

醫療儀器的規管



Regulation of
Medical Devices

Supplementary Notes

for

**Submitting Applications for Listing Medical Devices
under the Medical Device Administrative Control System**

Guidance Notes : GN-01S



中華人民共和國

香港特別行政區政府衛生署

Department of Health

The Government of the Hong Kong Special Administrative Region
of the People's Republic of China

Supplementary Notes for Submitting Applications for Listing Medical Devices under the Medical Device Administrative Control System (MDACS)

1. Submitting the Conformity Assessment Certificates issued by a recognised Conformity Assessment Body (CAB) in the applications for listing medical devices under the MDACS

CABs are required to check and verify the MDACS requirements in accordance with Guidance Notes GN-04: Conformity Assessment Framework and Conformity Assessment Bodies before they issue the Conformity Assessment Certificates for any products. Applicants are also required to prepare all the related documents required by the MDACS including the Essential Principles Conformity Checklist (MD-CCL); Risk Analysis Report/Summary; and Clinical Evaluation Documents before the audits conducted by the CABs. If applicants have already acquired the Conformity Assessment Certificates for their products before submitting the applications, they may elect to submit the Conformity Assessment Certificates in lieu of the Essential Principles Conformity Checklists (MD-CCL); Risk Analysis Reports/Summaries; and Clinical Evaluation Documents for the corresponding products. However, the applicants may be required to submit these documents later if deemed necessary. It is the applicants' obligation to prepare these documents and make them available for checking and verification under the MDACS. The unavailability of these documents may render their applications unsuccessful.

2. Submission of the Form MD-CCL

Applicants are required to prepare the form MD-CCL: Essential Principles Conformity Checklist and attached it to their application forms for listing their medical devices unless the product has acquired marketing approvals from any of the Global Harmonization Task Force (GHTF) founding members on or before 31 December 2004. On the other hand, if they have already prepared the Essential Requirements Checklist in accordance with the EU Medical Device Directives and have sufficient evidence that their products also comply with the MDACS requirements, they may submit the Essential Requirements Checklist and a Essential Principles Declaration of Conformity (see sample at Appendix 1) in lieu of the MD-CCL. It is the applicants' obligation to provide the evidence that the product complies with all the MD-CCL requirements for checking and verification when required. The unavailability of the required evidence may render their applications unsuccessful.

3. Change of “Scope of the MDACS” for the launch of Listing In Vitro diagnostic (IVD) medical device

Sub-Section 3.2.1(vi) of Guidance Notes GN-01 is to be deleted. That is,

~~(vi) *in vitro* diagnostic medical devices.~~

Now, *in vitro* diagnostic medical devices would be included in the scope of MDACS.

4. New or revised entries for definitions & abbreviations

The following new or revised entries are to be found in Section 2 of Guidance Notes GN-01.

Revised entries

2.9 **Central circulatory system** means the major internal blood vessels including the following: pulmonary veins, pulmonary arteries, cardiac veins, coronary arteries, common carotid arteries, cerebral arteries, brachiocephalic artery, aorta, inferior and superior vena cava, ~~renal arteries~~ and common iliac arteries.

2.23 **MDCO** stands for Medical Device Control Office. Address: Room 3101, 31/F., Hopewell Centre, 183 Queen’s Road East, Wanchai, Hong Kong. ~~18/F., Wu Chung House, 213 Queen’s Road East, Wanchai, Hong Kong.~~ Facsimile number: 3157 1286, Telephone number: 2961 8788. (Our Office has been relocated.)

Appendix 1: Sample Essential Principles Declaration of Conformity

<Name of Manufacturer/Local Responsible Person>

<Address of Manufacturer/Local Responsible Person>

<Date>

Medical Device Control Office,
Department of Health,
Room 3101, 31/F., Hopewell Centre,
183 Queen's Road East,
Wan Chai,
Hong Kong

Dear Sirs

Product: <Make> / <Model>

We declare that the captioned product fully complies with all the relevant clauses stipulated under the Essential Principles of Safety and Performance of Medical Devices as required under the Medical Device Administrative Control System. We undertake to provide the necessary evidence to demonstrate the compliance within two weeks upon request.

Yours faithfully

<signature>

<name and title>

<company name>