxes below to confirm the following have been included with the application.[ ]  Letter of application[ ]  Certificate of Incorporation of proposed holder[ ]  Fees[ ]  If any current key personnel are to change, please provide CVs and training records in relation to the changing personnel.  |

Send to:

Compliance Department

Health Products Regulatory Authority

Earlsfort Centre

Earlsfort Terrace

Dublin 2

D02 XP77

Tel: + 353 1 676 4971

Fax: + 353 1 676 7836

Email: compliance@hpra.ie