MEDICAL DEVICE PRE-SUBMISSION CONSULTATION FORM

Version No.: 001
Effective Date: 20 May 2024

INSTRUCTIONS:

1. Please download the latest version of the form at the following url: http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Medical_Devices/Regulatory_Updates/md_initiatives.html

2. The form should be completed in English.

3. Please ensure that all fields are completed. Incomplete forms will not be accepted.

4. Please send the completed form and documents* compiled for pre-market product registration to HSA_MD_Tech@hsa.gov.sg at least **30 days** before the appointment date, with the subject of the email in the following format:
"Medical Device Pre-submission Consultation <Appointment date> Ref: <Booking Reference>"

   **Documentary requirements for pre-market product registration can be found in the following guidance documents:*

   - *GN-15: Guidance on Medical Device Product Registration*
   - *GN-17: Guidance on Preparation of a Product Registration Submission for General Medical Devices using the ASEAN CSDT*
   - *GN-18: Guidance on Preparation of a Product Registration Submission for In-Vitro Diagnostic (IVD) Medical Devices using the ASEAN CSDT*

   The above guidance documents are available at:
   http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Medical_Devices/Overview/Guidances_for_Medical_Device_Registration.html

NOTE TO APPLICANT:

1. This pre-submission consultation is to verify the completeness and appropriateness of the documents. This is not a scientific evaluation of the medical device. The consultation is not meant to be an iterative process and this does not guarantee approval or clearance for pre-market registration.

2. Advice given is based on the information you have provided prior to the meeting. Any changes made to the documents or availability of new information after the meeting may affect the advice given during the appointment.

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Clear Form

BOOKING REFERENCE NO.:		DATE OF APPOINTMENT:	

SECTION A: ATTENDEE PARTICULARS		
NAME OF ATTENDEE		**DESIGNATION / COMPANY NAME**
1.		
2.		
3.		

SECTION B: MEDICAL DEVICE DETAILS	
Have you enquired on this medical device previously?	○ Yes ○ No If yes, please state the reference number of the previous enquiry: _____ *(You may attach the email communications of the previous enquiry, where necessary.)*
Name of Product Owner	
Name of Medical Device	
Medical Device Type	*Please select one:* ○ General Medical Device ○ In-Vitro Diagnostic Medical Device
Proposed Risk Classification	*Please select one:* ○ Class B (Low moderate risk) Based on Rule _____ ○ Class C (Moderate high risk) Based on Rule _____ ○ Class D (High risk) Based on Rule _____ *Reference documents:* • *GN-13: Guidance on the Risk Classification of General Medical Devices* • *GN-14: Guidance on the Risk Classification of In-Vitro Diagnostic Medical Devices*

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Proposed Evaluation Route	*Please select one:* ○ Full ○ Abridged ○ Expedited ○ Immediate (For Class B Medical Devices only) *Reference documents:* • *GN-15: Guidance on Medical Device Product Registration*
Proposed Grouping Type	*Please select one:* ○ SINGLE ○ FAMILY ○ SYSTEM ○ TEST KIT ○ CLUSTER ○ DEVICE SPECIFIC (GN-12-2):_____ *Reference documents:* • *GN-12-1: Guidance on Grouping of Medical Devices for Product Registration – General Grouping Criteria* • *GN-12-2: Guidance on Grouping of Medical devices for Product Registration – Device Specific Grouping Criteria*

SECTION C: DECLARATION

☐ I hereby attest that the information provided is accurate, authentic and complete.