

# The pilot of new requirement on procurement of Medical Devices (MD) by the Department of Health



衛生署

Department of Health

# Purpose

- ▶ To enhance the customer protection for Department of Health (DH) as a buyer of medical devices
- ▶ To ensure the safety, quality and performance of the medical devices procured and to ensure the availability of after-sale (post-market) support from suppliers
- ▶ To strike a balance between value for money purchase while enhancing public safety
- ▶ To raise public awareness of the importance of MD safety and pave way for the introduction of long-term statutory control

# Procurement Requirements

- ▶ MD being procured by DH is preferably be listed under the Medical Device Administrative Control System (MDACS)
- ▶ Quotation: A preference will be given in the quotation for listed MDs under the MDACS
  - ▶ If there are more than one lowest conforming offers offering the same price, preference will be given to the MD offered which are listed under the MDACS.
- ▶ Tender: A technical score will be given in the marking scheme for listed MDs under the MDACS
  - ▶ In assessment criterion under the tender evaluation, marks will be given for MD offered which are preferably be listed under the MDACS.
- ▶ If the proposed MD is accepted by the Government, the Tenderer shall be bound by such offer and shall be deemed to form part of the Contract.
- ▶ For details of the procurement requirements for a particular MD procurement, please refer to the tender documents.

# Submissions to be provided by Supplier for indicating the compliance of the desirable requirements

- ▶ To indicate in the schedule of tender/ quotation whether the Item(s) offered is listed under MDACS
- ▶ To provide HKMD listing number and a valid copy of the Certificate of Listing under MDACS.
  - ▶ For application for listing of Medical Device, please refer to MDD website (<https://www.mdd.gov.hk/en/mdacs/listing-application/medical-device/index.html>)
  - ▶ The vetting and approval of an application for listing a device should normally be completed within *12 weeks* following the submission of the application and all the required supporting information, including labelling samples. (ref.: [Guidance Notes GN-01](#))

# Implementation of the Pilot

- ▶ To allow stakeholders to get familiarized with the new procurement requirement, a pilot of the initiative will be implemented w.e.f 1<sup>st</sup> Oct 2022.
- ▶ Under the pilot, certain MD (including, condoms, lubricants of Class II or above\*, blood glucose meter and blood glucose strip) being procured by the DH will include the new procurement requirement in the quotation/tender exercises that the MD under purchase is preferably be listed under the MDACS.
- ▶ Subject to the experience gained from the pilot, DH will extend to include more MD into the scheme.
- ▶ Traders are encouraged to submit the listing application for their MDs under MDACS as soon as possible.

\* Note: According to the Classification Rules of MDACS.

# Online Medical Device Classification Tools

- ▶ To facilitate traders and public users to determine if a product is a MD, and if so, its associated class. On-line tools have been developed on website <https://www.mdd.gov.hk/en/mdacs/online-tools/index.html>
- ▶ Online Tools  
(For Medical Device Administrative Control System Only)
  - ▶ [Is Your Product A Medical Device?](#)
  - ▶ [General Medical Device Classification Program](#)
  - ▶ [In Vitro Diagnostic Medical Device Classification Program](#)

# Enquiries

- ▶ For general enquiries on the new procurement requirement and application for listing of MDs under MDACS:
  - ▶ Medical Device Division, Department of Health
    - ▶ Tel: 3107 8484
    - ▶ Fax: 3157 1286
    - ▶ Email: [mdd@dh.gov.hk](mailto:mdd@dh.gov.hk)
    - ▶ Website: <https://www.mdd.gov.hk/>
- ▶ For enquiries on the other requirements of a particular MD procurement tender/ quotation:
  - ▶ Please contact the officer(s) of the procurement service as stipulated in the quotation/tender document.