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DEPARTMENT OF HEALTH
HEALTH TECHNOLOGY AND ADVISORY DIVISION

New / Renewal Application for Exemption of Regulated Products under the Human Organ Transplant Ordinance (Chapter 465)

Notes to Applicant:

1. Please read the following documents before completing this form:
   (a) The Human Organ Transplant Ordinance (Chapter 465) and its subsidiary legislations; and
   (b) Guidance Notes on Application for Exemption of Regulated Products.
2. Applicant should complete one application form for each regulated product.
3. Please note that information required for items/parts marked with the symbol (^) in this form may be shown in the Register of Exemptions, which is available for inspection by the public as required by the Ordinance, if the application is approved.
4. Please consult the manufacturer of the regulated product before completing this form.
5. (*For renewal application only*) Applicant should submit updated document(s) [i.e. an updated list of facilities involved in tissue procurement and tissue processing/product manufacturing steps for producing the regulated product to be supplied in Hong Kong, new authorisation letter(s), new declaration letter(s) and updated certificate(s)] required under Section VI (Appendix B) and Section IX.A2-6 and B2(i). For other parts of the application form, only updated information is required if it is not exactly the same as that in the last approved application.
6. Please use separate sheets to provide information if necessary.
7. Keys: @ Please delete as appropriate.
   # Please tick as appropriate.

I, in accordance with the Human Organ Transplant Ordinance (Chapter 465), hereby apply for an exemption of a regulated product from the application of the Ordinance.

I. Type of Application#

☐ New application ☐ Renewal application

Exemption number (HK-RPEx No.): _____

II. Particulars of Applicant

[*For a company applicant, please complete section A under this part; for an individual applicant, please complete section B*.]

☐ A. Company applicant#

1. Company name^: _____
2. Telephone: _____
3. Fax: _____
4. E-mail: _____
5. Address: _____
6. Website^: _____
7. Nature of business/activities (*in relation to the regulated product under application*)#:
   ☐ Manufacturer ☐ Importer/Distributor/Seller
   ☐ Healthcare institution ☐ Others (*Please specify*): _____
8. Particulars of authorised representative (*for making this application on behalf of the applying company*):

   (Given Name) (Surname)

   (a) Name: _____
   (b) Post: _____
   (c) Telephone: _____
   (d) Fax: _____
   (e) E-mail: _____
9. Particulars of contact person (*for post-marketing adverse events*):

   (Given Name) (Surname)

   (a) Name: _____
   (b) Post: _____

(c) Telephone: _____

(d) Mobile (*for after office hours use*): _____

(e) Fax: _____

(f) E-mail: _____

☐ **B. Individual Applicant#**

	(Given Name)	(Surname)
1. Name^:		
2. Telephone:		
3. Mobile:		
4. Fax:		
5. E-mail^:		
6. Correspondence address:		

III. Particulars of Manufacturer^

(*For renewal application only*)

Is the up-to-date information for items 1–7 below **exactly the same as** that in the last approved application?#

☐ Yes ☐ No

Please provide relevant updated information.

[*For new application and renewal application (if the information to be provided under current renewal application is not exactly the same as that provided in the last approved application)*]

1. Name: _____
2. Address of head office:

3. Country: _____
4. Telephone: _____
5. Fax: _____
6. E-mail: _____
7. Website: _____

IV. Particulars of Regulated Product^

(*For renewal application only*)

Is the up-to-date information for items 1-11 below **exactly the same as** that in the last approved application?#

☐ Yes ☐ No

Please provide relevant updated information.

[*For new application and renewal application (if the information to be provided under current renewal application is not exactly the same as that provided in the last approved application)*]

1. Product name:

_____

2. Other product identifiers:

	Catalogue number	Product name	Pack size	Current exemption no. (HK-RPEx No.) (*if any*)
(1)				
(2)				
(3)				
(4)				
(5)				
(6)				
(7)				
(8)				
(9)				
(10)				

3. Type of human organ/tissue from which the product is made#:

☐ Bone ☐ Skin

☐ Others (*Please specify*): _____

4. Source of the donated organ/tissue for making the product#:

☐ Deceased donors ☐ Living donors

5. List of other components or ingredients in the final product (*including residual ingredients during tissue processing*):

6. Product description or specifications:

7. An outline of tissue procurement, tissue processing and product manufacturing steps:

8. Intended uses or indications:

9. Contraindications:

10. Shelf life:

11. Storage conditions:

V. Marketing Approval Status of Regulated Product Outside Hong Kong

(*For renewal application only*)

Is the up-to-date information for items 1-3 below **exactly the same as** that in the last approved application?#

☐ Yes ☐ No

Please provide relevant updated information.

[*For new application and renewal application (if the information to be provided under current renewal application is not exactly the same as that provided in the last approved application)*]

1. Has the regulated product under application been approved for marketing outside Hong Kong?#

   ☐ Yes (*If yes, please complete* ***Appendix A*** *to provide details and submit the supporting documents required under Part IX.A4 for each marketing approval.*)

   ☐ No

2. Has there been any post-marketing remedial action such as recall taken?#

   ☐ Yes ☐ No

   If yes, please provide details:

3. Has the regulated product under application been rejected for marketing outside Hong Kong?#

☐ Yes ☐ No

If yes, please provide details for each place/country, which, where applicable, should include the name of the place/country, name of the regulatory authority, and date and reasons for rejection:

VI. Manufacturing Facilities

(*For new application and renewal application*)

1. Please list all facilities involved in the tissue procurement and tissue processing/product manufacturing steps for producing regulated products to be supplied in Hong Kong at **Appendix B** and provide supporting documents required under Part IX.A5 for each of these facilities.

VII. Import and Local Distribution Chain

(*For renewal application only*)

Is the up-to-date information for the item below **exactly the same as** that in the last approved application?#

☐ Yes ☐ No

Please provide relevant updated information.

[*For new application and renewal application (if the information to be provided under current renewal application is not exactly the same as that provided in the last approved application)*]

1. Is/are there any other party(ies) authorised by the applicant to import, distribute and/or sell the regulated product, if exempted, in Hong Kong?#

   ☐ Yes ☐ No

   If yes, please provide the name, address and contact information, i.e. telephone, fax and e-mail, of all authorised importers, distributors and sellers in Hong Kong:

VIII. Post-Marketing Monitoring and Reporting

(*For renewal application only*)

Is the up-to-date information for items 1-2 below **exactly the same as** that in the last approved application?#

☐ Yes ☐ No

Please provide relevant updated information.

[*For new application and renewal application (if the information to be provided under current renewal application is not exactly the same as that provided in the last approved application)*]

1. Does the manufacturer have a system in place to identify, investigate and report serious adverse events and reactions associated with the manufacturing and clinical use of the regulated product?#

   ☐ Yes ☐ No

2. Does the applicant have a system in place to receive from the manufacturer and report to the Director of Health all of the following incidents, irrespective of whether they occur in Hong Kong or elsewhere?#

   (a) any serious adverse event or reaction;

   (b) issuance of any recall or alert by the manufacturer or relevant regulatory authority irrespective of the classification or severity; and

   (c) any regulatory action taken by relevant regulatory authority

   ☐ Yes ☐ No

IX. Supporting Documents

- *Please label the supporting documents with the corresponding Encl. No., i.e. A1, A2, etc. and submit them along with the completed application form.*
- *For new application, please submit **ALL** required supporting documents, i.e. A1-6, B1-2 and C1-4.*
- *For renewal application, please submit the required supporting documents and the updated documents (if the document to be submitted under current renewal application is not exactly the same as that submitted in the last approved application).*

		(*For renewal application only*) Is the up-to-date document for applicable items below **exactly the same as** that in the last approved application?#	
		YES	NO (*Please submit updated document*)
A.	**Administrative documents**		
A1	A copy of the HKID card or passport of the applicant; or for a company applicant, a copy of the business registration certificate of the company or equivalent document	☐	☐
A2	An authorisation letter from the applying company designating a representative ("authorised representative") to make this application and handle related matters on behalf of the company unless the applicant is an individual applicant or the sole proprietor	**Updated document is required.**	
A3	A letter from the manufacturer to authorise the applicant to apply for an exemption unless the applicant is the manufacturer of the product	**Updated document is required.**	
A4	A documentary proof of marketing approval (*e.g. free sale certificate*) by the regulatory authority in the US, EU, Canada or Australia, or in a country with equivalent product assessment standards	**Updated document is required.**	
A5	A documentary proof of compliance with the Good Tissue Practice (GTP), Good Manufacturing Practice (GMP) or equivalent standard for each of the facilities listed in Appendix B involved in	**Updated document is required.**	

	tissue procurement, tissue processing and/or product manufacturing steps		
A6	A documentary proof from the manufacturer certifying that in accordance with section 7A(3)(b) to (d) of the HOT Ordinance, in obtaining tissues from donors and in processing the tissues for the purpose of producing regulated products to be supplied in Hong Kong: (i) the donor of the tissues concerned has given his consent to the removal of the tissues for the purpose of producing the product without coercion or the offer of inducement, or that the tissues are removed for the therapy of the donor; (ii) no payment has been made, or is intended to be made to that donor for his supplying the tissues from his body; and (iii) all applicable laws of the place where the tissues were obtained or processed have been complied with in obtaining and processing the tissues.	**Updated document is required.**	
B.	**<u>Technical documents</u>**		
B1	Product assessment reports issued by overseas regulatory authorities (*if available*)	☐	☐
B2	A technical dossier to provide the following information: *Organ/tissue donation:* (i) The policy of the manufacturer and the laws of the place/country where human organ/tissue is procured governing obtaining consent and payment to donation	**Updated document is required.**	
	Donor screening and testing: (ii) Criteria for selection or exclusion of donors including a list of examinations and laboratory tests required for donor	☐	☐

	evaluation		
	Evaluation of product safety, quality and efficacy:	☐	☐
	(iii) Overview of the product development		
	(iv) Overview of the manufacturing processes and controls, and other quality aspects relating to the manufacturing of the product	☐	☐
	(v) Summary of non-clinical and clinical studies substantiating the safety and, if applicable, efficacy of the product	☐	☐
C.	**<u>Other supporting documents</u>**		
C1	Photographs of the regulated product (*including the sales pack, inner container or package, and the tissue product itself*) – labels on all sides of the packaging should be clearly shown in the photographs	☐	☐
C2	Labels and package inserts for use in Hong Kong – which should be the same as the ones approved by the overseas regulatory authority	☐	☐
C3	A sample of the outer package of the sales unit of the regulated product, or its drawing, with a designated space for displaying the exemption number (i.e. HK-RPEx No.: XXXXXX)	☐	☐
C4	Description of the track and trace systems of the manufacturer and the applicant that allow tracking of individual products from donors to end users or recipients, and tracing from end users or recipients to donors	☐	☐

X. Declaration by Applicant

☐ I understand that under section 7B(7) of the Human Organ Transplant Ordinance (Chapter 465), any person who, for the purpose of application for exemption of regulated product, provides information that he/she knows to be false or misleading in a material respect, or recklessly provides information that is false or misleading in a material respect commits an offence.

☐ The information provided in this form and the supporting documents is true, complete and accurate to the best of my knowledge and belief.

☐ I have read and understood the Personal Information Collection Statement below. I agree that my personal data and information may be used for the purposes as set out in the Statement.

☐ (*For renewal application only*) I hereby declare that none of the exemption conditions specified in the last approval letter have been violated.

Signature: _____

@(*for and on behalf of the applying company*)

(Given Name) (Surname)

Name: _____

Post: _____

Date: _____ _____

(DD/MM/YYY) Company Chop (*if applicable*)

Personal Information Collection Statement

Purpose of Collection

1. Personal data are provided by applicants to the Department of Health ("DH") for the purpose of application for exemption of a regulated product under the Human Organ Transplant Ordinance (Chapter 465) and related matters. The provision of personal data asked for in the relevant application form is obligatory by virtue of section 7B under the Human Organ Transplant Ordinance.

Classes of Transferees

2. The personal data you provided are mainly for use within DH but they may also be disclosed to other Government bureaux/departments or relevant parties for the purposes mentioned in paragraph 1 above, if required. Apart from this, the data may only be disclosed to parties where you have given consent to such disclosure or where such disclosure is allowed under the Personal Data (Privacy) Ordinance.

Access to Personal Data

3. You have the right of access and correction with respect to your personal data as provided for in Sections 18 and 22 and Principle 6 of Schedule 1 of the Personal Data (Privacy) Ordinance. Your right of access includes the right to obtain a copy of your personal data. A fee may be imposed for complying with a data access request.

Enquiries

4. Enquiries concerning personal data provided, including the making of access and corrections, should be addressed to:

Principal Medical and Health Officer (Health Technology and Advisory)
Department of Health
21/F, Wu Chung House
213 Queen's Road East, Wanchai, Hong Kong
Tel: 2961 8944

Disclaimer

1. The decision of the Director of Health to exempt a regulated product and inclusion of such product into the register of exemptions must not be regarded as an official advice, recommendation or warranty, or a substitute for advice or opinions from appropriate health professionals on using such product for patient treatment.

2. Neither the Department of Health of the Government of Hong Kong Special Administrative Region nor any of its employees or agents shall in any circumstances whatsoever be liable or responsible for any loss or damage whatsoever arising out of or in connection with the use of any exempted regulated products, the use of any of the information contained in or retrieved from the register of exemptions, or any errors or omissions in such register.

Appendix A

Marketing Approval Status of Regulated Product Outside Hong Kong

	Country of approval	**Name of regulatory authority**	**Date of first approval (DD/MM/YYYY)**	**Expiry date of the latest approval (*if any*) (DD/MM/YYYY)**
1.				
2.				
3.				
4.				
5.				
6.				
7.				
8.				
9.				
10.				

Appendix B

List of All Facilities Involved in the Tissue Procurement and Tissue Processing /Product Manufacturing Steps

(a) Tissue procurement

No.	Name	Address	Step(s) involved
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			

Tissue procurement (cont'd)

No.	Name	Address	Step(s) involved
9.			
10.			
11.			
12.			
13.			
14.			
15.			
16.			

(b) Tissue processing/ product manufacturing

No.	Name	Address	Step(s) involved
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			

Tissue processing/ product manufacturing (cont'd)

No.	Name	Address	Step(s) involved
9.			
10.			
11.			
12.			
13.			
14.			
15.			
16.			