COP-03:2026(E) (Ed. 1.0)

Medical Device Administrative Control System (MDACS)

Code of Practice for

Listed Local Manufacturers of Medical Devices

Code of Practice: COP-03

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

Edition Number	Date of Revision	Summary of Revisions	Reference Number
0	13 Aug 2007	• First issue of COP-03	COP-03:2007(E)
1	30 Sep 2021	• Update document format; and • Rename of Medical Device Control Office to Medical Device Division	COP-03:2021(E)
2	2 April 2024	• “Make” is replaced with “Manufacturer” • Update document format	COP-03:2024(E)
3	8 August 2024	• Clause 5.1 to 5.4 are revised • Clause 5.5 is added • Update document format	COP-03:2024-1(E)
4	1 September 2026	• Clause 2.1.10 is moved to Clause 2.11 (Notification of changes) • Clause 2.12 (Renewal of listing), 2.13 (Requirements for inspections), 2.14 and 6 (Compliance with the Prevention of Bribery Ordinance) are added • Clause 2.3, 5.1 and 5.4 are revised • Update document format	COP-03:2026(E)
5	29 October 2026	• Clause 2.12.1 is revised • The abbreviation for "Global Accreditation Cooperation Incorporated" is revised from "GACI" to "Global ACI"	COP-03:2026(E) (Ed. 1.0)

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1. Introduction

1.1 The purpose of this document is to stipulate the requirements that the listed local manufacturers of medical devices have to comply with.

1.2 The primary requirement for the listing of a local manufacturer is that the manufacturer shall establish, document, implement and maintain a quality management system.

1.3 The requirements for a quality management system together with the other conformity assessment elements are intended to ensure that medical devices manufactured, or (as the case may be) designed and manufactured, under the quality management system will be safe and perform as intended by the manufacturer.

1.4 Manufacturers are listed on the List of Local Manufacturers of Medical Devices by their names, Listing Numbers and Listed Scope of Manufacture. The Listed Scope of Manufacture of a listed manufacturer shall not exceed the scope of its quality management system. If the manufacturer manufactures or places on market (whether under its name or not) a product that falls outside its Listed Scope of Manufacture, it shall not claim itself as a listed manufacturer of that product or imply such a claim.

1.5 A listed manufacturer needs to demonstrate its ability to provide medical devices within its Listed Scope of Manufacture that consistently meet customer requirements and the Medical Device Administrative Control System (MDACS) requirements applicable to those medical devices. Manufacturers must demonstrate compliance with this requirement through an established and effectively implemented quality management system that meets the MDACS requirements.

1.6 The scope and complexity of the quality management system that the manufacturer needs to establish is influenced by varying needs, objectives, products provided, processes employed, the size and structure of the organization, and the specific MDACS requirements.

2. Requirements for Listing of Local Manufacturers of Medical Devices

For a manufacturer to be included on the List of Local Manufacturers of Medical Devices, and for as long as it remains on the list, it shall meet the following requirements:

2.1 The manufacturer shall be a local manufacturer, and shall maintain its business registration for its business as a manufacturer of medical devices or for a business of which its business as a manufacturer of medical devices is a part.

2.2 The local manufacturer shall establish, document, implement and maintain a quality management system which complies with the requirements of ISO 13485 or equivalent which also covers all the MDACS requirements.

2.3 The local manufacturer shall demonstrate compliance with ISO 13485 or equivalent by means of certification by a recognized conformity assessment body. Alternatively, it may obtain the certification of its quality management system by a certification body that has been accredited by a Global Accreditation Cooperation Incorporated (Global ACI) (previously International Accreditation Forum (IAF)) member signatory as a body competent in certifying quality management systems.

2.4 Manufacturers of Classes III and IV general medical devices shall have a full quality management system that includes design and development. Manufacturers of Classes I and II general medical devices shall have a quality management system that need not include design and development activities.

2.5 If the manufacturer places any classes of medical devices on the market (in or outside Hong Kong), it shall provide the full list of the devices to the MDD. The list shall include the manufacturers, models and, preferably, the classes and common names or descriptions of the devices. The local manufacturer shall submit an updated list (preferably in soft copy) to the MDD at every 12 month intervals even if there is no change.

2.6 The listing of a local manufacturer or assignment of a Listing Number to the manufacturer does not in any way denote approval or listing of the manufacturer's products. The product labelling shall not include or refer to the local manufacturer's Listing Number or any communications that claim or suggest that the manufacturer has been listed, registered or approved by the Medical Device Division (MDD)/ Department of Health/ HKSAR Government.

2.7 Requirements in Respect of Advertisements, Promotional Materials etc.

2.7.1 Where any document, statement, information, claim, advertisement, promotional material (or any other communication by any means) published to the public, customers or potential customers includes any representation that the manufacturer is a listed local manufacturer, or that the manufacturer is in compliance with the MDACS requirements on listed local manufacturers, it shall at the same time

(a) clearly state the manufacturer's Listed Scope of Manufacture;

(b) include a statement to the effect that the listing of a manufacturer carries no implication that its medical device products are listed, whether or not they are within the Listed Scope of Manufacture; and

(c) clearly state whether any of the medical devices presented in the same article are listed under the MDACS or not.

2.8 Where the representation that the manufacturer is a listed local manufacturer, or that the manufacturer is in compliance with the MDACS requirements on listed local manufacturers, is in writing, then the statements required by 2.7.1(1) to (3) above shall be in the same format (in terms of font size, colour, etc.) as the aforesaid representation.

2.9 The adverse event reporting requirements of the Guidance Notes GN-03 (entitled "Guidance Notes for Adverse Event Reporting by Local Responsible Person") shall be extended to the reporting of adverse events involving any of the products (including Class I products) that fall within the manufacturer's Listed Scope of Manufacture. This extension requires the manufacturer to report such adverse events according to the requirements of the Guidance Notes GN-03 as if it were the Local Responsible Person for those products.

2.10 Upon request of the MDD, the manufacturer shall:

2.10.1 as soon as possible provide the requested records or documents related to the manufacturer's quality management system or products to the MDD for inspection;

2.10.2 allow the MDD to perform audits on the manufacturer and any major contract manufacturers/sterilizers that it employs. The manufacturer must make provision for such audits and provide all the necessary assistance to the MDD to facilitate the conduct of the audits.

2.11 Notification of changes

2.11.1 The manufacturer shall submit Change Application Form for Listed Local Manufacturer through the online Medical Device Information System (MDIS) (https://mdis.mdd.gov.hk/) to notify MDD of any major changes in its quality management system, including any change in respect of the certification of the system e.g. change of the scope of certification, or suspension or withdrawal of certification, not later than 4 weeks after either the change takes effect or the manufacturer has noticed the change, whichever is the earlier.

2.12 Renewal of listing

2.12.1 The Listed Local Manufacturer should apply for renewal of its current inclusion on the List of Distributors (current listing) between 12 weeks and 1 year (inclusive) before the expiry of the three-year validity period. The Listed Local Manufacturer shall submit a Renewal Application through the online Medical Device Information System (MDIS) (https://mdis.mdd.gov.hk/). No renewal application will be accepted outside of this submission window. [For example, if a listing expires on 31 December 2027, the window for submitting renewal application is between 31 December 2026 and 8 October 2027, inclusive]

2.12.2 Applicants shall submit a new application if the local manufacturer listing has expired.

2.13 Requirements for inspections

2.13.1 Upon request by the MDD during the application stage or after the application is approved, the applicant / listed local manufacturer shall:

(a) Make available to the MDD for inspections, as soon as possible, the supply records, documented procedures and other requested documents maintained by them; and

(b) Allow the MDD to perform inspections of the applicant's / listed local manufacturer's premises where business operations are carried out as well as any related storage and/or transportation facilities. The applicant / listed local manufacturer must make provision for such inspections and provide all the necessary assistance to the MDD to facilitate the conduction of the inspections.

2.14 The manufacturer shall also retain the records for a period of time not less than the projected service life of the medical device as defined by the manufacturer, or seven (7) years after the date on which the medical device is manufactured, whichever is longer.

3. Undertaking by the Listed Local Manufacturer of Medical Devices

3.1 A listed local manufacturer shall, on the terms set out in the Undertaking in the Application Form, undertake inter alia to indemnify the Government of the Hong Kong Special Administrative Region against any loss or claim that flows from any of the following: any act or default of the applicant, any defective design of the medical device products of the applicant, any defect in such products, and any information supplied by the listed local manufacturer to the Government.

3.2 It is open to the listed local manufacturer to take out insurance to cover any of the insurable liabilities that it might incur under the Undertaking.

4. Delisting

4.1 A listed local manufacturer may be removed from the List of Local Manufacturers of Medical Devices at the discretion of the Local Manufacturer Listing Approval Board if:

(a) the manufacturer does not comply with the MDACS requirements including but not limited to those in clause 2; or

(b) the manufacturer has been wound up or has ceased to exist; or

(c) the delisting is requested by the manufacturer; or

(d) where the manufacturer is also a Local Responsible Person for its products, it does not comply with any of the MDACS requirements that are imposed on it as a Local Responsible Person; or

(e) the manufacturer does not address or adequately address a situation that gives rise or that might give rise to a hazard of its medical device products or to a public health or public safety concern (whether or not the products fall within its Listed Scope of Manufacture); or

(f) the Local Manufacturer Listing Approval Board considers the delisting is necessary for public health or safety considerations; or

(g) the manufacturer has made a false, unjustified or misleading claim when advertising its medical device products (whether or not the products fall within its Listed Scope of Manufacture).

5. Appeal

5.1 The manufacturer may appeal against a decision of the Local Manufacturer Listing Approval Board to reject an application, or the conditions imposed to a conditionally approved application, or to remove a listed manufacturer from the List of Local Manufacturers within fourteen (14) working days of being notified of the decision.

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

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

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

5.5 The manufacturer 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.

6. Compliance with the Prevention of Bribery Ordinance

6.1 The Listed Local Manufacturers 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.

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