

Our ref.: (134) in HAHO(S)/A4 III

13 March 2024

Dear Suppliers,

Enhancement of Strategy on Procurement of Medical Devices to be implemented by the Hospital Authority ("HA")

With the view to raising public awareness on the safe use of medical devices (which may include medical equipment and consumables) ("MDs") and to paving the way for long-term statutory regulatory framework for MDs, the Department of Health ("DH") has introduced a voluntary Medical Device Administrative Control System ("MDACS") since 2004, under which a listing system for medical devices and traders as well as a post-market monitoring system are in place to ensure that MDs supplied in Hong Kong can meet the requirements on safety, quality and performance.

Over the past years, the HA supports the Government's objective to safeguard public health, and has already included requirement in tenders/quotations for certain MDs, namely implantable MDs, antimicrobial dressings and guidewires, for tenderers/bidders to commit the submission of their MDs to the DH for listing under the MDACS by a date not later than six months after the contract commencement.

Enhancement of Strategy on Procurement of MDs

To continue our support for the Government's policy direction to enhance protection of public health, HA will further strengthen our procurement strategy in the coming months by (i) extending the above-said MDACS-listing commitment requirement and (ii) giving preference to MDACS-listed MDs in the procurement of all applicable MDs*. For instance, preference will be given to the MDACS-listed MDs when there are more than one lowest conforming offers offering the same price, or HA may assign additional technical scores to MDACS-listed MDs and local responsible persons when marking scheme is used. In addition, tenderers/bidders will have to commit in the tender/quotation documents submitted to HA the submission of their MDs to the DH for listing under the MDACS before a certain date. Tenderers/ bidders may refer to relevant tender/quotation invitation documents issued by HA for details of the related procurement requirements.

Successful tenderers/bidders are required to update the HA the listing record of their MDs under MDACS and/or status of their submissions to DH for listing of their MDs under MDACS from time to time until the MDs are listed. For successful tenderers/bidders who have committed to submit their MDs for listing on the MDACS, please enclose the DH's dedicated "Supplementary Information Sheet" together with other required documents in their listing application submission(s) to the DH (available for download at https://www.mdd.gov.hk/en/useful-information/md-procured-by-ha/index.html). If any tenderers/bidders fail to submit their applications to DH before the committed date provided in their tender / quotation submission or the MDACS listing cannot be completed within the prescribed period stipulated in the contract document, the HA may, without prejudice to HA's other rights and remedies under the contract or by law, in its absolute discretion delete the MDs from the contract or terminate the contract, where appropriate.

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Guidance Notes and Application Forms

Suppliers who are interested in submitting bid/quotation/tender for the supply of MDs to HA are encouraged to apply to the DH for listing of their MDs under the MDACS as soon as possible. The guidance notes and application forms for listing under MDACS are available on DH's website https://www.mdd.gov.hk/en/mdacs/index.html and https://www.mdd.gov.hk/en/mdacs/listing-application/index.html, respectively.

For further information on the MDACS, please contact the DH:

Tel: 3107 8484 Fax: 3157 1286

E-mail: mdd@dh.gov.hk

Yours faithfully,

(Terence CHAM) for Chief Executive Hospital Authority

* Applicable MDs refer to Class II/III/IV general medical devices and Class B/C/D in-vitro diagnostic medical devices according to the classification rules of MDs under MDACS

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