

香港特別行政區政府
衛生署
醫療儀器科

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THE GOVERNMENT OF THE HONG KONG
SPECIAL ADMINISTRATIVE REGION
DEPARTMENT OF HEALTH
MEDICAL DEVICE DIVISION

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By mail and e-mail

4 July 2024

Dr. Lydia LEUNG
Chairlady
Hong Kong Medical and Healthcare Device Industries Association
Room 4, Unit 601
Core Building 1
Hong Kong Science Park
Pak Shek Kok
New Territories
Hong Kong

Dear Dr. LEUNG,

**Department of Health to implement enhanced measures
for the new strategy of procurement of medical devices**

We would like to inform you about the upcoming enhancements to the procurement strategy for all applicable medical devices* (AMDs) in the Department of Health (DH).

As you may be aware, the first phase of the new strategy on the procurement of medical devices (MDs) was adopted by DH since 21st June 2023. Building on this, DH is now preparing to further strengthen the strategy in the second phase, and we are seeking your support in disseminating this information to your fellow members.

The enhanced measures of the new strategy in the second phase will be implemented in two stages:

Stage 1 (effective from 1st November 2024):

- All quotation exercises in DH will require that all AMDs be listed under the Medical Device Administrative Control System (Listed MDs) or have a listing application submitted with an assigned Application Number by the quotation closing time.
- Preference will be granted to Listed MDs offered for all quotations and tenders.

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

- The essential requirement will be further elevated, mandating that all AMDs procured by DH must be Listed MDs.

This strategy aligns with the government's policy to prioritize the safety, quality, and performance of MDs used in public healthcare facilities. We understand that the implementation of these enhanced measures may lead to a surge in listing applications to DH. Therefore, we encourage traders who are interested in submitting bids, quotations, or tenders for the supply of MDs to DH Services to apply for the listing of their AMDs under the Medical Device Administrative Control System (MDACS) as soon as possible.

To introduce MDACS and the new enhanced strategy, DH will be hosting a briefing seminar via ZOOM on 9th August 2024. The details of the briefing seminar has been published on the Medical Device Division's (MDD) website, and we cordially invite you and your members to attend. Please scan the QR code below for details and enrolment of the briefing seminar. Your members can also subscribe to the MDD's mailing list to stay informed about our regular briefing sessions.



We value your continued support in this important initiative. Should you have any questions or require further assistance, please do not hesitate to contact the MDD at 3107 8484 or mdd@dh.gov.hk.

Yours sincerely,

A handwritten signature in black ink, appearing to be 'Addi Chan'.

(Dr. Addi CHAN)
for Director of Health

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

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Resources for listing of MDs under MDACS

Topic	Web link
1. Details of MDACS	https://www.mdd.gov.hk/en/mdacs/index.html
2. Application for listing of MDs under MDACS	https://www.mdd.gov.hk/en/mdacs/listing-application/medical-device/index.html
3. Database of listed MDs	https://www.mdd.gov.hk/en/mdacs/search-database/list-md/index.html
4. Examples of MDs classification	https://www.mdd.gov.hk/en/mdacs/classified-examples-of-medical-devices/index.html
5. On-line tool which helps to differentiate if a product is an MD	https://www.mdd.gov.hk/en/mdacs/online-tools/is-your-product-a-medical-device/index.html
6. On-line tool which helps to identify the class of a General Medical Device	https://www.mdd.gov.hk/en/mdacs/online-tools/general-medical-device-classification-program/index.html
7. On-line tool which helps to identify the class of an In Vitro Diagnostic Medical Device	https://www.mdd.gov.hk/en/mdacs/online-tools/in-vitro-diagnostic-medical-device-classification-/index.html