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醫療儀器的規管

Regulation of Medical Devices

Conformity Assessment Framework and Conformity Assessment Bodies

Guidance Notes: GN-04

中華人民共和國
香港特別行政區政府衞生署
Department of Health
The Government of the Hong Kong Special Administrative Region
of the People's Republic of China

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1. Introduction

1.1 Objectives of the Conformity Assessment Framework

The Conformity Assessment Framework of the Medical Device Administrative Control System (MDACS) is a collection of requirements designed to ensure the safety, efficacy and quality of medical devices so as to satisfy the conformity assessment requirements of listing. The scope of this Framework covers the following:

(i) conformity assessment requirements for the manufacturing of medical devices under the listing system of the MDACS;

(ii) requirements for independent assessment of manufacturers and their products by a Conformity Assessment Body already recognized by the Medical Device Control Office (MDCO); and

(iii) the Conformity Assessment Body (CAB) Recognition Scheme.

1.2 This Document

This document is an adjunct to the Guidance Notes GN-01 giving an overview of the Conformity Assessment Framework under the MDACS. It intends to provide guidance to parties applying for becoming a CAB recognized by the MDCO and manufacturers engaging CAB to conduct conformity assessment. Readers are advised to read the Guidance Notes GN-01 before reading this booklet.

2. Definitions and Abbreviations

Given below are the definitions and abbreviations of some of the terms which will appear in this booklet. Please refer to Section 2 of Guidance Notes GN-01 for the definitions and abbreviations of the terms not included in the following -

2.1 **Audit** means a systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.

2.2 **Conformity Assessment** means the systematic examination of evidence generated and procedures undertaken by the manufacturer, under requirements established by the MDCO, to determine that a medical device is safe and performs as intended by the manufacturer and, therefore, conforms to the

Essential Principles of Safety and Performance of Medical Devices under GN-01.

2.3 **Conformity Assessment Body (CAB)** means a body recognized by the MDCO to engage in the performance of procedures for determining whether the relevant MDACS requirements are fulfilled.

2.4 **Conformity Assessment Body Recognition Scheme or CAB Recognition Scheme (hereby referred as the Scheme)** means the scheme under which CABs are recognized by the MDCO under the MDACS.

2.5 **Conformity Assessment Certificate** means the certificate issued by the CAB to the manufacturer certifying the successful completion of the conformity assessment conducted in accordance with the MDACS requirements.

2.6 **Recognised Standards** means standards deemed to offer the presumption of conformity to specific essential principles of safety and performance. They are either international standards issued by IEC or ISO or equivalent or otherwise national standards in the absence of other relevant international standards.

2.7 **Subcontractors (of a CAB)** means persons or legal entities who contract with the CAB to carry out part of the CAB's conformity assessment tasks.

2.8 **Quality Management System (QMS)** means the organizational structure, responsibilities, procedures, processes and resources for implementing quality management that complies with the standard ISO 13485.

3. Conformity Assessment Requirements

3.1 Conformity assessment is one of the essential requirements under the MDACS to ensure that the medical device conforms to the Essential Principles of Safety and Performance of Medical Devices specified in GN-01.

3.2 A medical device is subject to conformity assessment during both design and manufacture. The manufacturer must demonstrate the compliance to the conformity assessment requirements of the MDACS either through the conformity assessment audits conducted by the CABs or the alternative route specified under Section 5. Besides the conformity assessment, the Local Responsible Person must also satisfy all other MDACS requirements before making the application for listing their devices. Please refer to the related

guidance notes for the detailed requirements for listing Class II/III devices (GN-05) and Class IV devices (GN-02).

4. Principles of Conformity Assessment

4.1 The conformity assessment includes many elements including the Quality Management System, Post Market Surveillance System, Summary Technical Document and Declaration of Conformity. Each medical device shall be allocated to one of four classes using the Classification Rules for Medical Devices under GN-01. Class I devices are the lowest risk devices, Classes II are moderate to low risk, Class III are moderate to high risk and Class IV are the highest risk. The level of scrutiny, evidence requirements that the device meets the *Essential Principles of Safety and Performance of Medical Devices* under GN-01 and the conformity assessment procedures become more robust and demanding for higher risk classes of devices. The detailed requirements of the conformity assessment procedures are stipulated in the Technical Reference TR-001: *Principles of Conformity Assessment for Medical Devices*.

5. Alternative Route of Compliance to the Conformity Assessment Requirements of MDACS

5.1 Besides going through the conformity assessment by a CAB, the manufacturer could alternatively demonstrate that the medical device conforms to the *Essential Principles of Safety and Performance of Medical Devices* specified in GN-01 by presenting approvals, which are currently valid, have been obtained for the medical device to be marketed in one or more of the GHTF founding members namely Australia, Canada, European Union (member countries having implemented the related European Council Directives), Japan and the United States of America. When in doubt, the MDCO may request for details and justifications for the demonstration of the compliance to the *Essential Principles of Safety and Performance of Medical Devices* on top of the marketing approval.

6. Conformity Assessment Body Recognition Scheme

6.1 Introduction

6.1.1 Under the CAB Recognition Scheme, the MDCO will recognize CABs that meet all the requirements in this Section. A CAB must have adequate resources, must be independent, impartial, competent, and

adequately insured, must have a quality management system in place to assure the quality of its services, and must observe its obligations as regards confidentiality. The MDCO will determine whether a body seeking recognition meets these requirements, by way of an initial assessment covering the full scope of the recognition being sought.

6.1.2 A CAB must meet all the requirements on a continuing basis in order to maintain the recognition status. To ensure that it meets those requirements, a CAB is subject to the ongoing scrutiny by the MDCO. The scrutiny includes mainly audits and other forms e.g. an investigation by the MDCO in case of a complaint against the CAB.

6.1.3 No charge will be levied on the applications for recognition under the CAB Recognition Scheme.

6.2 **Requirements of CABs**

6.2.1 **General Requirements**

6.2.1.1 A CAB must be a legal entity having an office in Hong Kong.

6.2.1.2 It shall be a Certification Body accredited for Quality Management System (QMS) by a member of the International Accreditation Forum (IAF).

6.2.1.3 It must have adequate resources to provide conformity assessment services that fall within its scope of recognition. Its resources must be adequate in terms of its financial capability, equipment, staffing, competence and (in some cases) subcontractors.

6.2.1.4 It must, prior to providing its client with conformity assessment services, sign an agreement with the client with the charge and conditions of the services explicitly specified.

6.2.1.5 It cannot subcontract or delegate its responsibility for the conformity asesssment. It is allowed however to subcontract some of the checking, examination and audits that are part of the conformity asessment, but the CAB must

monitor the performance of the subcontractor, review the results of any checking, examination and audits performed by the subcontractor, and determine the outcome of the assessment based on those results and the results of any additional checking, examination and audits performed by itself.

6.2.1.6 It shall make available to the MDCO upon request documentation about its financial situation.

6.2.1.7 It shall issue a certificate to the manufacturers complying with the MDACS conformity assessment requirements. The certificates shall be in Chinese or English or both and shall clearly specify all the makes and models covered.

6.2.2 **Quality Records**

6.2.2.1 The originals or copies of the following documents related to the conformity assessments shall be kept in the Hong Kong Office and be made available to the MDCO for inspection upon request:-

(a) contracts/agreements between the CAB and its client;
(b) contracts/agreements between the CAB and its subcontractors (if any);
(c) records that can demonstrate the competence of the CAB's employees and subcontractors;
(d) conformity assessment reports; and
(e) conformity assessment certificates.

6.2.3 **Disclosure of information to the MDCO**

The CAB must ensure, when contracting with a client/subcontractor in connection with any conformity assessment activities under the MDACS, that the contract will give the CAB permission to disclose to the MDCO any information that the CAB obtains or receives in the course of or in connection with the conformity assessment.

6.2.4 **MDCO Attending Audits**

The CAB must ensure, when contracting with a client/subcontractor in connection with any conformity assessment activities under the MDACS, that the contract will allow staff from the MDCO to attend the audits conducted by the CAB or its subcontractors.

6.3 **Criteria to be met for the Recognition of CAB**

6.3.1 The CAB, its Director and the assessment and verification staff shall not be the designer, manufacturer, supplier, installer, user or LRP of the devices which they inspect, nor the representative of any of these persons. They may not be directly involved in the design, construction, marketing or maintenance of the devices, nor represent the parties engaged in these activities. This in no way precludes the possibility of exchanges of technical information between the manufacturer and the CAB.

6.3.2 The CAB and its staff must carry out the assessment and verification operations with the highest degree of professional integrity and the requisite competence in the field of medical devices and must be free from all pressures and inducements, particularly financial, which might influence their judgment or the results of the inspection, especially from persons or groups of persons with an interest in the results of the verifications. Should the CAB subcontract specific tasks connected with the establishment and verification of the facts, it must first ensure that the subcontractor meets all the applicable MDACS requirements and, in particular any Guidance Notes and Code of Practice related to CAB. The CAB shall keep for the scrutiny of the MDCO the relevant documents assessing the subcontractor's qualifications and the work carried out by the subcontractor related to the MDACS.

6.3.3 The CAB must be able to carry out all the tasks for which it has been recognized, whether these tasks are carried out by the CAB itself or on its responsibility. In particular, it must have the necessary staff and possess the facilities needed to perform properly the technical and administrative tasks entailed in assessment and verification. This presupposes the availability of sufficient scientific staff within the

organisation who possess experience and knowledge sufficient to assess the medical functionality and performance of devices for which it has been recognized, having regard to the MDACS requirements and, in particular, those set out in the *Essential Principles of Safety and Performance of Medical Devices* stipulated in GN-01. It must also have access to the equipment necessary for the verifications required.

6.3.4 The CAB must have:

- ✧ sound vocational training covering all the assessment and verification operations for which the body has been recognized,
- ✧ satisfactory knowledge of the rules on the inspections which they carry out and adequate experience of such inspections,
- ✧ the ability required to draw up the certificates, records and reports to demonstrate that the inspections have been carried out.

6.3.5 The impartiality of the CAB must be guaranteed. The remuneration must not depend on the results of the conformity assessment.

6.3.6 The CAB must take out appropriate liability insurance.

6.3.7 The staff of the CAB are bound to observe professional secrecy with regard to all information gained in the course of their duties.

6.4 Monitoring of CABs

6.4.1 Audits

A CAB is subject to the continual scrutiny of the MDCO and most of the scrutiny is in the form of audits. There are two types of audit, namely the surveillance audit and the witnessed audit as depicted in Table 1. The frequency of the audits will be determined by the MDCO on a need basis.

Table 1 - Surveillance and Witnessed Audits

Type of Audit	Scope
Surveillance Audit	Auditors from the MDCO will perform the following: • To check that appropriate systems and procedures continue to be in place; and • To audit the CAB's operations and activities to verify that the MDACS requirements are complied with and to confirm the continuing effectiveness of the CAB.
Witnessed Audit	While the CAB is conducting an audit on a manufacturer's quality management system, auditors from the MDCO will be present in the audit, checking the CAB's related procedures and its compliance with the MDACS requirements.

6.4.2 **Investigations**

In case of a complaint about or related to a CAB, a product recall or alert, a report of an adverse incident, etc., the MDCO may determine that it is necessary for it to initiate and conduct an investigation. The investigation may involve the MDCO inspecting the facilities and equipment of a CAB, inspecting and checking records being kept by the CAB, interviewing the CAB's staff or subcontractors, and any other appropriate checking by the MDCO, in all of which cases the CAB and its subcontractors must fully cooperate with the MDCO and, to the greatest extent they can, facilitate the conduct of the investigation.

6.5 **Application for recognition as a CAB or change of scope of recognition**

Applications for recognition as a CAB under the MDACS or application for a change in the scope of recognition shall be made to the MDCO on the form CAB-AA (Appendix 1).

6.6 **Appeal against a Decision to Reject An Application Seeking Recognition/Change of scope of Recognition**

Where a decision has been made by the MDCO to reject an application seeking recognition or change of scope of recognition under the CAB Recognition Scheme-

- ✡ the decision shall remain effective unless and until it is set aside in an appeal;
- ✡ an appeal against the decision lies to the CAB Recognition Appeal Board, but it must be lodged by the applicant in writing to the Board, c/o the Medical Device Control Office, within 4 weeks after the applicant is notified of the decision; and
- ✡ the Board's ruling in the appeal shall be final.

6.7 **Cessation or Suspension of Recognition**

Failure of a recognized Conformity Assessment Body to comply with any requirements of the Scheme, or with an instruction issued by the MDCO in connection with an audit or investigation under the Scheme, will entitle the MDCO to cease or suspend recognition of the Conformity Assessment Body under the Scheme.

6.8 **Appeal against a Decision of the MDCO to Cease or Suspend Recognition or against an Instruction of the MDCO**

Where a decision has been made by the MDCO to cease or suspend recognition of a CAB under the Scheme, or an instruction has been issued to a CAB by the MDCO in connection with any audits or investigations under the Scheme-

- ✡ the decision or instruction shall remain effective unless and until it is set aside in an appeal;
- ✡ an appeal against the decision or instruction lies to the CAB Recognition Appeal Board, but it must be lodged by the CAB in writing to the Board, c/o the Medical Device Control Office, within 4 weeks after the CAB is notified of the decision or instruction; and
- ✡ the Board's ruling in the appeal shall be final.

7. Enquiries

Enquiries concerning this booklet and the MDACS should be directed to:

Medical Device Control Office,

Department of Health,

~~18/F, Wu Chung House~~ Rm 3101, 31/F, Hopewell Centre,

~~213 Queen's Road East~~ 183 Queen's Road East,

Wanchai, Hong Kong

Facsimile number: 3157 1286

Telephone number: ~~2961 8788~~ 3107 8484

E-mail address: mdco@dh.gov.hk

Appendix 1

Application for Recognition (or Change of Scope of Recognition)

Under the Conformity Assessment Body Recognition Scheme of the MDACS

(Note: Please use separate sheet if necessary)

Organization Profile				*
1	Name of Organization			
2	Address			
3	Telephone number			
4	Fax number			
5	Website			
6	E-mail address			
7	Certification Manager	Name		
		Position		
		Address		
		Telephone no.		
		Fax no.		
		E-mail address		
8	Local Representative	Name		
		Position		
		Address		
		Telephone no.		
		Fax no.		
		E-mail address		
9	Deputy Local Representative	Name		
		Position		

***** Please number all the documents submitted with this application form and enter the numbers in the respective cells in this column.

Organization Profile				*
		Address		
		Telephone no.		
		Fax no.		
		E-mail address		
10	Organization chart		*Please attach as Attachment (1)*	(1)
11	Business of Organization		☐ assessment and certification of quality systems ☐ product certification ☐ testing and calibration laboratories ☐ consultants ☐ others (please specify) _____	
12	Status of Organization (e.g. body corporate). Please also provide documentation that can identify its status.			
13	Number of employees			
14	Address(es) outside Hong Kong			
15	Has the Organization already been designated or accredited as a Conformity Assessment Body in the field of medical devices or one or more related fields (e.g. EMC) under regulatory systems of other countries (or any other systems, e.g., accreditation by a member of IAF for assessment of quality management system)? If yes, please provide details (including the scope of designation or accreditation) and supporting documents.			

***** Please number all the documents submitted with this application form and enter the numbers in the respective cells in this column.

Organization Profile			*
16	If the Organization is part of a larger organization, please provide details about this larger organization and its structure, indicating in particular its relationship with the Organization.		

Scope of Recognition Being Sought				*
17	A (revised) scope is being sought that is limited to: (Please indicate whether the scope includes type examination.)	Product ranges		

Resources of Organization			*
18	Test facilities. Please state their addresses and test capabilities and give details, including documentary proof, of any accreditation.		
19	In-house experts / specialists / assessors. Please list their names and their areas of competence and provide their CVs.		

***** Please number all the documents submitted with this application form and enter the numbers in the respective cells in this column.

Resources of Organization			*
20	Sub-contractors. Please specify their names, addresses, contact details, and their areas of competence. For individual sub-contract experts / specialists / assessors, please also provide their CVs. For sub-contract test laboratories, please state their testing capabilities and give details, including documentary proof, of any accreditation they have claimed.		
21	Liability insurance taken out by Organization (The insurance must cover its conformity assessment activities) *(Please provide a copy of the insurance certificate if possible)*	Sum Insured : _____ Insurer's name and address: _____ Renewal date: _____	

Further Information for Assessment			*
22	Please submit a copy of the system documentation of the Organization's quality management system (QMS). Detailed work instructions may be excluded from this submission.	*Please attach. Softcopy is acceptable.*	
23	Procedures by which cases of conflicts of interest or potential conflicts of interest are identified and resolved.	*Please indicate where in the QMS documentation these procedures can be located:* _____	
24	Procedures by which the Organization ensures impartiality of its employees and sub-contractors	*Please indicate where in the QMS documentation these procedures can be located:* _____	
25	Procedures for sub-contracting including documented procedures for monitoring subcontractors' performance	*Please indicate where in the QMS documentation these procedures can be located:* _____	

***** Please number all the documents submitted with this application form and enter the numbers in the respective cells in this column.

Further Information for Assessment			*
26	Mechanisms that ensure confidentiality between the Organization and its clients	*Please indicate where in the QMS documentation these procedures can be located:* _____	
27	Procedures according to which conformity assessment within the scope of recognition will be carried out by the Organization (and its sub-contractors if any)	*Please indicate where in the QMS documentation these procedures can be located:* _____	
28	Sample agreements between the Organization and its subcontractors	*Please attach if available.*	

***** Please number all the documents submitted with this application form and enter the numbers in the respective cells in this column.

Important Notes for Applicant

1. In these Notes and in the declaration below-

(i) "the MDACS" stands for "the Medical Device Administrative Control System";

(ii) "the MDCO" stands for "the Medical Device Control Office";

(iii) "the CAB Recognition Scheme" or "the Scheme" means the Conformity Assessment Body Recognition Scheme of the MDACS; and

(iv) "the Government" means the Government of the Hong Kong Special Administrative Region.

2. The current requirements of the CAB Recognition Scheme can be ascertained from this form and other publicly accessible documents issued by the MDCO, including but not limited to the Guidance Notes GN-04.

3. The CAB Recognition Appeal Board referred to in the Guidance Notes GN-04 is comprised of Government officials not directly involved in the administration of the CAB Recognition Scheme.

4. The information (which may include personal data) that the MDCO obtains in confidence from the applicant or other persons in connection with its implementation or management of the MDACS, and in particular in connection with this application, will be retained, processed, and used by and within the Government for the purpose of implementing or managing the MDACS. The Government will also use the information for other purposes, or disclose the information to another party, only if this use or disclosure-

(i) has the consent of the persons who originally provided the information in confidence; or

(ii) is required by the laws of the Hong Kong Special Administrative Region; or

(iii) is in the interest of the public and is lawful.

5. The MDACS including the CAB Recognition Scheme is intended, not as a permanent arrangement, but as a predecessor to a longer term, statutory regulatory system. Where appropriate the planning of the latter system will take account of the experience gained from the implementation of the MDACS. There is, however, no representation or warranty on the part of the Government as regards the similarities or differences between the requirements of the MDACS and those of the longer term system. This longer term system is to be implemented only if the legislation on which it is based is enacted.

Declaration

(Please read the Important Notes above before signing this declaration.)

1. We _____

(name and address of applicant)

declare -

(i) that the information given on this application form and on any separate sheets that supplement this form is true and correct; and

(ii) that the documents that are submitted with this application form are either original documents or true copies of their respective originals.

2. We understand and agree that the requirements of the CAB Recognition Scheme are subject to revisions from time to time. We understand that the updated requirements will be either communicated to us in writing by the MDCO or promulgated in publicly accessible documents issued by the MDCO (e.g. a revised edition of the Guidance Notes GN-04), or both. We undertake that we will abide by the latest requirements of the Scheme and by any instructions that the Department of Heath or the MDCO issues to us pursuant to any audits or investigations under the Scheme.

3. We agree that the Government may publish the following information to the public once this application is successful:

- **our name and contact details;**
- **our status as a recognized Conformity Assessment Body under the Scheme;**
- **our scope of recognition, as well as the date when this scope becomes effective.**

Signature (authorized representative):	
Name:	
Position:	
Telephone no:	
Organization:	
Date:	