

SUBMISSION GUIDE FOR NEW APPLICATION OF PRODUCT CLASSIFICATION APPLICATION

NO	PRODUCT CLASSIFICATION FORM	EXPLANATION	REQUIREMENT
SECTION 1 – APPLICANT/ ORGANIZATION INFORMATION*			
1.	Salutation <input type="checkbox"/> Mr. <input type="checkbox"/> Mrs. <input type="checkbox"/> Ms <input type="checkbox"/> Mdm <input type="checkbox"/> Dr. <input type="checkbox"/> Prof. <input type="checkbox"/> Others: _____	Please Tick the Appropriate Box.	✓
2.	Applicant's Role <input type="checkbox"/> Local Manufacturer <input type="checkbox"/> Authorized Representative <input type="checkbox"/> Distributor <input type="checkbox"/> Importer <input type="checkbox"/> 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 <input type="checkbox"/> Medical Device <input type="checkbox"/> Medicinal Product / Drug	Please tick the relevance classification of the product in country of Origin (manufacturer’s country).	✓

NO	PRODUCT CLASSIFICATION FORM	EXPLANATION	REQUIREMENT
	<input type="checkbox"/> Cosmetic Product <input type="checkbox"/> Traditional Medicine <input type="checkbox"/> Health Supplement <input type="checkbox"/> Others (specify): _____		
9.	Classification of the product in reference countries (US, EU, Canada, Australia, Japan) <input type="checkbox"/> Medical Device <input type="checkbox"/> Medicinal Product / Drug <input type="checkbox"/> Cosmetic Product <input type="checkbox"/> Traditional Medicine <input type="checkbox"/> Health Supplement <input type="checkbox"/> Others (specify): _____	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.	✓