Notes for the Expedited Approval Scheme for Medical Device Listing Applications

1. The “Expedited Approval Scheme for Medical Device Listing Applications” (“The Scheme”) aims to streamline application and approval process of Class II/III/IV General Medical Device and Class B/C/D In Vitro Diagnostic 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 events (local and worldwide)
   c. Two or more valid, independent regulatory agencies’ approval

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. Mainland China (National Medical Products Administration)
   b. Australia (The Therapeutic Goods Administration)
   c. Canada (Health Canada)
   d. Member countries of the European Union that have implemented the European Council Directives or Regulations on medical devices
   e. Japan (Ministry of Health, Labour and Welfare)
   f. Singapore (Health Sciences Authority)
   g. South Korea (Ministry of Food and Drug Safety)
   h. 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. Only existing local responsible person (LRP) shall be eligible to participate in the scheme.

6. 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.

7. 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.

8. 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) and GN-06 (Guidance Notes for Listing In Vitro Diagnostic (IVD) Medical Devices) for details and related requirements.

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

10. 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 (www.mdd.gov.hk) for the latest information of the Scheme.