

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



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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 the first phase of the new strategy on the procurement of medical devices (MDs) adopted by the Department of Health (DH) since 21 June 2023, DH is preparing to further strengthen the strategy of procurement of MDs for all applicable MDs\* (AMD) in the second phase.
- ▶ The enhanced measures of the new strategy in the second phase will be implemented in two stages:

## Stage 1 (effective from 1st November 2024):

- For procurement under quotation procedures (including minor purchases)

<b>Essential Requirement</b>	An AMD offered shall be - either (a) Listed MDs; or (b) having an application submitted for listing under MDACS with an Application Number issued by MDD of DH before the quotation closing time.
<b>Preference</b>	If there are more than one lowest conforming offers offering the same price, preference will be given to the one with Listed MDs offered.

\*Note: Applicable MDs means MDs classified as within Class II-IV or B-D according to the Classification Rules of medical devices under MDACS.

# Enhanced Measures of Procurement Requirements

## Stage 1 (effective from 1st November 2024):

- For procurement under tender procedures **without** marking scheme

<b>Desirable Requirement</b>	It is a desirable requirement that an AMD offered should be a Listed MD.
<b>Preference</b>	If there are more than one lowest conforming offers offering the same price, preference will be given to the one with Listed MDs offered.

- For procurement under tender procedures **with** marking scheme

<b>Desirable Requirement</b>	It is a desirable requirement that an AMD offered should be a listed MD.
<b>Marking Scheme</b>	A technical score will be given in the technical assessment of the marking scheme for listed MDs.

# Enhanced Measures of Procurement Requirements

Stage 2 (expected implementation in 2025, following a review of Stage 1)

- For procurement under quotation or tender procedures

**Essential  
Requirement**

All AMDs being procured shall be Listed MDs.

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

- ▶ Supporting document for MDs already listed under MDACS:
  - ▶ HKMD listing number and copy of a valid Certificate of Listing under MDACS
  - ▶ The expiry date of the certificate of listing shall be after the tender/quotation closing date
- ▶ Supporting document for applications for listing of MDs under MDACS already submitted to Medical Device Division (MDD) of DH:
  - ▶ A copy of acknowledgement e-mail from MDD with the application number(s) indicated relevant to the offered Item(s)
  - ▶ The time of the acknowledgement e-mail shall be before the tender/quotation closing time

# Apply your application 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, including labelling samples. (ref.: [Guidance Notes GN-01](#))

# Online Resources under MDACS

## ▶ Online Tools

### (For Medical Device Administrative Control System)

To facilitate traders and public users to determine if a product is an 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>

- ▶ [Examples of Medical Devices 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](mailto:mdd@dh.gov.hk)
    - ▶ Website: <https://www.mdd.gov.hk/>
- ▶ For enquiries on the procurement requirements of a particular tender/ quotation:
  - ▶ Please contact the officer(s) of the procurement service as stipulated in the quotation/tender document.