SUBMISSION GUIDE FOR NEW APPLICATION OF PRODUCT CLASSIFICATION APPLICATION

NO	PRODUCT CLASSIFICATION FORM	EXPLANATION	REQUIREMENT
	SECTION 1 – APPLICANT/ ORGANIZATION INFORMATION*		
1.	**Salutation** ☐ **Mr.** ☐ **Mrs.** ☐ **Ms** ☐ **Mdm** ☐ **Dr.** ☐ **Prof.** ☐ **Others:_____**	Please Tick the Appropriate Box.	✔
2.	**Applicant's Role** ☐ **Local Manufacturer** ☐ **Authorized Representative** ☐ **Distributor** ☐ **Importer** ☐ **Others:_____**	Role or responsibilities of the applicant's organisation.	✔
3.	**Name of Applicant**	Details of applicant who represents the company and is responsible for this application.	✔
4.	**Designation**		✔
5.	**ROC's Number**	Registration of Company's number. Mandatory to fulfill.	✔
6.	**Contact Number (Include Area/ Country Code)**	Mandatory to fulfill.	✔
	Office no.	At least 1 contact number is mandatory (Telephone / Mobile No)	✔
	Handphone no.	At least 1 contact number is mandatory (Telephone / Mobile No)	✔
	Email address (few email addresses)	**Please fill in few email addresses as in the application form (together with the person responsible who email the application)**	✔
7.	**Name & Address of Organization**	Details of applicant who represents the company and is responsible for this application.	✔

NO	PRODUCT CLASSIFICATION FORM	EXPLANATION	REQUIREMENT
	SECTION 2 – PRODUCT INFORMATION		
	PART A – GENERAL INFORMATION		
1.	**Generic Product Name/ Main Product Name** (List down in Part B if contain more than 1 product)	**Generic Product Name** i. Name of a general product without a brand name ii. (example: Micropipette, Bedpan, Linen) **Main Product Name** i. Name of the main product that consist of few products **share same brand** with **different models** / **identifier number** ii. (example: Micropipette with various model (Model 1, Model 1.0, Model 1.2x. Please fill in only the **main product name –** micropipette) If the product consists of more than 1 product, please list down the rest of the 10 items in the Part B, the **Main Product Name is compulsory to fill in.**	✔
2.	**Description of the Product**	The claim in this section must be proved and supported with **supporting document as declared and provided by the manufacturer (Refer Section 3 – Supporting Documents)**	✔
3.	**Primary Intended Purpose / Indication**		✔
4.	**Primary Mode of Action**		✔
5.	**Manufacturer's Name**	A person who **own or responsible** for the design, production, fabrication, assembly, processing, packaging and labelling of the product. Also, the **brand owner** of the product.	✔
6.	**Manufacturer's Address**		✔
7.	**Country**	Country of the manufacturer	✔
8.	**Classification of the product in country of Origin** ☐ **Medical Device** ☐ **Medicinal Product / Drug**	Please tick the relevance classification of the product in country of Origin (manufacturer's country).	✔

NO	PRODUCT CLASSIFICATION FORM	EXPLANATION	REQUIREMENT
	☐ **Cosmetic Product** ☐ **Traditional Medicine** ☐ **Health Supplement** ☐ **Others (speficy):_____**		
9.	**Classification of the product in reference countries (US, EU, Canada, Australia, Japan)** ☐ **Medical Device** ☐ **Medicinal Product / Drug** ☐ **Cosmetic Product** ☐ **Traditional Medicine** ☐ **Health Supplement** ☐ **Others (speficy):_____**	Please tick the relevance classification of the product in country of reference's countries (The product that has been sold in the reference countries is classified as what type of product?)	✔
	PART B LIST OF PRODUCTS (IF APPLICABLE)		
10.	**i. Name of Product**	To be filled in up if the application is **more than 1 product**. Conditions to be combined together in one application form: i. Products with **same specific intended use** ii. Products shares the **same manufacturer** iii. Products with **same brand** (Maximum: 10 products per application form) **Description & Intended Use of the product must be tally with the product brochure / product catalogue that contain the description & intended use.**	✔
	ii. Description of the Product		✔
	iii. Intended use of the Product		✔
	PART C – INFORMATION ON THE PRODUCT FORMULATION (IF APPLICABLE)		
11.	**i. Ingredient**	**ONLY APPLICABLE** for products that contain chemicals / drugs /active ingredients that need to be declared in this Section.	✔
	ii. Scientific Name		✔
	iii. Ingredient Function		✔
	iv. Quantity		✔

NO	PRODUCT CLASSIFICATION FORM	EXPLANATION	REQUIREMENT
	v. Composition Percentage (%)	****Please refer to the NPRA first if the product contains drug to get classification whether the product is fall under NPRA's jurisdiction or not.**	✔
	SECTION 3 – SUPPORTING DOCUMENTS		
1.	**Product information of intended purpose, mode of action**	Any type of document that contain the product information with details of intended purpose and mode of action of the product	✔
2.	**Product label (indicating product name and manufacturer)**	Product Name and Manufacturer in the product label must the same as stated in the application form	✔
3.	**Product leaflet / brochure / catalogue (contain description, intended use)**	Compulsory to provide which contain description and intended use of the product	✔
4.	**Other information (please specify):____**	Example: User manual, Instruction for use, Packaging Insert, Quality Management System certificate (ISO 13485), ISO 9001, registration certificate in recognize countries (US, EU, Australia, Canada / Japan)	✔
	SECTION 4 – APPLICANT DECLARATION		
1.	**I, the undersigned, on behalf of the company hereby declare that:** **i. All the information and attachment provided is true and complete** **ii. The attached documents contain an accurate account of the information available** **iii. I will submit relevant documents pertaining to this application whenever requested by MDA** **iv. I am aware on the consequences of pending of this application if I failed / refused to submit satisfactory document(s)/information as requested.** **v. I will be fully responsible for this product.**	A sworn declaration which recites duties, responsibilities and obligations of applicant and shall be made by person responsible. Please read, understand and agree to the conditions.	✔