Trial Scheme for Expedited Approval of Class II/III/IV General Medical Device Listing Applications Terms and Conditions

1. The "Trial Scheme for Expedited Approval of Class II/III/IV General Medical Device Listing Applications" ("The Scheme") aims to streamline application and approval process of Class II/III/IV general medical device listing applications if they meet the following criteria:
   a. There are no reported deaths or serious injury associated with the device (local and worldwide)
   b. There are no active recalls, field safety corrective actions or adverse incidents (local and worldwide)
   c. Two or more valid, independent regulatory agencies' approval have been obtained for at least three years
   d. There is at least one substantially equivalent device listed under the Medical Device Administrative Control System (MDACS)
2. The application would be reviewed and approved by the Medical Device Division (MDD) following an expedited approach. The applicant shall respond to any issues within TWO-(2) weeks after receiving the notice from the MDD.
3. Marketing approval documents issued by the following regulatory agencies with appropriate risk classification might be recognized by MDD under the MDACS:
   a. Australia (The Therapeutic Goods Administration)
   b. Canada (Health Canada)
   c. Member countries of the European Union that have implemented the European Council Directives or Regulations on medical devices
   d. Japan (Ministry of Health, Labour and Welfare)
   e. United States of America (U.S. Food and Drug Administration)
4. "Independent regulatory agencies' approval" means the status of a marketing approval document that is not dependent on the approval status of another marketing approval document. The applicant should provide full set of marketing approval document (such as licences, certificates, approval documents, declarations, etc.) to demonstrate validity and independence.
5. Under the Scheme, a "substantial equivalent device" means a device, when compared with the device under application, has the same intended use and either one of the following characteristics.
   a. Same technological characteristics; or
   b. Different technological characteristics supplemented with appropriate clinical or scientific data, if deemed necessary, to demonstrate that the device under application is as safe and effective as the substantial equivalent device
6. Only existing local responsible person (LRP) shall be eligible to participate in the scheme.
7. Before submitting an application under the Scheme, the applicant shall ensure the device under application is covered by the existing scope of documented procedures established by the applicant and recognized by MDD.

8. An application quota of TWO-(2) is assigned to each applicant. Each applicant shall only submit a maximum of TWO-(2) applications each time. When two applications are being processed, MDD will not accept any additional application from the applicant until any one of the two applications is completed.

9. During the application stage, if MDD considers any issues not being effectively addressed to satisfaction after the date specified, or any criteria set under this Scheme is not satisfied, MDD reserves the right to process the application as an ordinary application. In this case, the application is still considered as occupying an application quota under the Scheme. The quota would be available again only when the application is approved. If the application is withdrawn or closed, the application quota will be frozen for ONE-(1) year from the date the application reached MDD.

10. Applicants who wish to submit applications via the Scheme must sign the declaration in Appendix 1, prepare a device profile with format suggested in Appendix 2, and submit to MDD together with application form and dossier. For the preparation of application form and dossier, please refer to Guidance Notes GN-02 (Guidance Notes for Listing Class II/III/IV Medical Devices) for details and related requirements.

11. If there exists inconsistency in the expression of device model(s) and/or product identifier(s) throughout the application dossier, the applicant shall submit additional information demonstrating equivalence between the expressions in device model(s) and/or product identifier(s), in terms of device description and brief specifications. The unavailability of this information may render the application unsuccessful.

12. In case of disputes arising out of the Scheme, the decision of MDD shall be final and conclusive.

13. The MDD reserves the right to amend or change the terms and conditions of the Scheme from time to time. Please refer to the MDD website (Link: www.mdd.gov.hk) for the latest information of the Scheme.

Trial Scheme for Expedited Approval of Class II/III/IV General Medical Device Listing Applications DECLARATION

1. We, _____ *[name and address of the Applicant]*, have read and agreed to the Terms and Conditions of "Trial Scheme for Expedited Approval of Class II/III/IV General Medical Device Listing Applications" and have also read related documents issued by the Medical Device Division (MDD).
2. We declare that, regarding the device in this application:
   a. There are no reported deaths or serious injury (local and worldwide)
   b. There are no active recalls, field safety corrective actions or adverse incidents (local and worldwide)
3. We fully understand and agree that any future changes or additions to the requirements of the Medical Device Administrative Control System (MDACS) can be imposed by the Department of Health without prior notice. We hereby undertake to comply with the latest requirements of the MDACS that are in force.
4. We confirm that we have neither amended any wording in this form, nor otherwise altered the form in any material manner, apart from filling in the appropriate blanks / boxes.

Signature: _____

Name: _____

Position: _____

Contact telephone number: _____

The Applicant (Local Responsible Person): _____

LRP Listing Number: _____

Date: _____ (Company Chop)

Trial Scheme for Expedited Approval of Class II/III/IV General Medical Device Listing Applications Device Profile

(Note: Please provide precise and concise information within 4 pages of A4 papers in font size 10 or larger)

1. Technological Background

(Provide brief information about technological background of the device, intended application and/or technique.)

2. Device Description

(Include general description on device and associated components/accessories needed in order to achieve the intended use. Indicate device and associated components/accessories that are included in this application.)

3. Intended application

(Include intended clinical application, user population, etc.)

4. Material/Substance subjected to control by other local ordinance(s)

(Indicate material(s)/substance(s) in the device that is/are subjected to control by other local ordinance(s).)

5. Image/Photo of the device and components included

(Device and and components included in visible and clear image quality. For any scanned digital colour images, the resolution should be at least 200 dpi. For digital colour photographs, the pixel size should be at least 1024x768.)

6. Substantial equivalent device listed under MDACS

(Provide list of substantial equivalent device(s) listed under MDACS with format suggested below)

Listing No. (HKMD No.)	Make	Model	AMDNS Term	AMDNS Code	Description	Remarks

7. Evidence to support substantial equivalence

(Provide summary comparison information to identify similarities and differences in intended use, indications for use, key specifications and performances. A format is suggested below.)

Comparison	Device under application	Substantial equivalent device
Indications for use	Blood pressure measurement	Blood pressure measurement
Range	Cuff pressure range 0 to 299 mmHg Pulse Rate: 40 to 180 beats/min	Cuff pressure range 0 to 300 mmHg Pulse Rate: 30 to 200 beats/min
…	…	…