Enhanced Measures on Procurement of Medical Devices (MDs) by the Department of Health

Purpose

- To enhance the protection of public health

- To ensure the safety, quality and performance of the medical devices procured by DH and the availability of after-sale (post-market) support from suppliers

- To further promote and enhance understanding of the public, users and the industry on the Medical Device Administrative Control System (MDACS), with a view to having more MDs listed under MDACS (Listed MDs) to facilitate a smoother transition to the statutory system

Enhanced Measures of Procurement Requirements

- Building on Stage A[1] and Stage B[2] of the new strategy on the procurement of MDs adopted by DH since 21 June 2023 and 1 November 2024 respectively, DH is preparing to further strengthen the strategy in Stage C[3]

[1] Stage A of the new strategy on procurement of medical devices refer to the “first phase of new strategy on procurement of medical devices”

[2] Stage B on the new strategy on procurement of medical devices refer to the “second phase Stage 1 of new strategy on procurement of medical devices”. The strategy requires all AMDs be listed under the MDACS or having a listing application submitted with an assigned application number by the quotation closing time.

[3] Stage C on the new strategy on procurement of medical devices refer to the “second phase Stage 2 of new strategy on procurement of medical devices”

Enhanced Measures of Procurement Requirements

- The enhanced measures of the new strategy in Stage C will be effective from 23rd March 2026

- The essential requirement in Stage C will be further elevated, mandating that **all applicable MDs[4] (AMDs) procured by DH must be Listed MDs**

[4] Applicable MDs refer to Class II/III/IV general medical devices (GMDs) and Class B/C/D in vitro diagnostic medical devices (IVDMDs) according to the classification rules under MDACS

Documentary Evidence to be Provided by Supplier

- Supporting document for Listed MDs
  - Copy of valid Certificate of Listing with HKMD listing number
    - The listing shall be valid on the quotation / tender closing date

Apply Now

- Traders are encouraged to submit applications for their AMDs to be listed under MDACS as soon as possible

- For application for listing of MDs, 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 would normally be completed within *12 weeks* following the submission of the application and all the required supporting information (ref.: Guidance Notes GN-01)

Online Resources under MDACS

- To facilitate traders and public users to determine if a product is an MD, and if so, its associated class under MDACS, on-line tools have been developed on MDD website (https://www.mdd.gov.hk/en/mdacs/online-tools/index.html)

  - Examples of Medical Devices Classification
  - Examples of In Vitro Diagnostic Medical Device Classification
  - Is Your Product A Medical Device?
  - General Medical Device Classification Program
  - In Vitro Diagnostic Medical Device Classification Program

Enquiries

- For enquiries on this new procurement requirement, definition and classification of MDs 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
    - Website: https://www.mdd.gov.hk/
- For enquiries on the procurement requirements of a particular quotation / tender:
  - Please contact the officer(s) of the procurement service as stipulated in the quotation / tender document

Thank you & Stay Tuned with Us!

InstruMedica@DH

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Medical Device Division (MDD)
Department of Health

Room 604, 6/F, 14 Taikoo Wan Road,
Taikoo Shing, HK

(852) 3107 8484

mdd@dh.gov.hk

(852) 3157 1286

www.mdd.gov.hk