GN-06:2024-2(E)

Medical Device Administrative Control System (MDACS)

Guidance Notes for Listing

Class B, C and D

In Vitro Diagnostic Medical Devices

Guidance Notes:

GN-06

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	1 December 2009	• First issue of Guidance Notes GN-06 (Guidance Notes for Listing In Vitro Diagnostic (IVD) Medical Devices)	GN-06:2009(E)
1	11 July 2011	• Issue of revised Guidance Notes GN-06 (Guidance Notes for Listing In Vitro Diagnostic (IVD) Medical Devices); • Application Form for Listing is updated to MD-IVD (Jul 2011 Edition); • Reference is made to Guidance Notes GN- 00 (Guidance Notes for Definitions and Abbreviations for Medical Device Administrative Control System) for definitions and to Technical Reference TR- 006 (Principles of In Vitro Diagnostic (IVD) Medical Devices Classification) for classification of IVDMDs; and • Appendix III Sample Essential Principles Declaration of Conformity is added	GN-06:2011(E)
2	1 January 2019	• Clause 1 (Introduction) has been updated; • Clause 5.3 (Submission of applications (soft copies)) has been updated; • Clause 7 (Enquiries) has been updated; • Application Form for Listing has been updated to MD-IVD (2019 Edition); and • Appendix II Sample Essential Principles Conformity Checklist has been updated to Essential Principles Conformity Checklist for In Vitro Diagnostic Medical Devices MDIVD- CCL (2019 Edition)	GN-06:2019(E)
3	19 April 2021	• Update document style and layout; • Rename of Medical Device Control Office to Medical Device Division; • Clause 5.3 (Submission of applications) has been updated; • Clause 6 (Guide to application form MD-IVD)	GN-06:2021(E)

Edition Number	Date of Revision	Summary of Revisions	Reference Number
		has been updated; • Appendix I Sample Application Form for Listing has been updated to MD-IVD (2021 Edition); and • Appendix II Sample Essential Principles Conformity Checklist has been updated to Essential Principles Conformity Checklist for In Vitro Diagnostic Medical Devices MDIVD- CCL (2021 Edition)	
3.1	30 August 2021	• Appendix I Sample Application Form for Listing has been updated to MD-IVD (2021 2nd Edition)	GN-06:2021(E)
4	1 January 2022	• Appendix 1 Sample Application Form has been updated to MD-IVD (2022 Edition); • Note A003 and D001 in Clause 6 (Guide to Application Form MD-IVD) has been updated; • Updated document format.	GN-06:2022(E)
5	1 January 2024	• Appendix I Sample Application Form has been removed • Appendix II Sample Essential Principles Conformity Checklist has been removed • Appendix III has been renamed to Appendix I • Modified the scope of accepted Marketing Approvals	GN-06:2024(E)
6	2 April 2024	• “Make” is replaced with “Manufacturer” • Application Form “MD-IVD” is renamed as “MD102” • Modified the scope of accepted Marketing Approvals • Clause 5.5 (Time for vetting and approving an application) is added • Updated document format.	GN-06:2024-1(E)
7	14 June 2024	• Clause 5.1, 5.2, 5.3 and 6.1 are revised • Clause 5.4 and 5.5 are deleted • Updated document format	GN-06:2024-2(E)

Table of Contents

1. Introduction

1.1 This document is to provide guidance to applicants applying for inclusion of the In Vitro Diagnostic Medical Device (IVDMD) into the List of Medical Devices under the Medical Device Administrative Control System (MDACS). It provides detailed information to the applicants for preparing the application submission. Applicants should read this document in conjunction with the "Overview of Medical Device Administrative Control System (Guidance Notes GN-01)" as well as other Guidance Notes and Technical References to have a thorough understanding of the MDACS before making the submission. Applicants applying for listing medical devices other than IVDMD shall make reference to the corresponding Guidance Notes accordingly.

2. Definitions and abbreviations

2.1 Please refer to Guidance Notes GN-00 (Guidance Notes for Definitions and Abbreviations for Medical Device Administrative Control System) for the definitions and abbreviations of the terms that appear in this document.

3. The way to determine the Class of an In Vitro Diagnostic Medical Device (IVDMD)

3.1 Classification of IVDMD

3.1.1 Based on the classification rules of IVDMD of the MDACS (which are in line with those promulgated by the International Medical Device Regulators Forum (IMDRF) (previously Global Harmonization Task Force (GHTF))), the IVDMD are classified into four categories (Classes A to D) according to their risk levels, Class A being the category of the lowest overall risk and Class D the highest. The classification rules for defining the class of an IVDMD are given in Technical Reference TR-006.

3.2 Determining which is an appropriate class of IVDMD by the Classification Rules

3.2.1 The class of IVDMD could be determined by the IVDMD classification rules in Clause 9 of Technical Reference TR-006. The examples given in Table 1 illustrate the application of the rules to determine an appropriate class for an IVDMD.

Table 1 – Examples of IVD medical devices

Devices	IVDMD Class	Classification Rule
Test to detect infection by Hepatitis B (HBV)	D	Rule 1

Test to detect infection by Human Immunodeficiency Virus (HIV)	D	Rule 1
Tests to determine blood groups A, B, O & Rhesus	D	Rule 2
Test to determine Human Leukocyte Antigen (HLA)	C	Rule 2
Testing of Huntington's Disease	C	Rule 3
Blood glucose monitoring	C	Rule 4
Urine test-strips	B	Rule 4
Plain urine cup (an example of specimen receptacle)	A	Rule 5
H. pylori markers	B	Rule 6
Controls that the qualitative and quantitative value assigned by the user and not the manufacturer	B	Rule 7

3.3 Any product for general laboratory use not manufactured, sold or represented for use in specific in vitro diagnostic applications such as centrifuges, fraction collectors are not considered as IVDMDs.

4. Persons eligible to apply for the inclusion of an IVDMD into the list of medical devices

4.1 Only the Local Responsible Person (LRP) in relation to the device can make the application. Please see Clauses 3, 4 and 5 of Guidance Notes GN-01 for the requirements and obligations of an LRP.

5. Application procedures

5.1 Submission of applications

5.1.1 An application for inclusion of a Class B/ C/ D IVDMD into The List of Medical Devices must be made on the Form MD102 through the online Medical Device Information System (MDIS) (https://mdis.mdd.gov.hk/).

5.2 Acknowledgement of Application

5.2.1 On receiving an application the MDIS will acknowledge the receipt via notification to the applicant's registered email. If an applicant does not receive the acknowledgement within two (2) weeks after sending in an application, he may contact the MDD to check if the submission has been received by the MDD.

5.3 Time for vetting and approving an application

5.3.1 The vetting and approval of an application for listing a device should normally be

completed within 12 weeks following the submission of the application and all the required supporting information, including labelling samples.

6. Guide to application form MD102

6.1 The following table explains how to fill in the application form MD102 for Class B, C & D in vitro diagnostic medical devices.

Table 2 – Guidance for completing the application form MD102

Item	Explanation
A001	• Particulars of the manufacturer including the name (in English and/or Chinese), address of head office (in English and/or Chinese), post code, country, contact person, telephone number, fax number, email address and the website shall be provided. The name and address of the manufacturer shall be the same as those stipulated in the marketing approval certificate(s) or MDACS Conformity Assessment Certificate recognized by MDD and ISO 13485 latest edition (or equivalent) certificate provided by the applicant. This information is considered essential for the application.
A002	• If the manufacturer has a registered place of business in Hong Kong, both boxes shall be checked with a copy of the business registration enclosed under index (A1) of the submission folder. The contact person, telephone number, fax number and email address of the Hong Kong office shall be provided.
A003	• The manufacturer shall implement a quality management system and the appropriate box shall be checked to indicate whether it is a full quality management system or a partial system. If it is a partial system, the processes covered shall be specified. The boxes corresponding to the relevant standards shall be checked and the certification body of the quality management system shall be specified. A copy of the ISO 13485 latest edition (or equivalent) certificate shall be enclosed under index (A2) of the submission folder. This information is considered essential for the application.
A004	• The Local Responsible Person (LRP) must either be a legal person incorporated in Hong Kong or a legal person with a registered place of business in Hong Kong e.g. a company, a solicitor firm. • If the manufacturer has a registered place of business in Hong Kong, it could decide either to be the LRP itself or to designate another body to be the LRP. If the manufacturer has no registered place of business in Hong Kong, it must designate another body meeting the requirements of an LRP to make the application.

Item	Explanation
B001	• The details of the LRP including the name (in English and/or Chinese), address (in English and/or Chinese), contact person, position of contact person, telephone numbers, fax number and email address shall be provided. The details must include, among other things, a telephone number that the public may call for enquiries, as well as a mobile telephone number through which the LRP may be contacted by the MDD after office hours. The name and address of the LRP shall be the same as those stipulated in the Hong Kong business registration. This information is considered essential for the application. • A copy of the Hong Kong business registration shall be enclosed under index (B1) of the submission folder.
B002	• The date of designation as the LRP of the device shall be quoted and a copy of the designation letter issued by the manufacturer shall be enclosed under index (B2) of the submission folder. This information is considered essential for the application.
B003	• If the LRP has implemented any quality management system, the system and, if applicable, the certification body shall be specified. A copy of the certificate of the quality management system shall be enclosed under index (B3) of the submission folder if applicable.
B004	• A copy of the documented procedures for Keeping of supply records, Complaint handling, Management of product recalls and field safety notices, Handling of reportable adverse events in Hong Kong, Temperature requirements of IVDMDs during storage and transportation, Maintenance and service arrangements (if applicable) shall be enclosed under index (B4) of the submission folder. This information is considered essential for the application. • In case the applicant already has medical device listed under the MDACS, the LRP number shall be quoted without re-submitting the procedures if the procedures indicated under items (i) to (vi) have been submitted and there is no change to the procedures.
B005	• If the LRP is also an importer and/or distributor of the device, the box shall be checked and the listing number of the importer and/or distributor shall be entered.
B006	• If, to the knowledge of the LRP, the device has already been listed (albeit with another LRP), the box shall be checked with the known existing Listing Number of the device given.

Item	Explanation
C001	• The manufacturer, brand name and model of the IVDMD shall be specified in English and/or Chinese and they will be used as the identifier of the device. This information is considered essential for the application. • For the purpose of this listing, brand name may cover trade name, family name, series name or system name and model may cover other identification details such as model number or product number.
C002	• The appropriate box(es) shall be checked to indicate whether the IVDMD consists of reagent(s), control material(s), calibrator(s) or other components, or any of their combinations. • For each component of an IVDMD, please provide its Asian Medical Device Nomenclature System (AMDNS) term (if an AMDNS term is not available for a particular component, a short description shall be provided) and the corresponding AMDNS code, its identifier(s) (e.g. model number) and a brief description of its intended use. A short description on how the components are used together to achieve the intended purpose of the IVDMD shall also be provided. • When needed, information concerning the IVDMD could be provided on separate sheets enclosed under index (C1) of the submission folder.
C003	• An appropriate AMDNS term of the device together with the corresponding code shall be specified. If there is no applicable AMDNS term, a short description of the device shall be entered. The AMDNS is available at the MDD website for reference by applicants.
C004	• If there is any commonly used description of the device, it shall also be provided.
C005	• The intended use of the device shall be specified in English and/or Chinese and it shall be in agreement with the information provided in the labelling, the marketing approvals obtained from the GHTF founding members and / or certification obtained from a MDACS Conformity Assessment Body recognized by the MDD.
C006	• All accessories for the device shall be specified. An accessory is regarded as an article intended specifically by its manufacturer to be used with the device to enable that device to be used in accordance with its intended purpose. • Please indicate the member/component IVDMD with which each accessory is intended to work together to achieve the intended use. • When needed, the details of all the accessories of an IVDMD including their identifier(s) (e.g. part number) and descriptions could be provided on separate sheets enclosed under index (C1) of the submission folder.
C007	• Please check the appropriate box(es) to indicate the relevant characteristics of the device.

Item	Explanation
	• When needed, details of substance(s) from human or animal origin could be provided on separate sheets enclosed under index (C2) of the submission folder.
C008	• The appropriate box shall be checked to indicate the Class of the IVDMD. • The reasons in details (including the classification rule number and the corresponding description of the rule with which the IVDMD complies) for classifying the device as a Class B/C/D IVDMD shall also be provided. The applicant shall refer to the Technical Reference TR-006 for the Classification Rules for IVDMD.
C009	• All the manufacturing sites for the IVDMD with corresponding scopes under this application shall be specified. All manufacturing sites for the IVDMD shall be provided. Those manufacturing sites of the same manufacturer but not used for the production of the device to be marketed in Hong Kong need not be quoted. Besides, manufacturing sites or sub-contractors not engaged for production of the whole medical device but just a part of or some constituting components of the medical device need not be included. • Copies of ISO 13485 certificates covering the manufacturing sites shall be provided. The name and address of the manufacturing sites shall be the same as those stipulated in the ISO 13485 certificates. Where applicable, information on the manufacturing sites should be provided on separate sheets enclosed under index (C1) of the submission folder.
C010	• A summary of all recalls, suspensions, reportable adverse events, banning of the IVDMD in other countries or post-market surveillance studies shall be provided under index (C2) of the submission folder. • Where there are any recalls in progress, details and current status of the recalls shall be provided. • Where there are any adverse events involving the same IVDMD or a design close to the device reported to overseas regulatory authorities, the following information shall be provided: (i) Dates of the events; (ii) To which regulatory agencies, and when, the events were reported; (iii) Causes of the events; (iv) Number of deaths and the serious injuries in these events; and (v) Corrective and preventive actions taken (including those taken to prevent recurrence of similar events). • Where there is any banning of the IVDMD, the dates, causes and related regulatory agents shall be provided. • Where there are any proactive post-market surveillance studies conducted, details and results of those studies shall be provided.

Item	Explanation
C011	• Specific characteristics of the device shall be indicated by checking the appropriate box(es), including whether the IVDMD is for single use, supplied as sterile product, requires special precautions for disposal, intended to be used/operated by healthcare professionals only or by laypersons, and whether it is for self-use. This information shall be identical to the specifications in the labelling.
C012	• If the IVDMD requires regular servicing, testing, checking or calibration, the appropriate box shall be checked. • Where repairs and servicing are provided by the applicant or other parties appointed, please specify whether all or only some of the services are performed in Hong Kong. • If there is other technical support from the manufacturer, the appropriate box shall be checked. • This information is considered essential for the application.
C013	• If the instructions for use are available in either English, Chinese, or both languages, the appropriate boxes shall be checked. Devices intended for self-use by consumers must be accompanied by instructions for use written in both English and Chinese. • All labelling including instructions for use, manuals, device and package labels (as specified in the Technical Reference TR-005) and Special Listing Information (as specified in the Guidance Notes GN-01) shall be submitted under index (C3) of the submission folder. Where the labelling is provided on the packaging and there is no separate instruction manual, the packaging or clear scanned colour images or digital colour photographs in PDF or JPEG format showing all the labelling information is acceptable as an alternative. However, the LRP may be required to provide a sample of the device for inspection or testing if considered necessary and practicable. • If electronic labelling is included, the corresponding internet linkage shall be provided. • Where the labelling submitted does not include clear images of the device and/or its associated accessories, clear scanned digital colour images or digital colour photographs in PDF or JPEG format showing the front, side and back views of the device and/or its associated accessories should be provided. Device brochures, demonstration video clips and/or animation clips illustrating the usage and applications of the device should be provided as far as possible. • The locations in the submitted samples where the Indications for use; Contraindications against use; Cleansing, disinfection and/or sterilization procedures; User precautions; and Disposal precautions can be found shall be given in the appropriate space.

Item	Explanation
C014	• Please check the appropriate boxes. If the device is subject to the provisions under the Radiation Ordinance (Cap. 303), the Pharmacy and Poisons Ordinance (Cap. 138), the Antibiotics Ordinance (Cap. 137) or the Dangerous Drugs Ordinance (Cap. 134), a copy of the required licence (e.g. Irradiating Apparatus Licence, Wholesale Dealers Licence) shall be enclosed under index (C4) of the submission folder. • (Note: The ordinances listed under this item are not meant to be exhaustive. It is the applicant's responsibility to ensure compliance with other relevant ordinances.)
C015	• If batch verification of the IVDMD is conducted by the Notified Body in accordance with EC Directive 98/79/EC for the IVDMD including in Annex II List A, the appropriate box shall be checked. • If batch verification of the IVDMD is conducted by other arrangement, please provide details and the related supporting document under index (C5) of the submission folder.
C016	• If a MDACS Conformity Assessment Certificate issued by one of the Conformity Assessment Bodies recognized by MDD is available, the appropriate box shall be checked and the Conformity Assessment Body number shall be quoted. A copy of Conformity Assessment Certificate shall be submitted under index (C6) of the submission folder. • (Note: If applicants have already acquired the MDACS Conformity Assessment Certificates for their products, they may submit the Conformity Assessment Certificates in lieu of the Essential Principles Conformity Checklists for In Vitro Diagnostic Medical Devices (MDIVD-CCL); Risk Analysis Reports/Summaries; and Performance 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.)
C017	• If the IVDMD complies with any common specifications, international or national standards, the standards shall be specified in the space provided. • There shall be a risk analysis conducted and the report or the summary shall be provided under index (C7) of the submission folder. This information is considered essential for the application. • Where there are any type tests performed by the manufacturer or any other party, the test reports and certificates shall be provided under index (C7) of the submission folder. • For devices containing biological materials or medicinal substances and/or materials that will come into contact with body tissues and/or fluids, further information (e.g.

Item	Explanation
	biological safety data, biocompatibility report, and certificates of analysis of the materials/substances, etc.) shall be provided upon request. • For devices emitting ionizing radiation, further information (e.g. radiation source and materials for shielding of radiation) shall be provided upon request.
C018	• Performance evaluation is the review of relevant scientific literature and/or the review and assessment of data collected through investigation. It is a process to establish conformity of the device with the pertinent Essential Principles given in "Essential Principles of Safety and Performance of Medical Devices" (Technical Reference TR-004) and to demonstrate that the IVDMD performs as intended by the manufacturer. It establishes the acceptability of risks and side effects when weighed against the intended benefits of the IVDMD. The performance evaluation and its outcome must be documented in a performance evaluation report. • The performance evaluation should include at least the following aspects: diagnostic specificity, diagnostic sensitivity, analytical sensitivity, linearity, stability after first opening, in-use-stability, stability of calibration, precision, potential interfering substance and potential cross-reactivity if they are available. • Please check the appropriate box(es) and enclose the relevant documents under index (C8) of the submission folder.
D001	• If there are approvals for the device to be marketed in any of the GHTF founding members namely Australia, Canada, the European Union (EU), Japan and the USA; Mainland China, South Korea and/or Singapore, the appropriate boxes shall be checked and copy of the approval documents shall be provided under index (D1) of the submission folder. If the IVDMDs are approved for marketing in EU, a copy of the EC Declaration of Conformity shall be submitted together with a copy of the EC certificate(s). To facilitate consideration of the application, applicants are advised to submit all relevant marketing approval certificates as far as possible. • Where any of these approvals have been obtained on or before 31 December 2004, the Essential Principles Conformity Checklist for In Vitro Diagnostic Medical Devices (Form MDIVD-CCL) shall be submitted upon request. Otherwise, the duly completed Essential Principles Conformity Checklist for In Vitro Diagnostic Medical Devices (Form MDIVD-CCL) shall also be provided under index (D1) of the submission folder. • Alternatively, if the applicants could provide the Essential Requirements / General Safety and Performance Requirements Checklist in accordance with relevant EU In Vitro Diagnostic Medical Device directives or regulations 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 (refer to Appendix I of this Guidance Notes for sample) in lieu of the

Item	Explanation
	MDIVD- CCL. • Where no such marketing approval has been obtained, the application will not be processed unless a MDACS Conformity Assessment Certificate issued by one of the Conformity Assessment Bodies (CABs) recognized by the MDD could be provided.

7. Enquiries

7.1 Enquiries concerning this document and the Medical Device Administrative Control System 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

8. References

8.1 Department of Health. Guidance Notes for Definitions and Abbreviations for Medical Device Administrative Control System. Guidance Notes GN-00.

8.2 Department of Health. Overview of the Medical Device Administrative Control System. Guidance Notes GN-01.

8.3 Department of Health. Principles of In Vitro Diagnostic (IVD) Medical Devices Classification. Technical Reference TR-006.

8.4 Department of Health. Essential Principles of Safety and Performance of Medical Devices. Technical Reference TR-004.

8.5 Department of Health. Additional Medical Device Labelling Requirements. Technical Reference TR-005.

9. Appendix I

<Name of Manufacturer/Local Responsible Person>

<Address of Manufacturer/Local Responsible Person>

<Date>

Medical Device Division,
Department of Health.
Room 604, 6/F,
14 Taikoo Wan Road,
Taikoo Shing, Hong Kong

Dear Sirs

Product: < Manufacturer > <Brand Name and Model(s)>

<Product Description>

Manufactured by <Manufacturer>

<Address of Manufacturer>

We declare that the captioned product fully complies with all the relevant clauses stipulated under the Essential Principles of Safety and Performance of In Vitro Diagnostic 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>