MDACS

New procurement requirement of the DH for MDs

Online tools

Guidance Notes and Forms

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医疗仪器
行政管理制度

卫生署对医疗仪器
之新采购规定

线上小工具

表列指南
和表格

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衞生署
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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

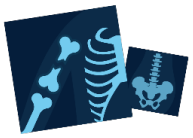
医疗仪器行政管理制度

卫生署的「 医疗仪器行政管理制度」包括自愿性中至高风险医疗仪器的表列制度 (即第II、III及IV级一般医疗仪器及第B、C及D级体外诊断医疗仪器)和自愿性贸易商的表列制度。已表列的医疗仪器在安全、质量及性能方面均符合「 医疗仪器行政管理制度」的表列要求。

推广使用已于「医疗仪器行政管理制度」表列的医疗仪器

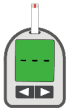
建议医护人员、仪器用户及公众在选购医疗仪器时，购买已于「 医疗仪器行政管理制度」下表列的医疗仪器。有关于已表列医疗仪器及其本地负责人的详情，请参阅卫生署医疗仪器科的网页。

卫生署现正推行新采购规定。在这项新规定下，由卫生署的服务单位所购买的一些指定医疗仪器将优先考虑已表列于「医疗仪器行政管理制度」下的医疗仪器。本署会进一步推广此新规定至其他机构。



医疗仪器及贸易商表列

欢迎医疗仪器的贸易商申请成为表列本地制造商、表列分销商及表列进口商及/或本地负责人以提交医疗仪器的表列申请。



- 有关表列的指南可参阅医疗仪器科网页
- 完成申请表格连同所需文件递交至医疗仪器科

线上小工具已启用，以帮助分辨您的产品是否属于医疗仪器及其分级。

马上行动！立即递交您的申请！

欢迎联络医疗仪器科作出任何关于「 医疗仪器行政管理制度」的查询