SUBMISSION GUIDE FOR NEW APPLICATION OF PRODUCT CLASSIFICATION APPLICATION

NO	PRODUCT CLASSIFICATION FORM	EXPLANATION	REQUIREMENT
i.	**New Application Form**	To create a new application form, click **the [Create New Application Form]** button **Please **save** your **Form Serial No. and Security Code** to access your application in future.*	✔
ii.	**Check Application Status / Re-submit Additional Information**	Please enter your Form Serial No. and Security Code in the provided column	✔
iii.	**Type of Application**	Click **New Application** – For new application Click Renewal Application – For renewal application	✔
	SECTION 1 – APPLICANT / ORGANIZATION INFORMATION*		
1.	Applicant's Full Name	Please provide **salutation along with the FULL NAME of applicant** (E.g., Mr. Ali bin Ahmad / Mrs. Chloe Chung) **Applicant name will be stated in the product classification letter.*	✔
2.	Registration of Company's Number (ROC)	Registration of Company's number. MANDATORY to fulfil.	✔
3.	Applicant Company Name	Mandatory to fulfill.	✔
4.	Company Postal Address	Please include the COMPLETE address of the organization including postcode, city and state for official correspondence.	✔
5.	Company Activity (Manufacturer / AR / Distributor / Importer / Others: Please specify)	Please provide company's activity	✔
6.	Email address	Please provide **email address of contact persons** for this application, as they will handle communication, respond to queries, and share information with MDA.	✔
7.	Additional Email Address	Please provide an **additional email address of contact persons** for this application, as they will handle communication, respond to queries, and share information with MDA.	✔
8.	Contact Person	Please provide name person in-charge	✔

9.	Contact Number	Please provide office number and handphone number	✔
10.	General / Overall Product Name	Please provide general / overall product name	✔
	SECTION 2 – MANUFACTURER DETAILS		
11.	Manufacturer Name	Please provide legal manufacturer name (brand owner of the product)	✔
12.	Manufacturer's full site address	Please include the COMPLETE address of the MANUFACTURER including postcode, city and state for official correspondence.	✔
13.	Quality Management System	Please tick the one that relevant to your QMS 1. ISO 13485 (p.1) 2. Or Equivalent QMS Recognised by the Authority	✔
	SECTION 3 – SUPPORTING DOCUMENTS		
14.	Document to upload:		
i.	Product Details Template	Please download the template in the Application Form and upload one you have filled in **System Note:** Download Product Details Template "Click Here" 	✔
ii.	Product Information of intended purpose, mode of action	Please provide product information that contain intended purpose and mode of action	✔
iii.	Product label (indicating product name and manufacturer)	Please provide product label that contain name and manufacturer details	✔
iv.	Product leaflet / brochure / catalogue (contain description, intended use)	Please provide product leaflet / brochure / catalogue that contain description of the product and their intended use *Please make sure to provide for each models/items (if contain different model of the product or many items in the application)	✔
v.	User manual, Instruction for use, packaging Insert	Please provide user manual, instruction for use (IFU) or packaging insert	✔
vi.	Manufacturing Process (For Human Tissue Based Products) (if applicable)	COMPULSORY FOR HUMAN TISSUE BASED PRODUCTS Please provide for each of the items of the human tissue (not general manufacturing process)	✔
vii.	Previous Product Classification Letter – for RENEWAL (if applicable)	COMPULSORY FOR RENEWAL APPLICATION	

		Please provide the previous product classification letter (not withdrawal letter)	
viii.	Declaration of Conformity (if applicable)	Please provide if applicable / relevant	✔
ix.	Quality Management System (QMS) Certificate or Equivalent QMS Recognised by the Authority (if applicable)	Please provide if applicable / relevant	✔
x.	Premarket Approval (if applicable)	Please provide if applicable / relevant	✔
xi.	Others	Please provide if applicable / relevant	✔
	SECTION 4 – ATTESTATION AND DECLARATION		
	I, the undersigned, hereby attest and declare that: * By completing this section, you declare that all information provided in this application is accurate and complete to the best of your knowledge. Please ensure that you have reviewed all details before submitting the form. I, the undersigned, hereby attest and declare that: All the information and attachment provided is true and complete The attached documents contain an accurate account of the information available I will submit relevant documents pertaining to this application whenever requested by MDA I am aware on the consequences of pending of this application if I failed / refused to submit satisfactory document(s)/information as requested. I will be fully responsible for this product.	Please ensure to provide as below: 1. Name of Authorized Person 2. IC Number 3. Designation	✔