



Product Classification Application Form

OBJECTIVE :

To determine whether a product is Medical Device or non Medical Device

THE MAIN CLASSIFICATION CRITERIA TO ASSESS MEDICAL DEVICE

The primary intended purpose/Indication

- a) The primary mode of action/the principal mechanism of action by which the claimed effect or purpose of the product is achieved;

Medical Device :

based on function by physical means eg; mechanical action, creation of a physical barrier or replacement or support of organ or body function.
(please refer to Medical device Definition)

Note:

The primary mode of action/the principal mechanism of action may be deduced from the scientific data and the manufacturer's labelling and claims. The claims made for a product, in accordance with its mode of action may represent an important factor for its qualification as a medical device or others.

Section 1 – APPLICANT INFORMATION

Salutation

Mr. Mrs. Mdm Ms Dr. Prof. Others: _____

Name of Applicant

Designation

Contact Number *(Include Area/Country Code)*

FAX Number *(Include Area/Country Code)*

Office tel:

H/p:

E-Mail Address

Manufacturer's Name *

AR/ Distributor/Importer Name *

Address

Address

Country

Country

**mandatory*

Section 2 – PRODUCT INFORMATION

Part A- General Information

Product Name:

**Description of Product:

** Primary intended purpose/Indication:

** Primary mode of action:

Classification of the product in country of Origin:

Medical Device

Medicinal Product/ Drug

Cosmetic Product

Traditional Medicine

Health Supplement

Others (specify): _____

Attach the supporting documents

** (please attach the supporting documents on the description of the product as declared and provided by the manufacturer)

Part B- Information on the Product Formulation (If applicable), Ingredient,Scientific Name,Ingredient Function, Quantity Composition Percentage (%)

(Please provide a complete product formulation in the table below.)

Part B- Information on the Product Formulation (If applicable)				
Ingredient	Scientific Name	Ingredient Function	Quantity	Composition Percentage (%)

Part C- Status of Product in reference countries

Reference countries	Status of product registration	Classification of the product ?
United States	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> Medical Device <input type="checkbox"/> Medicinal product/drug <input type="checkbox"/> Cosmetic product <input type="checkbox"/> Tradisional Medicine <input type="checkbox"/> Health supplement <input type="checkbox"/> Other's _____ Attach the supporting documents:
European Union (EU)	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> Medical Device <input type="checkbox"/> Medicinal product/drug <input type="checkbox"/> Cosmetic product <input type="checkbox"/> Tradisional Medicine <input type="checkbox"/> Health supplement Orther's: _____ Attach the supporting documents:
Australia	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> Medical Device <input type="checkbox"/> Medicinal product/drug <input type="checkbox"/> Cosmetic product <input type="checkbox"/> Tradisional Medicine <input type="checkbox"/> Health supplement Orther's: _____ Attach the supporting documents:
Canada	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> Medical Device <input type="checkbox"/> Medicinal product/drug <input type="checkbox"/> Cosmetic product <input type="checkbox"/> Tradisional Medicine <input type="checkbox"/> Health supplement Orther's: _____ Attach the supporting documents:
Japan	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> Medical Device <input type="checkbox"/> Medicinal product/drug <input type="checkbox"/> Cosmetic product <input type="checkbox"/> Tradisional Medicine <input type="checkbox"/> Health supplement Orther's: _____ Attach the supporting documents:

Note : Please provide full information and state Nil if the product not marketed in that country

** Please attach a separate sheet if space is insufficient*

Section 3 – Supporting Documents

Product Label (indicating product name and manufacturer)- intended purpose, mode of action

Product Leaflet/brochure

Other relevant documents:

Other information (please Specify): _____

Please provide supporting documents as listed below; (Tick the appropriate box)

Section 4 Applicant Declaration

I hereby declare that all statement provided and documents attached in this form are true.

.....
(Applicant's Signature)

Applicant's Name: _____

Applicant's Designation: _____

Date: _____

Email: _____

Contact number : _____

Company Official Attestation

For Official Use Only

Date Received		Ref No application:	
Officer		Unit:	
Remark:			