

# The new requirement 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 to ensure the availability of after-sale (post-market) support from suppliers
- ▶ To raise users' awareness of medical devices (MDs) listed under MDACS and to raise the public awareness of the importance of MD safety

# Procurement Requirements

- ▶ All applicable MDs being procured by DH are preferably be listed under Medical Device Administrative Control System (MDACS) w.e.f 21 June 2023.
- ▶ Quotation: A preference will be given in the quotation for listed MDs under MDACS
  - ▶ If there are more than one lowest conforming offers offering the same price, preference will be given to the MDs offered which are listed under MDACS.
- ▶ Tender: A technical score will be given in the marking scheme for listed MDs under MDACS
  - ▶ In assessment criterion under the tender evaluation, marks will be given for MDs 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, 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 copy of valid Certificate of Listing under MDACS.

# Apply your application now

- ▶ Traders are encouraged to submit applications for their MDs 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 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](#))

# Online Resources under MDACS

## ▶ Online Tools

### **(For Medical Device Administrative Control System Only)**

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.