醫療儀器的規管

Regulation of Medical Devices

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
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	NIL	• First issue of Guidance Notes GN-06 (Guidance Notes for Listing In Vitro Diagnostic (IVD) Medical Devices) on 1 December 2009.	GN-06:2009(E)
1.0	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)
2.0	1 Jan 2019	• Clause 1 (Introduction) has been updated; • Clause 5.3 (Submission of applications (softcopies)) 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)

Table of Contents

1. Introduction…… 1

2. Definitions and Abbreviations…… 1

3. The Way to Determine the Class of an In Vitro Diagnostic Medical Device (IVDMD)…… 1

4. Persons Eligible to Apply for the Inclusion of an IVDMD into The List of Medical Devices…… 2

5. Application Procedures…… 3

6. Guide to Application Form MD-IVD…… 4

7. Enquiries…… 10

8. References…… 11

9. Appendix I Sample Application Form…… 12

10. Appendix II Sample Essential Principles Conformity Checklist…… 23

11. Appendix III Sample Essential Principles Declaration of Conformity…… 33

1. Introduction

1.1 This booklet 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 booklet 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 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 Section 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

3.2.2 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 Sections 3, 4 and 5 of Guidance Notes GN-01 for the requirements and obligations of an LRP.

5. Application procedures

5.1 Application form

5.1.1 All the application forms and guidance notes related to the MDACS can be obtained from the Medical Device Control Office (MDCO) or downloaded

from the website http://www.mdco.gov.hk. A sample of the Form MD-IVD is given in Appendix I.

5.2 Submission of applications (hardcopies)

5.2.1 An application for inclusion of an IVDMD into The List of Medical Devices must be made on the Form MD-IVD. The completed form shall be submitted together with a submission folder containing copies of all the required documents indexed in accordance with the column "Encl." shown in the application form. *The originals of these documents are only required for validation when requested and they shall not be submitted together with the application form or enclosed in the submission folder.* The application form and all documents submitted including enclosures in the submission folder will not be returned. The submission shall be made by hand or by registered mail to the MDCO.

5.3 Submission of applications (softcopies)

5.3.1 The applicants are encouraged to use softcopies in optical disc format for making the application submission as far as possible. If softcopies are used, only the duly signed Application Form MD-IVD and Essential Principles Conformity Checklist for In Vitro Diagnostic Medical Devices (Form MDIVD-CCL) have to be submitted in paper format. The signed forms, together with duplicated copies of other required documents recorded in two separate CD-ROMs, shall be submitted by hand or by registered mail to the MDCO. Alternatively, an applicant with Hongkong Post e-Cert may submit an application entirely by softcopies (both the completed forms and the other documents in softcopies) to the email address mdco_app@dh.gov.hk of the MDCO, provided the total file size of these softcopies is less than 5MB.

5.4 Acknowledgement of Application

5.4.1 On receiving an application the MDCO will acknowledge the receipt of it. If an applicant does not receive the acknowledgement within two (2) weeks

after sending in an application, he may contact the MDCO to check if the submission has reached the MDCO.

6. Guide to application form MD-IVD

6.1 The following table explains how to fill in the application form MD-IVD. Given in Appendix I is a sample of a completed form MD-IVD. The number under the leftmost column “Note” in the form is used as an identifier for the notes given below (Table 2), while the rightmost column “Encl.” indicates the indexes in the submission folder where the required documents shall be enclosed. Under an item in the form where more than one box is applicable, all the applicable boxes should be selected and checked and all the related documents should be provided. Where under an item both the prompts “in English” and “in Chinese” appear, the entry for that item shall be given in both languages wherever applicable such that they could be recorded accordingly for the reference of the public.

Table 2 – Guidance for completing the application form MD-IVD

Note	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 MDCO and ISO13485 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 ISO13485 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.
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 MDCO 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 managing product recalls and field safety notices, reportable adverse incidents in Hong Kong, transaction records and low temperature requirements of IVDMDs during storage and transportation 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 (iv) have been submitted and there is no change to the procedures. • In addition to the procedures for managing product recalls and field safety notice, reportable adverse incidents in Hong Kong, transaction records and temperature requirements of IVDMDs during storage and transportation, the LRP is required to develop, implement and maintain documented procedures (no matter under the quality management system or not) for complaints handling, and maintenance and service arrangements (if applicable). The LRP must ensure that all these documented procedures are readily available for submission upon request before checking the corresponding box and submitting the application.
B005	• If the LRP is also an importer of the device, the box shall be checked and the listing number of the importer 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.
C001	• The make, 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, make refers to the manufacturer of the device while 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 MDCO website (http://www.mdco.gov.hk) 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 MDCO.
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. • 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 ISO13485 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 ISO13485 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 incidents, 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 incidents 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 incidents; (ii) To which regulatory agencies, and when, the incidents were reported; (iii) Causes of the incidents; (iv) Number of deaths and the serious injuries in these incidents; and (v) Corrective and preventive actions taken (including those taken to prevent recurrence of similar incidents). • 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.
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 (with resolution of at least 200 dpi) or digital colour photographs (with pixel size of at least 1024x768) 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 (with resolution of at least 200 dpi) or digital colour photographs (with pixel size of at least 1024x768) 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.
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 MDCO 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. 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, 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 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 III of this Guidance Notes for sample) in lieu of the 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 MDCO could be provided.

7. Enquiries

7.1 Enquiries concerning this booklet and the Medical Device Administrative Control System should be directed to:

Medical Device Control Office,

Department of Health.

Telephone number: 3107 8484

Facsimile number: 3157 1286

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

Website: www.mdco.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.

Medical Device Control Office
Department of Health
Medical Device Administrative Control System
Application for the Listing of
In Vitro Diagnostic Medical Devices

For official use only

Date Received: _____ *Application No.:* _____ *Officer:* _____

Date Approved/Rejected: _____ *Listing No.:* _____

Tracking Required: _____*Y / N*_____ *PMS Report Required:* ___*Y / N*___

Remarks: _____

_____

_____

Please read this section carefully before completing the form

1. Please note that information included in those parts that are marked with asterisks (*) may be included on The List of Medical Devices and uploaded to the MDCO website if this application is approved. They include (i) the manufacturer's name, address of its head office and its website (A001), (ii) the LRP's name, address in Hong Kong, and contact telephone number for public enquiries (B001), (iii) the make, brand name and model of the device (C001), and (iv) the intended use of the device (C005). The details will normally appear on The List of Medical Devices as they appear on this form. Where under an item both the prompts "in English" and "in Chinese" appear, the entry for that item shall be given in both languages wherever applicable such that they could be accordingly recorded on The List of Medical Devices for the reference of the public.

2. Please check the corresponding boxes in the "Encl." column if any document is enclosed under respective indexes of the submission folder.

3. Please note that the submitted information may be forwarded to third parties (such as but not limited to foreign regulatory authority, notified body or conformity assessment body) for validation purposes.

4. Submitted documents not in Chinese or English shall be accompanied by Chinese or English translations.

<table>
<tr><th>Note</th><th colspan="4">Part A: Particulars of Manufacturer</th><th>Encl.</th></tr>
<tr><td rowspan="6">A001</td><td rowspan="2">Manufacturer's name*</td><td>in English</td><td colspan="2">ABC Medical Ltd.</td><td rowspan="6"></td></tr>
<tr><td>in Chinese</td><td colspan="2">N.A.</td></tr>
<tr><td rowspan="2">Address of Head Office*:</td><td>in English</td><td colspan="2">1324N. Derby Road, Arlington VA, USA</td></tr>
<tr><td>in Chinese</td><td colspan="2">N.A.</td></tr>
<tr><td colspan="3">Post Code: VA 12345-6789</td><td colspan="2">Country: USA</td></tr>
<tr><td colspan="3">Contact person: John Smith</td><td colspan="2">Telephone: 800.332.2354</td></tr>
<tr><td colspan="3">Fax: 703.276.0314</td><td colspan="2">E-mail: jsmith@abcmed.com</td></tr>
<tr><td colspan="5">Website*: http://www.abcmedical.com</td></tr>
<tr><td rowspan="4">A002</td><td colspan="5">☐ Registered place of business in Hong Kong: _____</td><td rowspan="4">(A1)
☐</td></tr>
<tr><td colspan="5">☐ Copy of business registration certificate (with business registration number _____) is enclosed</td></tr>
<tr><td colspan="3">Contact person:</td><td colspan="2">Telephone:</td></tr>
<tr><td colspan="3">Fax:</td><td colspan="2">E-mail:</td></tr>
<tr><td>A003</td><td colspan="5">Established Quality Management System
☒ Full quality management system covering device design, production, and post-production processes
☐ Partial quality management system covering processes: _____ _____
Standards with which the system complies:
☒ ISO13485:2003 or later edition (ISO13485:_____)
☒ System certified by CAB Systems Ltd (certification body), and a copy of the certificate is enclosed</td><td>(A2)
☒</td></tr>
<tr><td>A004</td><td colspan="5">Has the manufacturer designated any Local Responsible Person (LRP)? (N.B. If the manufacturer has no registered place of business in Hong Kong, it must designate a legal person incorporated in Hong Kong or a legal person with a registered place of business in Hong Kong as the LRP.)
☒ Yes ☐ No, manufacturer itself acts as the LRP</td><td></td></tr>
</table>

<table>
<tr><th>Note</th><th colspan="3">Part B: Particulars of Local Responsible Person (LRP)</th><th>Encl.</th></tr>
<tr><td rowspan="8">B001</td><td rowspan="2">LRP's name*</td><td>In English</td><td colspan="2">REAGENT SUPPLIES LTD.</td><td rowspan="8">(B1)
☒</td></tr>
<tr><td>In Chinese</td><td colspan="2">試劑供應有限公司</td></tr>
<tr><td rowspan="2">Address in Hong Kong (Please give the registered place of business, if any)*</td><td>In English</td><td colspan="2">32/F., HOPEWELL CENTRE,
183 QUEEN'S ROAD EAST,
WANCHAI, HONG KONG</td></tr>
<tr><td>In Chinese</td><td colspan="2">香港灣仔皇后大道東183號合和中心32樓</td></tr>
<tr><td colspan="3">Contact person: CHAN TAI-MAN</td><td colspan="2">Telephone: 2800 0000</td></tr>
<tr><td colspan="3">Position: General Manager</td><td colspan="2">E-mail: tchan@reagent.com.hk</td></tr>
<tr><td colspan="3">Contact telephone for public enquiries:*
2000 0000</td><td colspan="2">Fax: 2900 0000</td></tr>
<tr><td colspan="5">Mobile telephone for urgent use (24 hours): 9000 0000</td></tr>
<tr><td colspan="5">☒ Copy of business registration certificate (with business registration number: BR123467) is enclosed</td></tr>
<tr><td>B002</td><td colspan="3">Date designated as LRP by the manufacturer: 30 June 2010
☒ Manufacturer's designation letter is enclosed</td><td>(B2)
☒</td></tr>
<tr><td>B003</td><td colspan="3">Established Quality Management System
☒ ISO9001:2015 or later edition
☐ ISO13485:2003 or later edition ☐ None
☒ System certified by ABC Agency (certification body), and a copy of the certificate is enclosed</td><td>(B3)
☒</td></tr>
<tr><td>B004</td><td colspan="3">Documented Procedures Established and Maintained

☒ The applicant does not have any medical device listed under the Medical Device Administrative Control System
☒ The procedures indicated in items (i) to (iv) below are enclosed; AND
☒ The procedures indicated in items (v) to (vi) have been established and will be submitted upon request.

(i) Keeping of transaction records
(ii) Management of product recalls and field safety notices
(iii) Handling of reportable adverse incidents in Hong Kong
(iv) Temperature requirements of IVDMDs during storage and transportation
(v) Complaints handling
(vi) Maintenance and service arrangements (if applicable)</td><td>(B4)
☒</td></tr>
</table>

	☐ The applicant already has one or more medical device listed under the Medical Device Administrative Control System (**LRP number:** _____) ☐ There is no change to the procedures indicated in items (i) to (iv). *(Please go to B005)*; OR ☐ The procedures indicated in items (i) to (iv) have been updated and enclosed.	
B005	☒ The LRP is also an importer of the device named in Part C Listing No. of Importer: IMP0123456 (if applicable)	
B006	☐ The device named in Part C is currently a listed device (under another LRP), with Listing No. .	

Note	Part C: Particulars of the In Vitro Diagnostic Medical Device (IVDMD)			Encl.
C001	Make*	*in English*	*ABC Medical*	
		in Chinese	*N.A.*	
	Brand Name*	*in English*	*VGOOD*	
		in Chinese	*N.A.*	
	Model*	*in English*	*HCV Antigen Kit version 2.3*	
		in Chinese	*N.A.*	
C002	An IVDMD may include reagents, calibrators, control materials, specimen receptacles, software and related instruments or apparatus or other articles. Please specify all the component(s) of this IVDMD that apply. ☒ Reagent(s) ☒ Control material(s) ☐ Calibrator(s) ☒ Others (Please specify) Probe cleaning solution, matrix cell wash solution and line diluent solution In addition, please provide the additional required information of the IVDMD in the following space, if any. Use separate sheets if required. _____ _____			(C1) ☒
C003	Description of the device: *(Please enter the appropriate AMDNS term. If none of the terms in AMDNS appears appropriate, enter a short description of the device.)* *Reagents, Serology, Virus, Hepatitis C, Core Antigen*			
	AMDNS Code: *19062*			
	Other Codes *(Please enter if known):*			
C004	Other common descriptions of the device: *Hepatitis C antigen determination reagents*			
C005	Intended use of the device*	*in English*	*To detect the presence of Hepatitis C virus antigen in patient serum samples. (Infectious immunology, hepatitis viruses, kit for Hepatitis C virus antigen).*	

		in Chinese	*檢測病人血液樣本中，是否存在丙型肝炎的抗原。*	
C006	Accessories and parts covered by the Marketing Approvals and Essential Principles under Note D001 of Part D. *(Please provide its identifier(s) (e.g. part number) and description). (Use separate sheet if required)*:			(C1) ☒
C007	The device Yes No ☒ ☐ is manufactured from or incorporating human cells/tissues/derivatives ☐ ☒ is manufactured from or incorporating animal cells/tissues/derivatives If the IVDMD contains substance(s) from human or animal origin, please state the location of such descriptions inside the submitted documentation, e.g. the Instruction for Use, or the additional information provided separately. *Information can be found inside the operator's manual (Page 2, section 1)*			(C2) ☒
C008	Class of the IVDMD: ☐ Class B ☐ Class C ☒ Class D Reasons for the classification: *It is a test system of reagents to detect the presence of HCV antigen in serum (Rule 1, Paragraph 2)*			
C009	Manufacturing site(s) *(Use separate sheet if required)*: *(1) 1324N, Derby Road, Arlington, VA 12345-6789, USA* *(2) DEF Medical Inc., 1000 Butler Road, Plymouth Place, PA 12486-1248, USA*			(C1) ☒
C010	History of previous recalls, reportable adverse incidents, banning in other countries or post-market surveillance studies ☐ No ☒ Yes (Please check the appropriate boxes and provide details): ☐ Recalls completed or in progress ☒ Reportable adverse incidents bearing implications to the device ☐ The device banned previously in other countries ☐ Proactive post-market surveillance studies			(C2) ☒

C011	Usage ☐ The IVDMD is for single use ☐ The IVDMD is supplied as sterile product ☐ Disposal of used device or any part thereof (including any used accessories or consumables) requires special precautions. ☐ The device is intended to be used/operated by healthcare professionals only ☐ The device is intended to be used/operated by laypersons ☐ It is intended for self-use	
C012	Repair & Servicing ☒ The IVDMD requires regular servicing/testing/checking/calibration ☐ Repairs and servicing provided by the LRP or appointed party in Hong Kong ☐ All repairs and servicing performed in Hong Kong ☐ Part of the repairs and servicing performed in Hong Kong ☐ Technical support provided by the manufacturer , please specify:_____ _____	
C013	Labelling Requirements Instructions for use are available (Note: Devices intended for self-use by consumers must be accompanied by instructions for use written in both English and Chinese): ☒ in English ☒ in Chinese ☒ A set of copies of device labelling is enclosed ☒ Electronic labelling is available: *http://www.abcmedical.com/hcv_antigen_kit* ☒ Sample of Special Listing Information is enclosed Please indicate where in the labelling the following information is given: (1) Indications for use of the IVDMD: *Pages 4 – 8 of the operator's manual* (2) Contraindications against use of the IVDMD: *Pages 9 – 11 of the operator's manual* (3) Cleaning, disinfection and/or sterilization procedures: *Pages 45 of the operator's manual* (4) User precautions: *Pages 24 – 28 of the operator's manual* (5) Disposal precautions: *N. A.*	(C3) ☒
C014	Licencing Requirements The device is subject to provisions under the following ordinances and a copy of the required licence(s) is/are enclosed: Yes ☐ No ☒ Radiation Ordinance (Cap. 303) Yes ☐ No ☒ Pharmacy and Poisons Ordinance (Cap. 138) Yes ☐ No ☒ Antibiotics Ordinance (Cap. 137) Yes ☐ No ☒ Dangerous Drugs Ordinance (Cap. 134)	(C4) ☐
C015	Verification during IVDMD batch release (for Class D IVDMD only) ☒ Batch Verification by the Notified Body as the IVDMD is included in Annex II List A of European Council Directive 98/79/EC ☐ Others, please provide details _____	(C5) ☒

C016	Conformity Assessment ☐ MDACS Conformity Assessment Certificate issued by Conformity Assessment Bodies recognized by MDCO. MDACS Conformity Assessment Body number: _____	(C6) ☐
C017	Performance and Risk Analysis Specifications, international or national standards with which the device complies: *EN ISO14971:2012, EN 13612:2002 & ISO18113:2009* ☒ Risk analysis conducted: report or summary is enclosed. ☒ Type test performed: report or test certificate is enclosed	(C7) ☒
C018	Performance Evaluation ☒ Performance evaluation report of the IVDMD is enclosed ☐ Demonstration of equivalence to another IVDMD (equivalent IVDMD) or a published method of diagnosis where safety and efficacy of which are well established: ☐ Performance evaluation report of the equivalent IVDMD or a published method of diagnosis and a report of demonstration of equivalence are enclosed ☐ Report demonstrating full equivalence to a well established product is enclosed	(C8) ☒

Note	Part D: Marketing Approvals and Essential Principles	Encl.
D001	Marketing Approvals in Foreign Countries ☒ Approval obtained for the IVDMD to be placed on the market of the following countries: ☐ Australia (The Therapeutic Goods Administration) ☐ Canada (Health Canada) ☒ Member countries of European Union that have implemented relevant EU directives or regulations and a copy of the EC Declaration of Conformity is enclosed ☐ Japan (Ministry of Health, Labour and Welfare) ☒ United States of America (U.S. Food and Drug Administration) ☐ Earliest approval obtained on or before 31 December 2004 ☒ Earliest approval obtained on or after 1 January 2005 ☒ Essential Principles Conformity Checklist for In Vitro Diagnostic Medical Devices (MDIVD-CCL) is attached; OR ☐ Essential Requirements Checklist in accordance with the EU In Vitro Diagnostic Medical Device Directive and Essential Principles Declaration of Conformity are enclosed	(D1) ☒

DECLARATION

1. To the maximum extent permitted by law and in consideration of the Department of Health of the Government of the Hong Kong Special Administrative Region ("the Government") processing our application under the MDACS, we, *REAGENT SUPPLIES LTD., 32/F., HOPEWELL CENTRE, 183 QUEEN'S ROAD EAST, WANCHAI, HONG KONG_[name and address of the Applicant]*, agree to exempt, relieve, exonerate, indemnify and hold harmless, and to keep indemnified and harmless, as the case may be, the Government from and/or against any and all losses, claims, demands and proceedings (including but not limited to all costs, charges and expenses) whatsoever and howsoever suffered or incurred by, or made or issued against, the Government, as the case may be, by any third party in respect of any loss of or damage to any property or injury to or death of any person arising out of and/or relating and/or incidental to:
   a. any act, neglect or default on our part or on the part of our employees or agents;
   b. any defect in the design, material, workmanship or installation of our device or devices;
   c. any use of any of the information supplied by us or our employees or agents in relation to our device or devices whether or not such information has materially contributed to the inclusion of the device or devices on the List of Medical Devices and whether or not such information is misleading, wrong or inaccurate.
2. We also agree and accept that:
   a. the Government, its employees or agents shall not be liable to us for any loss of or damage to property caused by the act, default or neglect of the Government or its employees or agents in the processing of our application, the inclusion or non-inclusion of any of our information and/or device or devices on the List of Medical Devices or any cause whatsoever arising out of or in connection with the implementation and management of the MDACS;
   b. neither the Government nor any of its employees or agents makes any representation, statement, warranty or guarantee, express or implied, that the devices (including any spares or replacement parts) listed or considered for listing under the MDACS, whether or not they are included in the List of Medical Devices, are of merchantable quality or are fit for the purposes for which they are commonly bought and that the spares or replacement parts are readily available.
3. We confirm that the information contained in our application is true and correct and that our device or devices (including any spares or replacement parts) are of merchantable quality and are fit for the purposes for which they are commonly bought.
4. We fully understand and agree that any future changes or additions to the requirements of the Medical Device Administrative Control System (MDACS) can be imposed by the Department of Health without prior notice. We hereby undertake to comply with the latest requirements of the MDACS that are in force. It is one of the current requirements of the MDACS that the LRP will, within two weeks after receiving the request from the Department of Health, produce the originals or certified copies of the documents that, according to the claims in this submission, are within the possession of the LRP or the manufacturer.
5. We confirm that we have neither amended any wording in this form, nor otherwise altered the form in any material manner, apart from filling in the appropriate blanks / boxes.

Signature: _____

Name: _____*CHAN TAI-MAN*_____

Position: _____*GENERAL MANAGER*_____

Contact telephone number:_____*2800 0000*_____

The Applicant (Local Responsible Person):

_____*REAGENT SUPPLIES LTD*_____ _____

Date: ____*2 Jan 2019*_____ Company Chop

Personal Data (Privacy) Ordinance

Statement of Purposes

1. Purpose of Collection

The personal data that are provided by you with whom the Department of Health (DH) interacts in connection with the Medical Device Administrative Control System (MDACS) will be used by the DH for the management and implementation of the MDACS.

2. Classes of Transferees

The personal data you provide are mainly for use within the DH but they may also be disclosed to other Government bureaux/departments or relevant parties for the purpose mentioned in para. 1 above, and related matters if required. Apart from this, the data may only be disclosed to parties where you have given consent to such disclosure or where it is allowed under the Personal Data (Privacy) Ordinance.

3. Access to Personal Data

You have a right of access and correction with respect to personal data as provided for in sections 18 and 22 and Principle 6 of Schedule 1 of the Personal Data (Privacy) Ordinance. Your right of access includes the right to obtain a copy of your personal data. A fee may be imposed for complying with a data access request.

4. Enquiries

Enquiries concerning the personal data provided, including the making of access and corrections, should be addressed to the Medical Device Control Office, Department of Health (fascimile number: 3157 1286; telephone number: 3107 8484). Please quote your application number when submitting the request.

Medical Device Control Office
Department of Health

Medical Device Administrative Control System
Essential Principles Conformity Checklist
For In Vitro Diagnostic Medical Devices

Make: *ABC Medical*
Brand Name and Model: *VGOOD HCV Antigen Kit version 2.3*

Clause	Essential Principle	Applicable	Method of Conformity	Identity of Specific Documents
General Requirements				
1.	Medical devices should be designed and manufactured in such a way that, when used under the conditions and for the purposes intended and, where applicable, by virtue of the technical knowledge, experience, education or training, and the medical and physical conditions of intended users, they will perform as intended by the manufacturer and not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.	*Yes*	1. *The devices are designed and manufactured under a full quality management system in accordance with EN ISO 13485:2016 and presently certified* 2. *The devices are designed and manufactured in conformity with the EU Common Technical Specifications published in OJEC.* 3. *Risk analysis has been performed in accordance with EN ISO 14971:2012. Together with the proactive surveillance studies, it shows that any risks which may be associated with the devices are acceptable when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.*	1. *EN ISO 13485:2016 Certificate No. 012345* 2. *Product Design & Manufacturing files.* 3. *Proactive Surveillance Report PSR-001* 4. *Risk Analysis Report RAR-001*

2.	The solutions adopted by the manufacturer for the design and manufacture of the devices should conform to safety principles, taking account of the generally acknowledged state of the art. When risk reduction is required, the manufacturer should control the risks so that the residual risk associated with each hazard is judged acceptable. The manufacturer should apply the following principles in the priority order listed: • identify known or foreseeable hazards and estimate the associated risks arising from the intended use and foreseeable misuse; • eliminate risks as far as reasonably practicable through inherently safe design and manufacture; • reduce as far as reasonably practicable the remaining risks by taking adequate protection measures, including alarms; and • inform users of any residual risks.	*Yes*	*- Ditto -*	*- Ditto -*
3.	Medical devices should achieve the performance intended by the manufacturer and be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose.	*Yes*	*- Ditto -*	*- Ditto -*
4.	The characteristics and performances referred to in Clauses A1, A2 and A3 should not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer's instructions.	*Yes*	*In addition to EN ISO 13485: 2016 and EN ISO 14971:2012, the devices are designed and tested in accordance with EN ISO 23640:2015 on stability testing of in vitro diagnostic reagents.*	*1. EN ISO 13485: 2016 Certificate No. 012345* *2. Product Design & Manufacturing files.* *3. Risk Analysis Report RAR-001* *4. Stability Testing Report STA-001*
5.	Medical devices should be designed, manufactured and packaged in such a way that their characteristics and performances during their intended use will not be adversely affected by transport and storage conditions (for example, fluctuations of temperature and humidity) taking account of the instructions and information provided by the manufacturer.	*Yes*	*1. The devices are designed and manufactured in accordance with EN ISO 13485: 2016 and presently certified* *2. Risk analysis has been performed in accordance with EN ISO 14971: 2012.*	*1. EN ISO 13485: 2016 Certificate No. 012345* *2. Product Design & Manufacturing files.* *3. Risk Analysis Report RAR-001*
6.	All known and foreseeable risks, and any undesirable effects, should be minimised and be acceptable when weighed against the benefits of the intended performance of medical devices during normal conditions of use.	*Yes*	*- Ditto -*	*- Ditto -*

Design and Manufacturing Requirements				
7.	Chemical, physical and biological properties			
7.1	The IVD medical devices should be designed and manufactured in such a way as to ensure the characteristics and performance referred to in clause 1 to 6. Particular attention should be paid to the possibility of impairment of analytical performance due to incompatibility between the materials used and the specimens and/or analyte (measurand) to be detected (such as biological tissues, cells, body fluids and micro-organisms), taking account of its intended purpose.	*Yes*	*The materials used to manufacture the device have been subject to biological evaluation in accordance with EN ISO 10993-1:2009 standards.*	*Biological Evaluation Test Report No. 012345*
7.2	The IVD medical devices should be designed, manufactured and packaged in such a way as to minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to patients, taking account of the intended purpose of the device.	*Yes*	*1. The materials used to manufacture the device have been subject to biological evaluation in accordance with EN ISO 10993-1:2009 standards.* *2. The devices are packaged in accordance with a system in compliance with ISO 11607-1:2006.*	*Biological Evaluation Test Report No. 012345*
7.3	The IVD medical devices should be designed and manufactured in such a way as to reduce as far as reasonably practicable and appropriate the risks posed by substances that may leach or leak from the IVD medical device. Special attention should be given to substances which are carcinogenic, mutagenic or toxic to reproduction.	*Yes*	*1. The materials used to manufacture the device have been subject to biological evaluation in accordance with EN ISO 10993-1:2009 standards.* *2. Risk analysis has been performed in accordance with EN ISO 14971:2012.*	*1. Biological Evaluation Test Report No. 012345* *2. Risk Analysis Report RAR-001*
7.4	IVD medical devices should be designed and manufactured in such a way as to reduce as far as reasonably practicable and appropriate risks posed by the unintentional ingress or egress of substances into or from the IVD medical device taking into account the device and the nature of the environment in which it is intended to be used.	*Yes*	*1. The materials used to manufacture the device have been subject to biological evaluation in accordance with EN ISO 10993-1:2009 standards.* *2. Risk analysis has been performed in accordance with EN ISO 14971:2012.*	*1. Biological Evaluation Test Report No. 012345* *2. Risk Analysis Report RAR-001*
8.	Infection and microbial contamination			

8.1	The IVD medical devices and manufacturing processes should be designed in such a way as to eliminate or to reduce as far as reasonably practicable and appropriate the risk of infection to user, professional or lay, or, where applicable, other person . The design should: • allow easy and safe handling; and, where necessary: • reduce as far as reasonably practicable and appropriate any microbial leakage from the IVD medical device and/or microbial exposure during use; and • prevent microbial contamination of the IVD medical device or specimen where applicable, by the user, professional or lay, or other person.	*Yes*	1. *The devices are designed in accordance to EN 13641:2002 Elimination or Reduction of risk of infection related to In Vitro diagnostic reagents.* 2. *Risk analysis has been performed in accordance with EN ISO 14971:2012.* 3. *The devices are packaged in accordance with a system in compliance with ISO 11607-1:2006.*	*Risk Analysis Report RAR-001*
8.2	IVD medical devices labelled either as sterile or as having a special microbiological state should be designed, manufactured and packaged to ensure they remain so when placed on the market and remain so under the transport and storage conditions specified by the manufacturer, until the protective packaging is damaged or opened.	*Yes*	1. *Risk analysis has been performed in accordance with EN ISO 14971:2012.* 2. *The devices are packaged in accordance with a system in compliance with ISO 11607-1:2006.*	*Risk Analysis Report RAR-001*
8.3	IVD medical devices labelled either as sterile or as having a special microbiological state should have been processed, manufactured and, if applicable, sterilized by appropriate, validated methods.	*No*	*Not applicable*	*Not applicable*
8.4	IVD medical devices intended to be sterilized should be manufactured in appropriately controlled (e.g. environmental) conditions.	*No*	*Not applicable*	*Not applicable*
8.5	Packaging systems for non-sterile IVD medical devices should maintain the integrity and cleanliness of the device.	*No*	*Not applicable*	*Not applicable*
9	IVD medical devices incorporating materials of biological origin			
9.1	Where IVD medical devices include tissues, cells and substances originating from animals, the processing, preservation, testing and handling of tissues, cells and substances of animal origin should be carried out so as to provide optimal safety for user, professional or lay, or other person. In particular, safety with regard to viruses and other transmissible agents should be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process. This may not apply to certain IVD medical devices if the activity of the virus and other transmissible agent are integral to the intended purpose of the IVD medical device or when such elimination or inactivation process would compromise the performance of the IVD medical device.	*No*	*Not applicable*	*Not applicable*

9.2	Where IVD medical devices include human tissues, cells and substances, the selection of sources, donors and/or substances of human origin, the processing, preservation, testing and handling of tissues, cells and substances of such origin should be carried out so as to provide optimal safety for user, professional or lay, or other person. In particular, safety with regard to viruses and other transmissible agents should be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process. This may not apply to certain IVD medical devices if the activity of the virus and other transmissible agent are integral to the intended purpose of the IVD medical device or when such elimination or inactivation process would compromise the performance of the IVD medical device.	*No*	*Not applicable*	*Not applicable*
9.3	Where IVD medical devices include cells and substances of microbial origin, the processing, preservation, testing and handling of cells and substances should be carried out so as to provide optimal safety for user, professional or lay, or other person. In particular, safety with regard to viruses and other transmissible agents should be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process. This may not apply to certain IVD medical devices if the activity of the virus and other transmissible agent are integral to the intended purpose of the IVD medical device or when such elimination or inactivation process would compromise the performance of the IVD medical device.	*No*	*Not applicable*	*Not applicable*
10	Environmental properties			
10.1	If the IVD medical device is intended for use in combination with other devices or equipment, the whole combination, including the connection system should not impair the specified performance of the devices. Any restrictions on use applying to such combinations should be indicated on the label and/or in the instructions for use.	*No*	*Not applicable*	*Not applicable*

10.2	IVD medical devices should be designed and manufactured in such a way as to remove or reduce as far as reasonably practicable and appropriate: • the risk of injury to user, professional or lay, or other person in connection with their physical and ergonomic features; • the risk of use error due to the ergonomic features, human factors and the environment in which the IVD medical device is intended to be used; • risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, pressure, humidity, temperature or variations thereof; • the risks associated with the use of the IVD medical device when it comes into contact with materials, liquids, and gases to which it is exposed during normal conditions of use; • the risk associated with the possible negative interaction between software and the environment within which it operates and interacts; • the risks of accidental penetration of substances into the IVD medical device; • the risk of incorrect identification of specimens/samples; • the risks of reasonably foreseeable interference with other devices such as carry over between IVD medical devices.	*Yes*	*1. The devices are designed in accordance with EN 13641:2002 Elimination or Reduction of risk of infection related to In Vitro diagnostic reagents.* *2. Risk analysis has been performed in accordance with EN ISO 14971:2012.*	*Risk Analysis Report RAR-001*
10.3	IVD medical devices should be designed and manufactured in such a way as to minimize the risks of fire or explosion during normal use and in single fault condition. Particular attention should be paid to IVD medical devices whose intended use includes exposure to or use in association with flammable substances or substances which could cause combustion.	*Yes*	*- Ditto -*	*- Ditto -*
10.4	IVD medical devices should be designed and manufactured in such a way that adjustment, calibration, and maintenance, where such is necessary to achieve the performances intended, can be done safely.	*Yes*	*- Ditto -*	*- Ditto -*
10.5	IVD medical devices should be designed and manufactured in such a way as to facilitate the safe disposal of any waste substances.	*Yes*	*The devices are designed and manufactured in conformity with the EU 2006/1907/EC Registration, Evaluation, Authorization & restriction of Chemicals (REACH) Regulation.*	*Product Design & Manufacturing files.*
11	Performance characteristics			

11.1	IVD medical devices should be designed and manufactured in such a way that the performance characteristics support the intended use, based on appropriate scientific and technical methods. In particular, where appropriate, the design should address sensitivity, specificity, accuracy which is trueness and precision (repeatability and reproducibility), control of known relevant interference and limits of detection. These performance characteristics need to be maintained during the lifetime of the IVD medical device as indicated by the manufacturer.	*Yes*	*The devices are designed and manufactured in conformity with the EU Common Technical Specifications published in OJEC.*	*Product Design & Manufacturing files.*
11.2	Where the performance of devices depends on the use of calibrators and/or control materials, the traceability of values assigned to such calibrators and/or control materials should be assured through available reference measurement procedures and/or available reference materials of a higher order.	*Yes*	*Traceability is achieved in compliance to ISO 18153:2003 standard.*	*Product Design & Manufacturing files.*
11.3	Wherever possible values expressed numerically should be in commonly accepted, standardised units, and understood by the users of the device.	*Yes*	*The devices are designed and manufactured in accordance with EN ISO 15193:2009 on IVDMD measurement.*	*Product Design & Manufacturing files.*
12	Protection against radiation			
12.1	IVD medical devices should be designed, manufactured and packaged in such a way that exposure of user, professional or lay, or other person to the emitted radiation (intended, unintended, stray or scattered) is reduced as far as reasonably practicable and appropriate.	*No*	*Not applicable*	*Not applicable*
12.2	When IVD medical devices are intended to emit potentially hazardous, visible and/or invisible radiation, they should as far as reasonably practicable and appropriate be: • designed and manufactured in such a way as to ensure that the characteristics and the quantity of radiation emitted can be controlled and/or adjusted; and • fitted with visual displays and/or audible warnings of such emissions.	*No*	*Not applicable*	*Not applicable*
13	IVD medical devices that incorporate software and standalone IVD medical device software			
13.1	For IVD medical devices which incorporate software or for standalone software that are IVD medical devices in themselves, the software must be validated according to the state of the art taking into account the principles of development lifecycle, risk management, verification and validation.	*No*	*Not applicable*	*Not applicable*
14	IVD medical devices connected to, or equipped with, an energy source			
14.1	IVD medical devices where the safety of the patient depends on an internal power supply in the IVD medical device, should be equipped with a means of determining the state of the power supply.	*No*	*Not applicable*	*Not applicable*

14.2	IVD medical devices should be designed and manufactured in such a way as to reduce as far as reasonably practicable and appropriate the risks of creating electromagnetic interference which could impair the operation of this or other devices or equipment in the usual environment.	*No*	*Not applicable*	*Not applicable*
14.3	IVD medical devices should be designed and manufactured in such a way as to provide an adequate level of intrinsic immunity to electromagnetic disturbance to enable them to operate as intended.	*No*	*Not applicable*	*Not applicable*
14.4	IVD medical devices should be designed and manufactured in such a way as to avoid, as far as reasonably practicable, the risk of accidental electric shocks to the user, professional or lay, or other person both during normal use of the device and in the event of a single fault condition in the device, provided the IVD medical device is installed and maintained as indicated by the manufacturer.	*No*	*Not applicable*	*Not applicable*
15	Protection against mechanical and thermal risks			
15.1	IVD medical devices should be designed and manufactured in such a way as to protect the user, professional or lay, or other person against mechanical risks connected with, for example, resistance to movement, instability and moving parts.	*No*	*Not applicable*	*Not applicable*
15.2	Where there are risks due to the presence of moving parts, risks due to break-up or detachment, or leakage of substances, then appropriate protection means must be incorporated.	*No*	*Not applicable*	*Not applicable*
15.3	IVD medical devices should be designed and manufactured in such a way as to reduce to the lowest practicable level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.	*No*	*Not applicable*	*Not applicable*
15.4	IVD medical devices should be designed and manufactured in such a way as to reduce to the lowest practicable level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source.	*No*	*Not applicable*	*Not applicable*
15.5	Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user, professional or lay, or other person has to handle should be designed and constructed in such a way as to minimize all possible risks.	*No*	*Not applicable*	*Not applicable*

15.6	IVD medical devices should be designed and manufactured in such a way as to reduce to the lowest practicable level, the risk of error when certain parts within the device are intended to be connected or reconnected before or during use.	*No*	*Not applicable*	*Not applicable*
15.7	Accessible parts of the IVD medical devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings should not attain potentially dangerous temperatures under normal use.	*No*	*Not applicable*	*Not applicable*
16	Protection against the risks posed by IVD medical devices for self-testing			
16.1	IVD medical devices for self-testing should be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to lay persons and the influence resulting from variation that can reasonably be anticipated in the lay person's technique and environment. The information and instructions provided by the manufacturer should be easy for the lay person to understand and apply.	*No*	*Not applicable*	*Not applicable*
16.2	IVD medical devices for self-testing should be designed and manufactured in such a way as to reduce as far as reasonably practicable the risk of error by the lay person in the handling of the device and, if applicable, the specimen, and also in the interpretation of results.	*No*	*Not applicable*	*Not applicable*
16.3	IVD medical devices for self-testing should, where reasonably possible, include a procedure by which the lay person can verify that, at the time of use, the product will perform as intended by the manufacturer.	*No*	*Not applicable*	*Not applicable*
17	Label and Instructions for Use			
17.1	Users should be provided with the information needed to identify the manufacturer, to use the device safely and to ensure the intended performance, taking account of their training and knowledge. This information should be easily understood.	*Yes*	*1. The information supplied with the device complies with ISO 18113-1:2009.* *2. The information supplied with the device complies with the labelling requirements specified under MDACS.*	*1. EC Design Dossier – labelling details* *2. Labels and instructions for use enclosed under index (C3) of the submission folder*
18	Performance evaluation including analytical performance and, where appropriate, clinical performance			

18.1	For an IVD medical device a performance evaluation should be conducted in accordance with GHTF guidance. The performance evaluation should review analytical performance data and, where appropriate, clinical performance data in the form of any: • literature; • performance study reports; and • experience gained by routine diagnostic testing. to establish that the IVD medical device achieves its intended performance during normal conditions of use and that the known, and foreseeable risks, and any undesirable effects, are minimised and acceptable when weighed against the benefits of the intended performance.	*Yes*	*Performance evaluation of the devices is to be conducted in accordance with EN 13612:2002.*	*Performance evaluation report PER-001*
18.2	Clinical investigations on human subjects should be carried out in accordance with the spirit of the Helsinki Declaration. This includes every step in the clinical investigation from first consideration of the need and justification of the study to publication of the results.	*Yes*	*Performance evaluation of the devices is to be conducted in accordance with EN 13612:2002*	*Performance evaluation report PER-001*

I confirm that I have neither amended the wording in this form, nor otherwise altered the form in any material manner, apart from filling in the blanks.

I declare that the information provided in this form is accurate and correct and the device conforms to all the applicable requirements stipulated above.

Signature:

Name: *CHAN TAI-MAN*

Position: *GENERAL MANAGER*

The Applicant (Local Responsible Person): *REAGENT SUPPLIES LTD*

Date: *2 Jan 2019*

Company Chop

<Name of Manufacturer/Local Responsible Person>
<Address of Manufacturer/Local Responsible Person>
<Date>

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

Dear Sirs

Product: <Make> <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>