APPENDIX 1 DOCUMENTARY REQUIREMENTS FOR CLASS 1 CELL, TISSUE AND GENE THERAPY PRODUCTS NOTIFICATION

1 DOCUMENTARY REQUIREMENTS

Use the relevant application checklists below to assist you in compiling a complete dataset for your application:

- Checklist 1A: Documentary Requirements for Class 1 Cell, Tissue and Gene Therapy Products Notification
- Checklist 1B: Documentary Requirements for Update Product Notification

1.1 File format

Scanned colour copies of the original documents should be submitted, and hard copies of original documents are not required. However, HSA reserves the rights to request for the original or certified true copy of submitted documents if there is any doubt that a submitted scanned document is not an accurate reflection of the original document.

Due to cybersecurity reasons, only the following file types will be accepted. Please ensure all documents are saved in one of these file formats before submitting them in SHARE.

File Types	Extension
PDF files	‘pdf’
Microsoft application files	‘docx’, ‘pptx’, ‘xlsx’
Image files	‘bmp’, ‘gif’, ‘jpeg’, ‘jpg’, ‘png’, ‘tif’, ‘tiff’
Video files	‘avi’, ‘mpeg’, ‘mpg’
OpenOffice files	'ods'
Other file formats	‘csv’, ‘rtf’, ‘txt’

It is important to ensure that HSA officers have access to the content of the files. For protected files, password(s) must be provided as appropriate.

1.2 Language and Translation

All documents submitted to HSA in support of an application must be in English. If the original documents are in a language other than English, a certified or verified translation may be acceptable.

2 APPLICATION SUBMISSION VIA SHARE

2.1 Product List

Multiple Class 1 CTGTP can be grouped in one application, provided they have the same proprietary or brand names from the same product owner. For example, the company can submit three different types or formulations of demineralised bone matrix products under the brand name "XYZ®" below in one application.

Product Name
XYZ® Demineralised Bone Matrix Gel
XYZ® Demineralised Bone Matrix Paste
XYZ® Demineralized Bone Matrix Putty

In this case, all the product information, including product name and product code, should be listed in "Overview-Product List" of SHARE. You may download and use the excel template from SHARE or input them manually.

2.2 Uploading Supporting Documents

Under 'Supporting Documents' module in SHARE, download and use the "Product Notification Supporting Document Template.zip" to facilitate filing of your supporting documents into the respective template folders as shown in the table below:

Template Folders	Supporting documents
1 - Cover Letter	• Cover Letter • Table of Contents
2 - Site Accreditations 2.1 Tissue Procurement	• Certified true copy of a valid certificate of accreditation (e.g., American Association of Blood Banks [AABB], American Association of Tissue Banks [AATB], Eye Bank Association of America [EBAA], Foundation for the Accreditation of Cellular Therapy [FACT], College of American Pathologists [CAP], tissue bank licence) for site where human tissues are sourced
2.2 Manufacturing	• Evidence demonstrating that the establishment is registered with local regulatory agency (e.g., US FDA establishment registration and listing for HCT/Ps [human cells, tissues, and cellular and tissue-based products], Health Canada Cells, Tissues and Organs registration certificate, UK

	Human Tissue Authority) for product manufacturing site
2.3 Sterilisation	• Certified true copy of a valid certificate of accreditation (e.g., ISO 11135, ISO 11137) for site which perform product sterilisation (*where applicable*)
2.4 Others	• Supporting documents (*where applicable*) e.g., ISO 13485 certificate
3 - CoA	• Product release specifications or Certificate of Analysis (CoA)
4 - Package Insert	• Package insert for all products
5 - Product Label	• Product label for all products
6 - Shelf Life CCS	• Product shelf-life and container closure (packaging) information
7 - Others	• Other supporting documents (*where applicable*)

CHECKLIST 1A: DOCUMENTARY REQUIREMENTS FOR CLASS 1 CELL, TISSUE AND GENE THERAPY PRODUCTS NOTIFICATION

- This application checklist should be used to ensure the submission of a complete dataset for product notification.
- Scanned colour copies of the original documents should be submitted, and hard copies of original documents are not required. However, HSA reserves the rights to request for the original or certified true copy of submitted documents if there is any doubt that a submitted scanned document is not an accurate reflection of the original document.

	Documents	
1	Table of Contents	☐
2	Cover letter	☐
3	Certified true copy of a valid certificate of accreditation (e.g., AABB, AATB, EBAA, FACT, CAP, tissue bank licence) for site where human tissues are sourced	☐
4	Evidence demonstrating that the cell or tissue establishment is registered with local regulatory agency (e.g., US FDA establishment registration and listing for HCT/Ps [human cells, tissues, and cellular and tissue-based products], Health Canada Cells, Tissues and Organs registration certificate, UK Human Tissue Authority) for product manufacturing site	☐
5	Certified true copy of a valid certificate of accreditation (e.g., ISO 11135, ISO 11137) for site which perform product sterilisation (*where applicable*)	☐
6	Certified true copy of a valid certificate of accreditation (e.g., ISO 13485) (*where applicable*)	☐
7	Product release specifications or Certificate of Analysis	☐
8	Package insert	☐
9	Product label	☐
10	Product shelf-life and container closure (packaging) information	☐
11	Other supporting documents (*where applicable*)	☐
12	List of Class 1 CTGTP prepared using the excel template from SHARE	☐

CHECKLIST 1B: DOCUMENTARY REQUIREMENTS FOR UPDATE OF PRODUCT NOTIFICATION

- This application checklist should be used to ensure the submission of a complete dataset.
- Scanned colour copies of the original documents should be submitted and hard copies of original documents are not required. However, HSA reserves the rights to request for the original or certified true copy of submitted documents if there is any doubt that a submitted scanned document is not an accurate reflection of the original document.

	Documents	
1	For changes to the accreditation status: • Certified true copy of a valid certificate of accreditation (e.g., AABB, AATB, EBAA, FACT, CAP or tissue bank licence)	☐
2	For change to product label or product shelf-life: • Current product label. • Proposed product label, a clean and annotated version highlighting the changes	☐

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