MDACS

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衞生署
Department of Health

Medical Device Administrative Control System (MDACS)

MDACS of the Department of Health (DH) includes a voluntary listing system for medium to high risk medical devices (MDs) (i.e. Class II/III/IV general MDs and Class B/C/D in vitro diagnostic MDs) and a voluntary listing system for traders. MDs listed under MDACS meet the listing requirements on safety, quality and performance.

Promoting the use of MDs listed under MDACS

Healthcare professionals, device users and members of the public are encouraged to make reference to the list of MDs under MDACS in selecting MD. Please refer to the website of Medical Device Division (MDD) of DH for details of the listed MDs and their Local Responsible Person (LRP).

DH is now running a new requirement on the procurement of MDs by the DH. Under the new strategy, certain MDs being purchased for use in the Services of DH should preferably be listed under MDACS. DH will further promote the new strategy to other organisations.

Listing of MDs & Traders

MD traders are welcomed to join MDACS as Listed Local Manufacturers, Listed Distributors and Listed Importers and/or an LRP to apply for the listing of their MDs.

- Browse MDD's website for Guidance Notes
- Complete the application form and, together with the documents required, submit to MDD's office.

On-line tools are available on MDD's website for checking if your product is a MD and its classification.

Act now! Submit your applications now!

Feel free to contact MDD should you have any questions related to MDACS

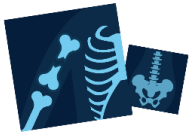
醫療儀器行政管理制度

衞生署的「 醫療儀器行政管理制度」包括自願性中至高風險醫療儀器的表列制度 (即第II、III及IV級一般醫療儀器及第B、C及D級體外診斷醫療儀器)和自願性貿易商的表列制度。已表列的醫療儀器在安全、品質及性能方面均符合「 醫療儀器行政管理制度」的表列要求。

推廣使用已於「醫療儀器行政管理制度」表列的醫療儀器

建議醫護人員、儀器使用者及公眾在選購醫療儀器時，購買已於「 醫療儀器行政管理制度」下表列的醫療儀器。有關於已表列醫療儀器及其本地負責人的詳情，請參閱衞生署醫療儀器科的網頁。

衞生署現正推行新採購規定。在這項新規定下，由衞生署的服務單位所購買的一些指定醫療儀器將優先考慮已表列於「醫療儀器行政管理制度」下的醫療儀器。本署會進一步推廣此新規定至其他機構。



醫療儀器及貿易商表列

歡迎醫療儀器的貿易商申請成為表列本地製造商、表列分銷商及表列進口商及/或本地負責人以提交醫療儀器的表列申請。

- 有關表列的指南可參閱醫療儀器科網頁
- 完成申請表格連同所需文件遞交至醫療儀器科

線上小工具已啟用，以幫助分辨您的產品是否屬於醫療儀器及其分級。

馬上行動！立即遞交您的申請！

歡迎聯絡醫療儀器科作出任何關於「 醫療儀器行政管理制度」的查詢