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Medical Device Administrative Control System (MDACS)

Code of Practice for Conformity Assessment Bodies

Code of Practice: COP-02

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

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0	30 Mar 2007	• First issue of COP-02	COP-02:2007(E)
1	30 Sep 2021	• Update document format; and • Rename of Medical Device Control Office to Medical Device Division	COP-02:2021(E)
2	2 April 2024	• “Make” is replaced with “Manufacturer” • Update document format	COP-02:2024(E)
3	8 August 2024	• Section 4, 5, 6 are updated • Update document format	COP-02:2024-1(E)
4	1 September 2026	• Clause 4 (Application for change of scope of recognition) and 7 (Compliance with the Prevention of Bribery Ordinance) are added • Clause 2.1.2, 6.1 and 6.4 are revised • Clause 8.2 is removed • Update document format	COP-02:2026(E)
5	29 October 2026	• The abbreviation for "Global Accreditation Cooperation Incorporated" is revised from "GACI" to "Global ACI"	COP-02:2026(E) (Ed. 0.1)

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1. Introduction

1.1 Conformity assessment is one of the essential requirements under the Medical Device Administrative Control System (MDACS) to ensure that the medical device conforms to the Essential Principles of Safety and Performance of Medical Devices specified in GN-01.

1.2 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*.

2. Requirements of CABs

2.1 General Requirements

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

2.1.2 It shall be a Certification Body accredited for Quality Management System (QMS) by a Global Accreditation Cooperation Incorporated (Global ACI) (previously International Accreditation Forum (IAF)) member signatory.

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.

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.

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.

2.1.6 It shall make available to the MDD upon request documentation about its financial situation.

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.

2.2 Quality Records

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.

2.3 Disclosure of information to the MDD

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.**

2.4 MDD Attending Audits

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**.**

2.5 Obligations

2.5.1 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.

2.5.2 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.

2.5.3 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.

2.5.4 The CAB must have:

(a) Sound vocational training covering all the assessment and verification operations for which the body has been recognized;

(b) satisfactory knowledge of the rules on the inspections which they carry out and adequate experience of such inspections; and

(c) the ability required to draw up the certificates, records and reports to demonstrate that the inspections have been carried out.

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

2.5.6 The CAB must take out appropriate liability insurance.

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

3. Monitoring of CABs

3.1 Audits

3.1.1 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.

3.2 Investigations

3.2.1 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.

4. Application for change of scope of recognition

4.1 Applications for a change in the scope of recognition shall be submitted through the online Medical Device Information System (MDIS) (https://mdis.mdd.gov.hk/).

5. Cessation or Suspension of Recognition

5.1 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. Appeal

6.1 The CAB may appeal against a decision of the Conformity Assessment Body Recognition Approval Board to reject an application seeking recognition, or the conditions imposed to a conditionally approved application, 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.

6.2 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.

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

6.4 An appeal lodged after the time limit specified above will not be considered.

6.5 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. Compliance with the Prevention of Bribery Ordinance

7.1 The CAB and their employees or agents must not offer an advantage as defined in the Prevention of Bribery Ordinance (Cap. 201) to any government officer in connection with their applications or while having dealings of any kind with government departments.

8. Enquiries

8.1 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: https://www.mdd.gov.hk/