GN-04:2024-1(E)

Medical Device Administrative Control System (MDACS)

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
The People's Republic of China

Revision History

Version Number	Date of Revision	Summary of Revisions	Reference Number
0	13 Oct 2006	• First issue of GN-04	GN-04:2006(E)
1	30 Sep 2021	• Update document format; and • Rename of Medical Device Control Office to Medical Device Division	GN-04:2021(E)
2	2 April 2024	• “Make” is replaced with “Manufacturer” • Clause 3.2 and 5.1 have been revised • Update document format	GN-04:2024(E)
3	8 August 2024	• Clause 6.6 (Cessation or Suspension of Recognition) to 6.7 (Appeal) are revised • Clause 6.8 is merged to clause 6.7	GN-04:2024-1(E)

Table of Contents

1. Introduction

1.1 Objectives of the Conformity Assessment Framework

1.1.1 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:

1.1.1.1 conformity assessment requirements for the manufacturing of medical devices under the listing system of the MDACS;

1.1.1.2 requirements for independent assessment of manufacturers and their products by a Conformity Assessment Body already recognized by the Medical Device Division (MDD); and

1.1.1.3 the Conformity Assessment Body (CAB) Recognition Scheme.

1.2 This Document

1.2.1 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 MDD and manufacturers engaging CAB to conduct conformity assessment. Readers are advised to read the Guidance Notes GN-01 before reading this document.

2. Definitions and Abbreviations

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

2.1.1 **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.

2.1.2 **Conformity Assessment** means the systematic examination of evidence generated and procedures undertaken by the manufacturer, under requirements established by the MDD, 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.

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

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

2.1.5 **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.

2.1.6 **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.

2.1.7 **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.

2.1.8 **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 Clause 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 GN-02 and GN-06 for the requirements for the listing of Class II/III/IV general medical devices and Class B/C/D in vitro diagnostic medical devices respectively.

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, the European Union (EU), Japan and the USA. Marketing approvals for the medical device from the Mainland China, South Korea and/or Singapore are also accepted. When in doubt, the MDD 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 MDD will recognize CABs that meet all the requirements in this Clause. 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 MDD 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 MDD. The scrutiny includes mainly audits and other forms e.g. an investigation by the MDD 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 assessment. It is allowed however to subcontract some of the checking, examination and audits that are part of the conformity assessment, 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 MDD 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 manufacturers 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 MDD 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 MDD

6.2.3.1 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 MDD any information that the CAB obtains or receives in the course of or in connection with the conformity assessment.

6.2.4 MDD Attending Audits

6.2.4.1 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 MDD 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 MDD 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:

6.3.4.1 sound vocational training covering all the assessment and verification operations for which the body has been recognized,

6.3.4.2 satisfactory knowledge of the rules on the inspections which they carry out and adequate experience of such inspections,

6.3.4.3 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

6.4.1.1 A CAB is subject to the continual scrutiny of the MDD 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 MDD on a need basis.

Table 1 - Surveillance and Witnessed Audits

Type of Audit	**Scope**
Surveillance Audit	Auditors from the MDD 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 MDD will be present in the audit, checking the CAB's related procedures and its compliance with the MDACS requirements.

6.4.2 Investigations

6.4.2.1 In case of a complaint about or related to a CAB, a product recall or alert, a report of an adverse incident, etc., the MDD may determine that it is necessary for it to initiate and conduct an investigation. The investigation may involve the MDD

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 MDD, in all of which cases the CAB and its subcontractors must fully cooperate with the MDD 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

6.5.1 Applications for recognition as a CAB under the MDACS or application for a change in the scope of recognition shall be made to the MDD on the form CAB-AA.

6.6 Cessation or Suspension of Recognition

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

6.7 Appeal

6.7.1 The CAB may appeal against a decision of the Conformity Assessment Body Recognition Approval Board to reject an application seeking recognition, or to reject the change of scope of Recognition, or to cease or suspend recognition of a CAB within fourteen (14) working days of being notified of the decision.

6.7.2 To appeal, the CAB shall write to the Secretary to Medical Device Administration Appeal Committee, c/o Medical Device Division, stating its grounds of appeal.

6.7.3 The lodging of an appeal against a decision of MDD does not suspend the decision unless MDD decides otherwise;

6.7.4 An appeal lodged after the time limit specified in clause 6.7.1 will not be considered.

6.7.5 The CAB will be notified of the outcome of the appeal application within four (4) weeks following the submission of the appeal application and all the required supporting information (if applicable). The decision of the Medical Device Administration Appeal Committee shall be final.

7. Enquiries

7.1 Enquiries concerning this document and the MDACS should be directed to:

Medical Device Division
Department of Health
Telephone number: 3107 8484
Facsimile number: 3157 1286
Email address: mdd@dh.gov.hk
Website: www.mdd.gov.hk/

7.2 All latest versions of published documents and application forms for MDACS are available at MDD website.