MEDICAL DEVICE BRANCH
PRE-MARKETING DIVISION
GROUPING ENQUIRY FORM ON MEDICAL DEVICE

E-Form ID: MDG Version No: 3 Effective Date: 21/05/2013

Notes:

a. Please download the latest version of the form at http://www.hsa.gov.sg

b. Please ensure that all mandatory fields (indicated by red boxes) are completed including the declaration in Section E. **Incomplete forms will not be processed and will be rejected.**

c. After completion of the form, click on the "Save" button on the first page or last page of the form to validate (check that all mandatory fields are completed) and save the form.

Please use **UP ARROW KEY / DOWN ARROW KEY** to navigate line by line.

And **PAGE UP and PAGE DOWN** key to navigate page by page.

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Save

SECTION A – PARTICULARS OF ENQUIRER			
Salutation			
Name			
Designation			
Email Address			
NRIC/Passport/Fin No.			
Telephone Country Code	65		
Home Telephone No.		Mobile No.	
Office Telephone No.		Fax No.	

SECTION B – COMPANY INFORMATION			
Company Name			
Block No			
Street Name			
Level		Unit	
Building			
City		State	
Country	SINGAPORE	Postal Code	

SECTION C - PRODUCT DETAILS			
Product Name			
Name of Manufacturer		Country of Manufacturer	SINGAPORE
Proposed Grouping			
Intended Use			
Indications of Use			

SECTION D – REMARKS	
Remarks	

SECTION E - DECLARATION
☐ I declare that the particulars given in this application are true and that the supporting documents enclosed are authentic or true copies.

Please read through **Annex 1** and submit this form to:

hsa_md_info@hsa.gov.sg OR

Medical Device Branch
Pre-Marketing Division
Health Products Regulation Group
Health Sciences Authority,
11 Biopolis Way #11-01 Helios
Singapore 138667

Annex 1

List of Required Product Information

1. **Product Instructions for Use (IFU) or Operator's Manual or Package Insert** that should elucidate the following: (If information is not present in these documents, please provide the following documents):

   - ✓ Primary mode of action of product (i.e. how the product achieves its intended use)
   - ✓ Accessories for use with this medical device
   - ✓ Method of operation/directions for use (i.e. procedure for use of the product)
   - ✓ Technical specifications of the product (e.g. power/frequency of ultrasonic emission)
   - ✓ Physical/chemical composition of product (e.g. concentration of chemical/biological ingredients if any)
   - ✓ Animal or biological tissue that has been incorporated. If none, please state so.

2. **Product Catalogue or Product Labels that represent all product codes**

3. **Summary of regulatory status (e.g. US- 510 (k), EU – CE mark)** of this product in each of the following countries/regions: Australia, Canada, EU, Japan, US.

4. **The List of Configurations for Grouping Enquiry** (Please see paragraph 5 below), with the following information provided:

   - ✓ Product codes of members of proposed FAMILY, constituent-components of proposed SYSTEM reagents or articles of a TEST KIT or CLUSTER, or device products in a GROUP (e.g. A typical total knee arthroplasty SYSTEM consists of the following components: femoral component, patella button, articulating surface, tibial tray, augments and extensions. Product codes for all components must be provided.)
   - ✓ List of differences/variations between each product code, which should cover the following:
     - Composition (e.g. material, incorporation of biological material, etc.)
     - Physical specifications/features (e.g. internal diameter of catheter, number of lumens in catheter, etc.)
       Technical specifications/features (e.g. Ethylene Oxide Steriliser vs H202 Plasma Sterilisers, ICD with Cardiac Resynchronisation Therapy capability, etc.)
     - Design and manufacturing processes (e.g. sterilisation method, etc.)
   - ✓ The common intended purpose for proposed FAMILY, TESKT KIT or SYSTEM. For CLUSTERs please specify the cluster category and testing methodology.
   - ✓ Justification for proposed grouping (e.g. for proposed FAMILY, justify why the variations between members should be considered to be permissible variant).

Important Information

1. Please ensure all the product information listed in **Annex 1** is provided. Failure to provide any of the required information would render the grouping enquiry incomplete. This Branch would not be able to advice on enquiries that are incomplete.

2. Please read through **GN-12: Guidance on Grouping of Medical Devices for Product Registration** before grouping of medical devices.

3. For other medical device related enquiries, please use the Medical Device Branch Product Enquiry form. Product enquiries submitted using Grouping Enquiry Form shall be deemed incomplete for review by this Branch.

4. **GN:12 Guidance on Grouping of Medical Devices for Product Registration** is accessible through the following link:
http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/medical_devices/regulatory_guidances.html

5. The **List of Configurations for Grouping Enquiry** is accessible through the following link:
http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/medical_devices/eservices_forms.html