RWANDA FDA
Rwanda Food and Drugs Authority

GUIDELINES FOR REGISTRATION OF IN VITRO DIAGNOSTICS DEVICES

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FOREWORD

Rwanda Food and Drugs Authority (Rwanda FDA) is a regulatory body established by the Law N° 003/2018 of 09/02/2018. One of the functions of Rwanda FDA is to regulate matters related to quality, safety and performance of medical devices including In vitro Diagnostics in order to protect public health by increasing their access and availability.

Considering the provisions of the technical regulations Governing Registration of Medical Devices including In Vitro Diagnostics in its article which gives the power to issue guidelines, Rwanda Food and Drugs Authority (Rwanda FDA) has issued Guidelines for registration of In Vitro Diagnostics Medical devices.

These guidelines were developed in reference to the Africa Medical Devices Forum (AMDF), World Health Organization (WHO) and the International Medical Device Regulators Forum (IMDRF).

The purpose of these guidelines is to provide guidance to In vitro Diagnostics medical devices importers, manufacturers and distributors intending to market or manufacture their devices in Rwanda, on the documentation requirements by Rwanda FDA to assess conformity of such devices to the essential principles of safety, quality and performance before market authorization can be issued.

These guidelines are hereby promulgated for information, guidance and strict compliance by all concerned.

Adherence to the guidelines by the manufacturers/applicants will facilitate timely assessments and approvals of medical devices dossiers by Rwanda FDA for pre-market authorization/ registration.

We wish to acknowledge all the efforts of key stakeholders and express our gratitude to all individuals who actively participated in the development and validation of these guidelines.

Prof. Emile BIENVENU
Director General

DOCUMENT DEVELOPMENT HISTORY

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Document Revision History

Revision number	Changes made and/or reasons for revision
1	-Change of the guidelines title -Revision of the definitions -Amendment of the technical file sections -The STED mode of submission has been superseded by the Table of Content (ToC) -inclusion of the renewal process -Revision of timelines -Revision and inclusion of forms and cover letter and their inclusion as appendices -Introduction of IVDs grouping/cluster -Editorial changes

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ACCRONYMS AND ABBREVIATIONS

PRC	Peer Review Committee
Rwanda FDA	Rwanda Food and Drugs Authority
EP	Essential Principles
FIFO	First In First Out
STED	Summary of Technical Documentation
IVD	In Vitro Diagnostic Device
QMS	Quality Management Systems
LTR	Local Technical Representative
EEC	European Economic Community
CAB	Conformity Assessment Body
IMDRF	International Medical Devices Regulators Forum
WHO	World Health Organisation
EAC	East African Community
EAC-MRH	East African Medicines Regulatory Harmonization
QCL	Quality Control Laboratory
SRA	Stringent Regulatory Authority
GMP	Good Manufacturing Practices
NRA	National Regulatory Authority
HIV	Human Immunodeficiency Virus
HCV	Hepatitis C Virus
HBV	Hepatitis B Virus

HTLV	Human T-lymphotropic virus

GLOSSARY/DEFINITIONS

For the purpose of these guidelines, the following definitions shall apply:

1. "**Authority**" means the Rwanda Food and Drugs Authority or its acronym "Rwanda FDA", established under Law N^0. 003/2018 of 09/02/2018.

2. **"Abridged assessment"** a limited independent assessment of specific parts of the dossier, or regulatory submission of data for suitability of use under local conditions and regulatory requirements, taking into account prior assessment (including dossier review and/or independent performance evaluation) and inspection outcomes from WHO prequalification or any National Regulatory Authority (NRA) deemed by the Authority as competent to inform the latter in its decision.

3. **"Applicant"** means the person by, or on whose behalf, an application for, an update or amendment to an existing registration, is made. After the product is registered, the applicant shall be the "Marketing Authorisation Holder".

4. **"Analytical Performance of an IVD Medical Device"** means The ability of an IVD medical device to detect or measure a particular analyte.

5. **"Collaborative procedure"** procedure for collaboration between the Authority and WHO or any regulatory authority in the assessment and accelerated national registration of IVDs.

6. **"Conformity Assessment Body (CAB)"** means A body, other than a regulatory authority, engaged in determining whether the relevant requirements in technical regulations or standards are fulfilled.

7. **"Law"** means Law N^0 003/2018 of 09/02/2018 establishing the Rwanda FDA and determining its mission, organization and function

8. **"Local Technical Representative (LTR)"** means any company registered in Rwanda and licensed by Rwanda FDA to deal with regulated products that has received a mandate from the Applicant to act on his/her behalf with regard to matters pertaining to the registration of regulated products.

9. **"In vitro diagnostic device (IVD)"** means a medical device, whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes.

   Note: IVD medical devices include reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles and are used, for example, for the following test purposes: diagnosis, aid to diagnosis, screening, monitoring, predisposition, prognosis, prediction, determination of physiological status.

10. "**Accessory to an IVD**" means an article intended specifically by its manufacturer to be used together with a particular IVD device to enable or assist that device to be used in accordance with its intended use.

11. "**Label**" means written, printed, or graphic information either appearing on the medical device itself, or on the packaging of each unit, or on the packaging of multiple devices.

Note: The definition above refers to the human readable label.

12. **"Labeling**" means the label, instructions for use, and any other information that is related to identification, technical description, intended purpose and proper use of the medical device, but excluding shipping documents.
Note 1: Labeling can also be referred to as "information supplied by the manufacturer."

Note 2: Labeling can be in printed or electronic format and may either physically accompany the medical device or direct the user to where the labeling information can be accessed (such as through a website).

13. "**Manufacture**" means all operations that involve preparation, processing, filling transforming, packaging, repackaging and labelling of an IVD;

14. "**Manufacturer**" means any natural or legal person1 with responsibility for design and/or manufacture of a medical device with the intention of making the medical device available for use, under their name; whether such a medical device is designed and/or manufactured by that person themselves or on their behalf by another person(s). (Modified from GHTF/SG1/N055:2009)

Note 1: This 'natural or legal person' has ultimate legal responsibility for ensuring compliance with all applicable regulatory requirements for the medical device in the countries or jurisdictions where it is intended to be made available or sold, unless this responsibility is specifically imposed on another person by the Regulatory Authority within that jurisdiction.

Note 2: The manufacturer's responsibilities are described in other GHTF and IMDRF guidance documents. These responsibilities include meeting regulatory requirements at various points during the product lifecycle, such as adverse event reporting and notification of corrective actions.

Note 3: 'Design and/or manufacture', as referred to in the above definition, may include specification development, production, fabrication, assembly, processing, packaging, repackaging, labeling, relabeling, sterilization, installation, or remanufacturing of a medical device; or putting a collection of devices, and possibly other products, together for a medical purpose.

Note 4: Any person who assembles or adapts a medical device that has already been supplied by another person for an individual patient, in accordance with the instructions

for use, is not the manufacturer, provided the assembly or adaptation does not change the intended use of the medical device.

Note 5: Any person who changes the intended use of, or modifies, a medical device without acting on behalf of the original manufacturer and who makes it available for use under his own name, should be considered the manufacturer of the modified medical device.

Note 6: An authorized representative, distributor or importer who only adds its own address and contact details to the medical device or the packaging, without covering or changing the existing labeling, is not considered a manufacturer.

Note 7: To the extent that an accessory is subject to the regulatory requirements of a medical device2, the person responsible for the design and/or manufacture of that accessory is considered to be a manufacturer.

15. **"Medical device"** means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:
    - diagnosis, prevention, monitoring, treatment or alleviation of disease,
    - diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury,
    - investigation, replacement, modification, or support of the anatomy, or of a physiological process,
    - supporting or sustaining life,
    - control of conception,
    - cleaning, disinfection, or sterilization of medical devices,
    - providing information by means of in vitro examination of specimens derived from the human body;

    and does not achieve its primary intended action by pharmacological, immunological, or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.

    Note 1: Products which may be considered to be medical devices in some jurisdictions but not in others include:
    - cleaning and disinfection substances,
    - aids for persons with disabilities,
    - devices incorporating animal and/or human tissues,
    - devices for in-vitro fertilization or assisted reproduction technologies.

    Note 2: For clarification purposes, in certain regulatory jurisdictions, devices for cosmetic/aesthetic purposes are also considered medical devices.

    Note 3: For clarification purposes, in certain regulatory jurisdictions, the commerce of

devices incorporating human tissues is not allowed.

16. **"Fee"** means the fee prescribed in Regulation CBD/TRG/004 related to regulatory services and fines.
17. **"Intended use/purpose"** The objective intent regarding the use of a product, process or service as reflected in the specifications, instructions and information provided by the manufacturer.
18. **"Batch number (or lot number, lot code, batch code)"** A set of numbers and/or letters that specifically identifies a device batch and permits its manufacturing, packaging, labeling and distribution history to be traced.
19. **"Packaging"** operations involved in the preparation of goods for containment, protection, handling, delivery, storage, transport and presentation of goods, from raw materials to processed goods, from the producer to the user or consumer
20. **"Packaging material"** means any material, including printed material, employed in the packaging of a medical device, excluding any outer packaging used for "transportation or shipment.
21. "**Instructions for Use**" General and technical information provided by the manufacturer to inform the user of the medical device or IVD medical device's intended purpose and proper use and of any contraindications, warnings, or precautions to be taken. It is provided by the manufacturer to support and assist the device users in its safe and appropriate use.
22. **"Intended Use / Intended Purpose"** means the objective intent regarding the use of a product, process or service as reflected in the specifications, instructions and information provided by the manufacturer.

    Note 1: The intended use/intended purpose are also part of promotional or sales materials or statements, although these materials lie outside the scope of this document.

    Note 2: The intended use can include the indications for use.
23. "**Dossier**" means a file that contains detailed information on the device description, manufacturing, quality control and biomedical studies that demonstrates quality, safety and performance of the finished medical device;
24. "**Quality Management System**" means a management system to direct and control an organization with regard to quality, from establishing quality policy, quality objectives and implementing and maintaining quality system;
25. "**Technical Documentation**" means documented evidence, normally an output of the Quality Management System that demonstrates compliance of a device to the Essential Principles of Safety and Performance of Medical Devices;

26. Expiry Date/Expiration Date" means an upper limit of the time interval during which the safety and performance characteristics of a material stored under specified conditions can be assured.

Note 1: This also applies to medical devices whose physical, chemical or functional properties are maintained during a specified and known period, such as for capital equipment.

Note 2: Expiry dates are assigned to IVD reagents, calibrators, control materials and other components by the manufacturer, based on experimentally determined stability properties.

27. "IVD test kit" an IVD test kit is an in vitro diagnostic Device (IVD) that consists of reagents or articles that are from the same manufacturer; intended to be used in combination to complete a specific intended purpose; sold under a single test kit name or the labeling, instructions for use (IFU), brochures or catalogs for each reagents or article states that the component is intended for use with the IVD test kit; and compatible when used as a test kit.

Note: An IVD test kit does not include the instruments, such as analyzers needed to perform the test.

28. "**Notified IVD Medical Devices**" means medical devices that have been granted marketing authorization through the notification process.

29. "**Marketing authorization/ Registration certificate or Notification letter**" means a legal document issued by the Authority for the purposes of marketing or free distribution of a product which has been approved after evaluation for safety, quality and performance.

30. "**Marketing Authorization holder**" means a company which holds an authorization to place a medical device on the Rwandan market and is responsible for that device.

INTRODUCTION

1.1. Background

Rwanda Food and Drugs Authority (Rwanda FDA) is established by the Law N° 003/2018 of 09/02/2018, especially in its article 8 and 9;

Considering the provisions of the technical regulations governing the registration of medical devices including In Vitro Diagnostics, especially in its article which grants the authority the power to issue guidelines, the authority has issued Guidelines for registration of In Vitro Diagnostics Devices.

Manufacturers of all classes of IVDs are expected to demonstrate conformity to the Essential Principles of Safety and Performance, through the preparation and holding of technical documentation that shows how each In Vitro Diagnostic device was developed, designed and manufactured together with the descriptions and explanations necessary to understand the manufacturer's determination with respect to such conformity. The technical documentation should be revised to reflect the current status of IVDs through normal application of the manufacturer's QMS.

1.2. Scope

These guidelines shall apply to all In Vitro Diagnostics devices intended to be marketed in Rwanda. They provide guidance on the summary technical documentation to be submitted to Rwanda Food and Drugs Authority (Rwanda FDA) for assessment and registration/notification.

1.3. General principles

For the purpose of conformity assessment, the manufacturer should assemble information from existing technical documentation to provide evidence that the subject In Vitro Diagnostic device is in conformity with the Essential Principles. The information submitted shall reflect the status of the IVD at a particular moment in time (e.g. at the moment of pre-market submission or when requested) and is prepared in order to meet regulatory requirements.

The submission may contain summary information on selected topics and may contain detailed information on certain specific topics including the Essential Principles checklist - EP checklist**.** All information should be submitted in any of the official language(s) and may also include, for example: abstracts, high level summaries, or existing controlled documents sufficient to communicate key relevant information and allow a reviewer to understand the subject and assess the validity of that information.

The EP checklist is created as part of the manufacturer's technical documentation and is controlled by the manufacturer's QMS. It provides a tabular overview of the Essential Principles and identifies those that are applicable to the IVD, the chosen method of

demonstrating that the device conforms to each relevant Essential Principle and the reference of the controlled document that is relevant to a specific Essential Principle. While many controlled documents are referenced in the EP checklist, only some may be contained within this submission. The cited references to the controlled documents also allow easy identification of additional relevant documents and data.

1.4. Submission of application and sample

An application for In Vitro Diagnosrics registration/notification for either locally manufactured or imported should be submitted to Rwanda FDA by the applicant via Rwanda FDA Online portal. Where applicable, samples can be submitted along with the cover letter (**Appendix 1**) together with a printed email notification bearing an application reference number generated at the time of application submission, at Rwanda FDA head Quarters reception to the following address:

Director General
Rwanda FDA Rwanda Food and Drugs Authority
P. O. Box 1948 Kigali- Rwanda

1.5. Application Requirements

1.5.1. Requirements for notification of new IVDs applications

In Vitro Diagnostics Medical Devices falling under class A not active, non-sterile or without measuring function, Laboratory equipment and apparatus (**List to be provided for guidance**) shall apply for notification to the Authority. Applicants shall submit (online) the following:

1. Signed and dated copy of the cover letter addressed to the DG of Rwanda FDA (**Appendix 1**)
2. Signed and dated and duly filled in application form for notification (**Appendix 2**)
3. Valid certificate of compliance to ISO 13485 standard or its equivalent from the manufacturer(s) of the device
4. Declaration of Conformity (DoC)
5. Instruction for Use (IFU) (where applicable)
6. Device artworks/ mock ups
7. One device commercial pack sample (where applicable). In case samples are not provided, a letter explaining the reason of non-submission should be provided and real life 3D pictures should be included the submitted documentation

1.5.2. Requirements for registration of new IVDs applications

Other In Vitro Diagnostics Medical Devices not eligible for notification shall apply (online) for registration and their applications shall include the following:

1. Signed and dated original hard-copy of cover letter (**Appendix 1**)
2. Signed and dated application form for device registration (**Appendix 3**)

3. Technical documentation/Technical file (Table of Content (ToC))
4. Declaration of Conformity (DoC)
5. Copies of referenced literature and other supporting documents
6. Two commercial samples of medical devices and certificate of conformity (where applicable), however additional samples might be required (in case samples are not provided, a letter explaining the reason of non-submission should be provided and real life 3D pictures should be included the submitted documentation)
7. Rwanda FDA QMS audit certificate or Proof of QMS audit application (for class C and class D medical devices)

8. For WHO prequalified Medical devices, in addition to the requirements above, submission of the following filled in and signed appendices:

   -**WHO Appendix 2:** Consent of WHO prequalification holder for WHO to confidentially share information with the NRA under the Procedure

   -**WHO Appendix 3 part A:** Expression of interest to the national regulatory authorities (NRAs) in the assessment and accelerated national registration of a World Health Organization (WHO)-prequalified in vitro diagnostic

   Note: These Appendices can be obtained upon request via the following email: info@rwandafda.gov.rw

1.5.3. Requirements for renewal of registered IVDs applications

An application for renewal of medical devices registration be submitted online and shall include the following:

1. Signed and dated copy of the cover letter addressed to the DG of Rwanda FDA **(Appendix 1)**
2. Signed and dated application form for registered devices **(Appendix 3)**
3. Current artworks/ mock ups of the device
4. Technical documentation/Technical file (Table of Content (ToC)) (renewal for registration)
5. Two commercial pack samples (where applicable)
6. Payment of renewal fee and QMS audit fee as per relevant regulations

1.5.4. Requirements for renewal of notified IVDs applications

1. Signed and dated copy of the cover letter addressed to the DG of Rwanda FDA **(Appendix 1)**
2. Signed and dated application form for notified devices **(Appendix 2)**
3. Valid certificate of compliance to ISO 13485 standard or its equivalent from the manufacturer(s) of the device

4. Current artworks/ mock ups of the device
5. One commercial pack samples (where applicable)
6. Payment of renewal fees as per relevant regulations

1.6. Receiving Applications For Medical Devices Registration/Notification

An application for registration/ notification of an In Vitro Diagnostic device is only received via the online platform and is considered complete by the Authority upon receiving all necessary information and the payment of prescribed notification/registration fees has been effected. After receiving a product notification/registration application, a reference number is assigned to the application and the latter will be used in all subsequent correspondences relating to the application.

1.7. Dossier Assessment Procedures

1.7.1. Dossier Notification Procedure

After receiving an application requesting notification via the online platform, the Authority shall proceed with the screening of the dossier for completeness based on the First in First out (FIFO) rules. An IVD dossier is reviewed by one assessor to verify the completeness of requirements. During the review, additional data and/or samples may be requested.

Once a query has been issued to the applicant, the notification process stops until the Authority receives via the online platform, a response to the raised queries. Further processing of the application may only be undertaken if responses to queries issued contains all outstanding information requested in one submission. Failure to comply with this condition or if the queries have been reissued for a **second time** and the applicant provides unsatisfactory responses, the application will be rejected.

In the event that the responses to the queries are not submitted within the specified time, from the date they were issued, it will be considered that the applicant has withdrawn the application unless the applicant has requested an extension of the deadline to the Authority. Thereafter, notification of the IVD may only be considered upon submission of a new application.
In case the dossier is complete, the application will be scheduled for peer review.

The applicant shall receive a notification letter within twenty (**20**) working days.

1.7.2. Dossier Registration Procedure

After receiving an application requesting registration via the online platform, the Authority shall proceed with the screening of the dossier for completeness. In the event that the dossier is incomplete, it will not be scheduled for assessment and the applicant will be notified via the platform within twenty (**20)** working days and requested to comply with requirements.

In case of a positive outcome from the screening, the application will be scheduled for assessment according to the First in First out (FIFO) rules. Priority assessment may be granted where the IVD is intended for diagnosis of rare disease conditions or in the case of an emergency situation.

An IVD dossier is reviewed by two assessors whose role is to provide scientific and regulatory oversight regarding the quality, safety and performance of the medical device. The Authority reserves the right during the assessment procedure, to request any additional information/samples so as to establish the quality, safety and performance of the device. Samples may be analysed in the Quality Control Laboratory on a risk basis approach, in order to guide the Authority's final decision.

In case of incompleteness during assessment, additional data will be requested from the applicant. The assessment process stops until the Authority receives a response to the raised queries. Further processing of the application may only be undertaken if responses to queries issued contain all outstanding information requested. Failure to comply with this condition or if the queries have been reissued for the **fourth** time and the applicant provides unsatisfactory responses, the application will be rejected.

In the event the responses to the queries are not submitted within the specified timeline for IVDs undergoing abridged assessment procedure from the date they were issued, it will be considered that the applicant has withdrawn the application unless the applicant has requested for extension of the deadline to the Authority. Thereafter, registration of IVDs may only be considered upon submission of a new application.

In case the dossier is deemed complete after the assessment, the application will be scheduled for peer review.

The applicant shall receive a certificate of registration within a **maximum** period of One hundred eighty **(180)** working days.

Note:

- **i.** For lower risk medical devices, the aforementioned timeline may be significantly shortened.
- **ii.** The Authority may rely on assessments and audits conducted by other recognized regulatory authorities or conformity assessment bodies (CABs); An abridged assessment procedure may then be conducted, as per relevant Guidelines on Reliance.

1.8. Compliance with the Quality Management System (QMS)

The QMS audit is part of an IVD registration process. All devices under classes C and D shall apply and pay relevant QMS audit fees. The Authority should conduct an inspection of the

manufacturing facility or use other means to verify whether the manufacturing site complies with QMS before the IVD is registered. During the assessment, assessors may highlight QMS's issues and communicate them to the department that has the mandate of inspection and compliance.
QMS audit compliance of the manufacturing site of devices under the abridged assessment procedure shall be confirmed through desk review; however, if deemed necessary the Authority may conduct an onsite inspection.

Note: The Authority reserves the right to conduct a Quality Management System (QMS) audit for other classes of medical devices should regulatory review or technical assessment indicate the necessity.

More information on QMS requirements and application for QMS audit is detailed in relevant guidelines.

1.9. Authority's Internal Scientific Review Committee for Medical Device Registration

After the assessment completion, a final dossier assessment report shall be presented to the Authority's Internal Scientific Review Committee (ISRC) before making final decisions for granting or rejecting the medical device market authorization.

In the event, that there are safety, quality or performance issues to be resolved as per the decision of the ISRC, the application shall remain pending until the resolution of the raised issues. If the applicant fails to provide the required data within the specified timeline, the application shall be considered as **withdrawn.**

The Authority shall register/ notify the IVD, in the event that data on safety, quality and performance or other requirements are considered satisfactory and a certificate of registration/ certificate of notification shall be granted.

1.10. Timelines for IVDs Registration/Notification

1.10.1. Timelines for registration/notification of new applications

IVDs dossiers shall be scheduled for assessment according to the First in First out (FIFO) basis upon compliance with the requirements.
Medical Devices dossiers shall be scheduled for assessment according to the First in First out (FIFO) basis upon compliance with the requirements.
An application for registration/notification shall be processed within:

- Twenty **(20)** working days for the notification procedure
- Sixty **(60)** working days for the abridged assessment procedure
- One hundred eighty **(180)** working days for the full assessment procedure

Any additional data shall be submitted within:
- Ten **(10)** working days for Medical Devices undergoing notification procedure
- Twenty **(20)** working days for Medical Devices undergoing abridged assessment procedure
- Sixty **(60)** working days undergoing the full assessment procedure

Note: The registration certificate shall be valid for a period of five (**5**) years, whereas the notification letter shall be three (**3**) years.

In the event that the Authority suspends or cancels the registration/notification validity, a written official communication shall be issued to the applicant.

1.10.2. Timelines for renewal of notified/registered devices applications

Marketing authorisation holders must apply for renewal of notification/registration to the Authority at least Sixty **(60)** working days before the expiry of the Marketing Authorization.

Applications for renewal of notified/ registered medical devices shall be processed within:
- Twenty **(20)** working days for notified Medical Devices
- Sixty **(60)** working days for registered Medical Devices

Any additional data shall be submitted within:
- Ten **(10)** working days for notified Medical Devices
- Twenty **(20)** working days for registered Medical Devices

Note: Failure to comply with the above timeline, or if the queries have been reissued for a **second time** and the applicant provides unsatisfactory responses, will result in the MA suspension

1.11. Classification of In Vitro Diagnostics Devices

In Vitro Diagnostics Devices are classified into four classes based on risk levels (Class A represents the class with the lowest risk and Class D represents the class with the highest risk to the individual and/or to public health) Table 1. The classification of risks is based on the intended use and indications for use as specified by the manufacturer, the technical/scientific/medical expertise of the intended user (lay person or healthcare professional), the importance of the information to the diagnosis (sole determinant or one of several), taking into consideration the natural history of the disease or disorder including presenting signs and symptoms which may guide a physician and the impact of the result (true or false) to the individual and/or to public health.

Table 1: Classification examples for IVDs

Class	Risk Levels
A	Low (reagents, specimen receptacles, urine cups…)
B	Low-Moderate (Pregnancy self-test, urine test strips…)
C	Moderate-High (Cardiac markers, Prothrombin time testing…)
D	High (tests to identify HIV, HCV, HBV, HTLV,…)

Where an In Vitro Diagnostic Device falls into more than one class, the class representing the higher class shall apply. Where one IVD is intended to be used together with a different IVD, that may or may not be from the same manufacturer, a separate submission should be made and the conformity assessments of the IVD shall be applied separately to each of the devices.

Whilst the manufacturer has the primary responsibility to classify its devices, the Authority may challenge the classification and will have the final say in deciding the class of the IVDs.

Each submitted application shall contain only one of the following:

a. A single IVD
b. An IVD test kit
c. A group of IVDs/ IVDs cluster (**refer to Appendix VI**)

1.12. Technical Documentation Format and Data Presentation of The Dossier

All medical devices in classes A, B, C & D require pre-market submission of technical documentation demonstrating conformity with Essential Principles except for those requiring notification (**List to be provided for guidance)**

The information within the Technical file shall be organized in the Table of Content (ToC) submission structure such that it incorporates the relevant sections described in these guidelines.

1.13. Content of the technical documentation

The technical documentation shall be submitted as **Table of content (ToC)** format

The ToC comprises of **6 chapters** as well as **subchapters** which shall be compiled in a well-organized structure within the technical documentation as **one file** or **one folder** with all relevant sections. Files shall be presented in a searchable format so as to avoid unnecessary delays during the registration process.

Note: For chapters/ subchapters that are not applicable to a specific device, the applicant is requested to indicate "NA" and provide a brief explanation as to why the chapters/ subchapters are not applicable.

CHAPTER 1 – REGIONAL ADMINISTRATIVE	
1.01	**Cover Letter** The cover letter is provided under **Appendix 1**, it should be filled and signed by the applicant.
1.02	**Submission Table of Contents** The table of content should specify the page number for each item referred to in the technical file.
1.03	**List of Terms/Acronyms** In case specific terms or acronyms have been used in the technical file, they should be defined under this section.
1.04	**Application Form/Administrative Information** Application Form for Medical Devices and In Vitro Diagnostics Devices (IVDDs) registration is provided under **Appendix 3**, it should be filled and signed by the applicant.
1.05	**Listing of Device(s)** Where applicable, a table listing each variant/model/configuration/component/accessory that is the subject of the submission and the following information for each variant/model: a) the identifier (e.g. bar code, catalogue, model or part number, UDI) b) a statement of its name/description that provides (e.g. Trade name, size, material)
1.06	**Quality Management System, Full Quality System or Other Regulatory Certificates** Under this section, the applicant should provide a valid QMS audit (applicable for class C and D) issued by Rwanda FDA, or equivalent certificates from other competent authorities (i.e. ISO 13485, QMS

	certificates from other National Regulatory Authroties,…)
1.07	**Free Sale Certificate/ Certificate of Marketing authorization** The applicant should provide the following: -List of the Regulatory Authorities that have provided current regulatory approval for the supply of this product in their country/region of authority -Details of the type of regulatory approval obtained from each Regulatory Authority -Current evidence of the regulatory approval, such as certificates provided by the Regulatory Authority
1.08	**Expedited Review Documentation** This section applies for applications of WHO prequalified devices, and devices registered in countries with which Rwanda FDA has signed Memorandum of understanding. Under this section, the applicant should state whether the submitted application falls under one of the two cases above
1.09	**User Fees** To be paid after submission of the dossier in the portal
1.10	**Pre-Submission Correspondence and Previous Regulator Interactions** Where applicable/relevant, the applicant will be requested to submit a List prior submission or pre-submissions where regulator feedback was provided
1.11	**Acceptance for Review Checklist** Where applicable
1.12	**Statements/Certifications/Declarations of Conformity** Under this section, the applicant should provide a Declaration of Conformity (DoC), dated and signed by the manufacturer. The DoC should contain at least the following information: Manufacturer's Information, Authorized Representative (if applicable), Medical Device Information, Risk classification, Statement of Conformity which should include Applicable Regulations or Standards

1.12.01	**Performance and Voluntary Standard** Where applicable
1.12.02	**Environmental Assessment** This section is only applicable for devices that present new environmental concerns. The applicant should provide an environment assessment
1.12.03	**Clinical Trial Certifications** where applicable
1.12.04	**Indications for Use Statement with Rx and/or OTC designation Enclosure** This information should figure on the IFU
1.12.05	**Truthful and Accurate Statement** Not applicable
1.12.06	**USFDA Class III Summary and Certification** Not applicable
1.12.07	**Declaration of Conformity**
1.13	**Letters of Reference** Where applicable, letter from the owner of any separate document referenced in the submission (e.g. Master File or previous regulatory submission), granting access to the information in the referenced document. The letter should include the information of the applicant who cited the separate document (e.g. Master File or previous regulatory submission), the product name, the document number that has been filed, and the page number/chapter information of the separate document authorized to be cited.
1.14	**Letter of Authorization** Under this section, a letter of authorization from the manufacturer authorizing the Local Technical Representative to submit the application to Rwanda FDA. The letter should clearly highlight the responsibility of the LTR.

1.15	**Other Regional Administrative Information** Not applicable
CHAPTER 2 – SUBMISSION CONTEXT	
2.01	**Chapter Table of Contents** Under this chapter, the applicant should include the following: -All headings and sub-headings for chapter 2 -Specify the page number for each item referred to in the table.
2.02	**General Summary of Submission** The applicant should provide a summary of the following: -Trade name, proprietary name - Statement of the device type (e.g. Tacrolimus test system, blood specimen collection device, calibrator) -The device's general purpose, -The type of submission (e.g. new, change of existing application (reason, description of change, renewal)
2.03	**Summary and Certifications for Regulatory Submissions** Where applicable
2.04	**Device Description** The content of this chapter should be captured in the subsections below
2.04.01	**Comprehensive Device Description and Principle of Operation** The applicant should provide the following under this subsection: -A general description of the device, including: • A statement of the device name • What the device does • Who uses it and for what? • Where to use the device (places/environment) • General description of the principle of the assay method or instrument principles of operation. • Description of the components (e.g. reagents, assay controls, calibrators, cassette, etc.) and where appropriate, a description of the reactive ingredients of relevant components (such as antibodies, antigens, nucleic acid primers, probes, etc.). • If applicable, labelled pictorial representation (diagrams,

	photos, drawings). • If system, how the components relate • If applicable, identify if the device incorporates software/firmware and its role • If applicable, identify the instrument(s) required to perform the test. -Product specification, including: i. Physical characteristics of relevance to the end user (dimensions, weight) ii. If applicable, technical features and operating modes iii. If applicable, operating specifications and performance characteristics (e.g. electrical power requirements, settings and associated allowable ranges/limits, units of measure, temperature and humidity limits, throughput (number of tests per hour), analytical and clinical sensitivity and specificity) iv. If applicable, a complete list of the configurations/models of the devices and a summary of the differences in specifications (comparison table and/or pictures/diagrams with supporting text). - Describe the different specimen types that can be used for this device (e.g. serum, plasma, urine, cerebrospinal fluid), including any additives that are required (e.g. anticoagulant). - Describe the use of controls. If applicable, a list of compatible control materials or control material specifications. - Description of the accessories, other IVD or non-IVD medical devices and other products, which are intended to be used in combination with the IVD medical device. - If approved by the regulator, provide the approval number and identification for each of the accessories, other IVD or non-IVD medical devices and other products, which are intended to be used in combination with the IVD medical device. - If applicable, indication of biological material or derivate used in the medical device, including: origin (human, animal, recombinant or fermentation products or any other biological material) and source (e.g.

	blood, bone, heart, any other tissue or cells). Where a significant risk is identified, a brief summary of evaluations performed to minimize biological risks, in particular, with regard to viruses and other transmissible agents - Description of the collection and/or transport container(s) provided with the IVD medical device or a description of specifications or recommended collection and/or transport container(s). - If applicable, a listing of assays that are compatible with the instrument. - If applicable, a listing of compatible instruments. - A list of any software to be used with the IVD medical device and a description of its role in the delivery of the intended purpose. - If applicable, engineering diagrams/prints/schematics of the device (should be provided as a separate file within the submission). **Note** : The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the comprehensive device description and principles of operations provided in this section regarding the subject device.
2.04.02	**Description of Device Packaging** The following information should be provided: - Details of relevant material identifications and specifications, including critical raw materials and components. Information should include complete chemical and physical characterization of all component materials. Note: If applicable, chemicals should be identified using either the IUPAC (International Union of Pure and Applied Chemistry) or the CAS (Chemical Abstract Service) Registry number. Reference to applicable material standards may also be useful in this description.
2.04.03	Description of Device Packaging The applicant should provide the following information: -A brief description of the packaging of the devices, including the packaging configuration and materials involved. This is not intended to include shipping/transport packaging.

<table>
<tr><td></td><td>-Specific packaging of accessories marketed together with the IVD medical devices shall also be described.</td></tr>
<tr><td>2.04.04</td><td>History of Development

Where the information is available, the applicant should provide the following information:
-A table describing preferably with 4 columns as below:
<table>
<tr><td>Device Name and/or Version</td><td>Description of changes from previous row</td><td>motivation for the change</td><td>list of verification/validation activities, including clinical studies, conducted using this version</td></tr>
</table>

-Where applicable, for any design verification or validation activities presented in this submission (including clinical studies) performed on any earlier versions of the subject device, include a justification for why the changes do not impact the validity of the data collected under those activities in supporting the safety and performance of the final IVD medical device design.</td></tr>
<tr><td>2.04.05</td><td>Reference and Comparison to Similar and/or Previous Generations of the Device

The applicant should provide the following information:
• A list of the similar devices (available on local and international market) and/or previous generation of the devices (if existent) relevant to the submission. This should include any similar/previous generation devices that were previously reviewed and refused by the subject regulator.
• Description of why they were selected.
• A key specification comparison, preferably in a table, between the references (similar and/or previous generation) considered and the device</td></tr>
<tr><td>2.04.06</td><td>Substantial Equivalence Discussion
Not applicable</td></tr>
<tr><td>2.05</td><td>Indications for Use and/or Intended Use and Contraindications
The content of this chapter should be captured in the subsections below</td></tr>
<tr><td>2.05.01</td><td>Intended Use; Intended Purpose; Intended User; Indications for Use</td></tr>
</table>

	This section should include the following information (If more than one device is included, the information should be provided for each device) as appropriate: **-Intended Use:** The statement of intended use should specify what specific disorder, condition, or risk factor of interest (i.e. the analyte to be measured) is detected and the purpose provided by the device (e.g. screening, monitoring, diagnosis or aid to diagnosis). It should identify: i. Instruments on which the device can be used, ii. if the assay is automated or not, iii. is the IVD medical device qualitative or quantitative, iv. and the specimen types (e.g. serum, plasma, urine, cerebrospinal fluid), including any additives that are required (e.g. anticoagulant) **-Intended user:** Lay person or professional? -Identify if the device is intended for **single or multiple use** **-Indications for Use:** • Disease or medical condition that the device will diagnose, treat, prevent, mitigate, or cure, parameters to be monitored and other considerations related to indication for use. • If applicable, information about patient selection criteria. • If applicable, when/where the use of the IVD medical device should be avoided. • If applicable, information about intended patient population (e.g. adults, pediatrics or newborn) or a statement that no subpopulations exist for the disease or condition for which the device is intended. - For amendments/supplements or changes to existing approvals, identify any **changes to the previously approved intended use/intended purpose/intended user/indications.** If there are no changes, this should be stated and a reference should be made to the precise regional regulatory tracking number associated with the previous submission/approval. **Notes:** i. The statements of intended use and indications for use must be as presented in the labelling. ii. If more than one device is included, the information should be provided for each device
2.05.02	**Intended Environment/Setting for use** The applicant should provide the following information under this subsection - The setting where the device is intended to be used (e.g. home use,

	domestic use, self-testing, near-patient, point of care). Multiple options can be indicated. - If applicable, environmental conditions that can affect the device's safety and/or performance (e.g. temperature, humidity, power, pressure, movement)
2.05.03	**Pediatric Use** Where applicable the applicant should provide the following: Description of any pediatric subpopulations that suffer from the disease or condition that the device is intended to treat, diagnose or cure,
2.05.04	**Contraindications For Use** If applicable, provide a statement that specifies the disease or medical conditions that would make use of the device inadvisable due to unfavorable risk/benefit profile. Note: The statement of contraindications for the device must be as presented in the labelling.
2.06	**Global Market History** The content of this chapter should be captured in the subsections below
2.06.01	**Global Market History** The applicant should provide and up to date list of the markets (all countries or jurisdictions) where the device is approved for marketing, and include as well a list of all countries in which the device has been removed from marketing and explain the reason for removal.
2.06.02	**Incident Reports and Recalls** The applicant should provide the following information: - List adverse events/incidents associated with the device and a statement of the period associated with this data. - If the number of events is voluminous, provide a summary by event type that state the number of reported events for each event type. - List of the IVD medical device recalls and/or advisory notice, and a discussion of the handling and solution given by the manufacturer in each case.

	- A description of any analysis and/or corrective actions undertaken in response to items listed above. - If there have been no adverse events/incidents, recalls and/or advisory notice to date, provide an attestation from device owner on company letterhead, that there have been no adverse events/incidents, recalls and/or advisory notice since commercial introduction of the device. Note: It is acknowledged that the definition of recall may vary from one jurisdiction to another; hence this heading is labelled as regionally focused (RF).
2.06.03	**Sales, Incident and Recall Rates** Where available, a summary of the number of units sold in each country/region, incident rate, recall rate and a statement of the period associated with this data should be provided.
2.06.04	**Evaluation/Inspection Reports** Where available or where deemed necessary by the Authority, the applicant should provide copies of full audit reports and technical reports issued by other parties (e.g. Notified Body certification reports).
2.07	**Post-Market Study Plans** The information to be provided under this subchapater are found in the subchapters below
2.07.01	**Post-Market Study Plans** The applicant should provide the Post-Market Study Plans, which may include clinical or nonclinical study plans. The documentation provided here will not include final reports and analysis, and instead includes study plan information only. This may include the following • Study Objectives • Study Design • Subjects and Sites information • Endpoints (primary and secondary) • Summary of Data Analysis plan • Length and frequency of follow-up
2.07.02	**Real World Data** The applicant may conduct other clinical experience data/real world data

	(including device registries, post-market studies conducted in other jurisdictions)
2.08	**Risk Management** The applicant should provide the following information: -A summary of the risks identified during the risk analysis process and how these risks have been controlled to an acceptable level. -The results of the risk analysis should provide a conclusion with evidence that remaining risks are acceptable when compared to the benefits. -Where a standard is followed, identify the standard.
2.09	**Essential Principles (EP) Checklist** The applicant should duly fill in the EP checklist (**Appendix 4**),
2.10	**Standards** No content at this level
2.10.01	**List of Standards and Guidance Documents** The list of standards complied to can be submitted together with the Essential Principles Checklist.
2.10.02	**Declaration and/or Certification of Conformity** The applicant is advised to prepare the Declaration of Conformity to recognized standards, if not submitted in chapter 1.
2.11	**Other Submission Context Information**
CHAPTER 3 – NON-CLINICAL EVIDENCE	
3.01	**Chapter Table of Contents** Under this chapter, the applicant should include the following: -All headings and sub-headings for chapter 3 -Specify the page number for each item referred to in the table.
3.02	**Chapter Retired**

3.03	**Chapter Retired**
3.04	**Chapter Retired**
3.05	**Analytical Performance** Information under this subchapter should be provided under the subchapters below
3.05.01	**Stability of Specimen(s)** The applicant should provide the following under this subchapter: - Information regarding and studies to support the stability, storage and where appropriate, transport, of all of the specimen type(s) identified in the labelling, including any and all recommended additives (e.g. anticoagulants) is to be provided in this section. This should include: • For each specimen type identified in the labelling, a description of the recommended storage parameters and when applicable, transport conditions (e.g. duration, temperatures and freeze/thaw cycles). • A justification on the selection of the studies performed. • Provide summary of the evidence that falls within this category. • A discussion and a conclusion to support why the evidence presented is sufficient to support the application. Note: In case this subchapter is not applicable, the applicant should provide a statement of why this category of non-clinical study is not applicable to this case.
3.05.01.01	**Study description, study identifier, date of initiation, date of completion** Where applicable, the applicant should provide a separate entry for each study conducted on the device. For each study, provide: • Study description • Study identifier • Date of initiation and date of completion
3.05.01.01.01	**Summary** The applicant should provide a summary(ies) of the specific study(ies) provided and described in the subchapter above
3.05.01.01.02	**Full Report** The applicant should include test report(s) for the study/test(s) described in

	the subchapter above.
3.05.01.01.03	**Statistical Data** Where available, the applicant should provide statistical data associated with the study(ies)/tests described in the subchapter above
3.05.02	**Validation of Specimens** The applicant should provide the following, where applicable. Studies to support the validity of specimen type(s) used in the analytical and clinical studies as representative of all of the sample type(s) identified in the labelling, including any and all recommended additives (e.g. anticoagulants), as well as contrived specimens used in certain analytical studies. This should include: - A list of the specimen type(s) used, including any additives (e.g. anticoagulants), in each of the analytical performance studies. If the same specimens are used for all analytical studies this can be stated and the specimen type identified. - For any or all of the analytical and clinical studies, if a particular specimen type(s) including additives (e.g. anticoagulants), has been chosen as representative of other specimen types identified in the labelling, this should be described and supported. - If the preparation of the specimen has not followed the protocol described in the current labelling, this should be identified and validated. - A justification of the selection of the studies performed. - Provide summary of the evidence that falls within this category. - A discussion and a conclusion to support why the evidence presented is sufficient to support the application. Note: In case this subchapter is not applicable, the applicant should provide a statement of why this category of non-clinical study is not applicable to this case.
3.05.02.01	**Study description, study identifier, date of initiation, date of completion** Where applicable, the applicant should provide a separate entry for each study

	conducted on the device. For each study, provide: • Study description • Study identifier • Date of initiation and date of completion
3.05.02.01.01	**Summary** The applicant should provide a summary(ies) of the specific study(ies) provided and described in the subchapter above
3.05.02.01.02	**Full Report** The applicant should include test report(s) for the study/test(s) described in the subchapter above.
3.05.02.01.03	**Statistical Data** Where available, the applicant should provide statistical data associated with the study(ies)/tests described in the subchapter above
3.05.03	**Metrological traceability of calibrator and control material values** Evidence that supports the metrological traceability of values assigned to calibrators and trueness control materials. This should include: • A description of all calibrators and trueness control materials associated with the system. • A justification of the selection of the studies performed. • Provide summary of the evidence that falls within this category, including for example, methods and acceptance criteria for the metrological traceability to reference materials and/or reference measurement procedures and a description of value assignment and validation. • A discussion and a conclusion to support why the evidence presented is sufficient to support the application. Notes: - Precision control materials used during analytical studies to establish the reproducibility of a measurement procedure do not require the assessment of metrological traceability to a reference material or a reference method. - In case this subchapter is not applicable, the applicant should provide a statement of why this category of non-clinical study is not applicable to this case.

3.05.03.01	**Study description, study identifier, date of initiation, date of completion** Where applicable, the applicant should provide a separate entry for each study conducted on the device. For each study, provide: • Study description • Study identifier • Date of initiation, date of completion
3.05.03.01.01	**Summary** The applicant should provide a summary(ies) of the specific study(ies) provided and described in the subchapter above
3.05.03.01.02	**Full Report** The applicant should include test report(s) for the study/test(s) described in the subchapter above.
3.05.03.01.03	**Statistical Data** Where available, the applicant should provide statistical data associated with the study(ies)/tests described in the subchapter above
3.05.04	**Accuracy of Measurement** Information under this subchapter should be provided under the subchapters below Note: The general term measurement accuracy is currently used to cover both trueness and precision, whereas this term was used in the past to cover only the one component now named trueness. While measurement trueness, affected by systematic error, is normally expressed in terms of bias, measurement precision, affected by random error, is naturally expressed in terms of standard deviation. Accuracy is affected by a combination of systematic and random effects that contribute as individual components of the total error of measurement.
3.05.04.01	**Trueness** This section should provide a summary of information and evidence relating to the trueness of the measurement procedure. Trueness measures apply to both quantitative and qualitative assays only when a reference standard or method is available. This should include: a) A rationale for the reference standard or method(s) used b) A summary of the evidence that falls within this category c) A discussion and a conclusion to support why the evidence presented is

	sufficient to support the application. Note: In case this subchapter is not applicable, the applicant should provide a statement of why this category of non-clinical study is not applicable to this case.
3.05.04.01.01	**Study description, study identifier, date of initiation, date of completion** Where applicable, the applicant should provide a separate entry for each study conducted on the device. For each study, provide: • Study description • Study identifier • Date of initiation, date of completion
3.05.04.01.01.01	**Summary** The applicant should provide a summary(ies) of the specific study(ies) provided and described in the subchapter above
3.05.04.01.01.02	**Full Report** The applicant should include test report(s) for the study/test(s) described in the subchapter above.
3.05.04.01.01.03	**Statistical Data** Where available, the applicant should provide statistical data associated with the study(ies)/tests described in the subchapter above
3.05.04.02	**Precision (Repeatability and Reproducibility)** A summary of evidence that supports the precision characteristics of the measurement of the subject IVD medical device is to be included in this section. This should include: - A justification of the selection of the studies performed. - A summary of the evidence that falls within this category, including: • Repeatability estimates and a brief summary about the studies used to estimate, as appropriate, within-run variability. • Reproducibility estimates and a brief summary of the studies used to estimate, as appropriate, variability between days, runs, sites, lots, operators (intended users) and instruments. Such variability is also known as “Intermediate Precision”. - A discussion and a conclusion to support why the evidence presented is sufficient to support the application. Note:

	- Studies should include the use of specimens that represent the full range of expected analyte (measured) concentrations that can be measured by the product, as claimed by the manufacturer. - In case this subchapter is not applicable, the applicant should provide a statement of why this category of non-clinical study is not applicable to this case.
3.05.04.02.01	**Study description, study identifier, date of initiation, date of completion** Where applicable, the applicant should provide a separate entry for each study conducted on the device. For each study, provide: • Study description • Study identifier • Date of initiation, date of completion
3.05.04.02.01.01	**Summary** The applicant should provide a summary(ies) of the specific study(ies) provided and described in the subchapter above
3.05.04.02.01.02	**Full Report** The applicant should include test report(s) for the study/test(s) described in the subchapter above.
3.05.04.02.01.03	**Statistical Data** Where available, the applicant should provide statistical data associated with the study(ies)/tests described in the subchapter above
3.05.05	**Analytical Sensitivity** The applicant should submit an evidence that supports the analytical sensitivity of the subject IVD medical device in this section. This may include studies to establish the limit of blank (LoB), limit of detection (LoD), and/or limit of quantitation (LoQ). This should include: • A justification of the selection of the studies performed. • A summary of the evidence that falls within this category • A discussion and a conclusion to support why the evidence presented is sufficient to support the application. Note: In case this subchapter is not applicable, the applicant should provide a statement of why this category of non-clinical study is not applicable to this case

3.05.05.01	**Study description, study identifier, date of initiation, date of completion** Where applicable, the applicant should provide a separate entry for each study conducted on the device. For each study, provide: • Study description • Study identifier • Date of initiation, date of completion
3.05.05.01.01	**Summary** The applicant should provide a summary(ies) of the specific study(ies) provided and described in the subchapter above
3.05.05.01.02	**Full Report** The applicant should include test report(s) for the study/test(s) described in the subchapter above.
3.05.05.01.03	**Statistical Data** Where available, the applicant should provide statistical data associated with the study(ies)/tests described in the subchapter above
3.05.06	**Analytic Specificity** The applicant should provide evidence that supports the analytical specificity (interference, including as appropriate, selectivity, and cross reactivity) of the subject IVD medical device. This should include: • A justification of the selection of the studies performed. • A summary of the evidence that falls within this category • A discussion and a conclusion to support why the evidence presented is sufficient to support the application. Note: In case this subchapter is not applicable, the applicant should provide a statement of why this category of non-clinical study is not applicable to this case
3.05.06.01	**Study description, study identifier, date of initiation, date of completion** Where applicable, the applicant should provide a separate entry for each study conducted on the device. For each study, provide: • Study description • Study identifier

	Date of initiation, date of completion
3.05.06.01.01	**Summary** The applicant should provide a summary(ies) of the specific study(ies) provided and described in the subchapter above
3.05.06.01.02	**Full Report** The applicant should include test report(s) for the study/test(s) described in the subchapter above.
3.05.06.01.03	**Statistical Data** Where available, the applicant should provide statistical data associated with the study(ies)/tests described in the subchapter above
3.05.07	**High Dose Hook Effect** The applicant should provide the evidence that supports the absence of a high dose hook effect or prozone effect. This should include: • A justification of the selection of the studies performed. • A summary of the evidence that falls within this category • A discussion and a conclusion to support why the evidence presented is sufficient to support the application. Note: In case this subchapter is not applicable, the applicant should provide a statement of why this category of non-clinical study is not applicable to this case
3.05.07.01	**Study description, study identifier, date of initiation, date of completion** Where applicable, the applicant should provide a separate entry for each study conducted on the device. For each study, provide: • Study description • Study identifier Date of initiation, date of completion
3.05.07.01.01	**Summary** The applicant should provide a summary(ies) of the specific study(ies) provided and described in the subchapter above
3.05.07.01.02	**Full Report**

	The applicant should include test report(s) for the study/test(s) described in the subchapter above.
3.05.07.01.03	**Statistical Data** Where available, the applicant should provide statistical data associated with the study(ies)/tests described in the subchapter above
3.05.08	**Measuring Range of the Assay** Evidence that supports the measuring range (linear and non-linear measuring systems) should be provided . This measuring range should include the lower limit of quantification. This should include: • A justification of the selection of the studies performed. • A summary of the evidence that falls within this category • A discussion and a conclusion to support why the evidence presented is sufficient to support Note: In case this subchapter is not applicable, the applicant should provide a statement of why this category of non-clinical study is not applicable to this case
3.05.08.01	**Study description, study identifier, date of initiation, date of completion** Where applicable, the applicant should provide a separate entry for each study conducted on the device. For each study, provide: • Study description • Study identifier Date of initiation, date of completion
3.05.08.01.01	**Summary** The applicant should provide a summary(ies) of the specific study(ies) provided and described in the subchapter above
3.05.08.01.02	**Full Report** The applicant should include test report(s) for the study/test(s) described in the subchapter above.
3.05.08.01.03	**Statistical Data**

	Where available, the applicant should provide statistical data associated with the study(ies)/tests described in the subchapter above
3.05.09	**Validation of Assay Cut-off** The applicant should provide evidence that supports the determining assay cut-off is. This should include: • A justification of the selection of the studies performed. • A summary of the evidence that falls within this category • A discussion and a conclusion to support why the evidence presented is sufficient to support the application. Note: In case this subchapter is not applicable, the applicant should provide a statement of why this category of non-clinical study is not applicable to this case
3.05.09.01	**Study description, study identifier, date of initiation, date of completion** Where applicable, the applicant should provide a separate entry for each study conducted on the device. For each study, provide: • Study description • Study identifier Date of initiation, date of completion
3.05.09.01.01	**Summary** The applicant should provide a summary(ies) of the specific study(ies) provided and described in the subchapter above
3.05.09.01.02	**Full Report** The applicant should include test report(s) for the study/test(s) described in the subchapter above.
3.05.09.01.03	**Statistical Data** Where available, the applicant should provide statistical data associated with the study(ies)/tests described in the subchapter above
3.05.10	**Validation of the Assay Procedure** The applicant should submit a summary of information and evidence supporting the validity of the assay procedure in terms of important reaction

	conditions (e.g. reaction time, reaction temperature, reagent volume, reading time). This should include: • A justification of the selection of the studies performed. • A summary of the evidence that falls within this category • A discussion and a conclusion to support why the evidence presented is sufficient to support the application. Note: In case this subchapter is not applicable, the applicant should provide a statement of why this category of non-clinical study is not applicable to this case
3.05.10.01	**Study description, study identifier, date of initiation, date of completion** Where applicable, the applicant should provide a separate entry for each study conducted on the device. For each study, provide: • Study description • Study identifier Date of initiation, date of completion
3.05.10.01.01	**Summary** The applicant should provide a summary(ies) of the specific study(ies) provided and described in the subchapter above
3.05.10.01.02	**Full Report** The applicant should include test report(s) for the study/test(s) described in the subchapter above.
3.05.10.01.03	**Statistical Data** Where available, the applicant should provide statistical data associated with the study(ies)/tests described in the subchapter above
3.06	**Other studies** The content under this subchapter can be provided under the subchapters below
3.06.01	**Electrical Systems: Safety, Mechanical and Environmental Protection, and Electromagnetic Compatibility** Evidence supporting electrical safety, mechanical and environmental protection, and electromagnetic compatibility are to be included in this

	section. This should include: • A justification of the selection of the studies performed. • A summary of the evidence that falls within this category • A discussion and a conclusion to support why the evidence presented is sufficient to support the application. Note: In case this subchapter is not applicable, the applicant should provide a statement of why this category of non-clinical study is not applicable to this case
3.06.01.01	**Study description, study identifier, date of initiation, date of completion** Where applicable, the applicant should provide a separate entry for each study conducted on the device. For each study, provide: • Study description • Study identifier Date of initiation, date of completion
3.06.01.01.01	**Summary** The applicant should provide a summary(ies) of the specific study(ies) provided and described in the subchapter above
3.06.01.01.02	**Full Report** The applicant should include test report(s) for the study/test(s) described in the subchapter above.
3.06.01.01.03	**Statistical Data** Where available, the applicant should provide statistical data associated with the study(ies)/tests described in the subchapter above
3.06.02	**Software/Firmware/Programmed or programmable medical** The applicant should include Studies and supporting information on the software design, development process and evidence of the validation of the software, as used in the finished IVD medical device, and the associated sub-sections. It should also address all of the different hardware configurations and, where applicable, operating systems identified in the labelling
3.06.02.01	**Software/Firmware Description** The applicant should provide the following information:

	• Specify the name of the software • Specify the version of the software - The version tested must be clearly identified and should match the release version of the software, otherwise justification must be provided. • A description of the software including the identification of the IVD medical device features that are controlled by the software, the programming language, hardware platform, operating system (if applicable), use of Off-the-shelf software (if applicable), a description of the realization process. • A statement about software version naming rules; specify all fields and their meanings.
3.06.02.02	**Hazard Analysis** The Hazard Analysis should take into account all device hazards associated with the IVD medical device's intended use, including both hardware and software hazards. Note: i. This document can be in the form of an extract of the software-related items from a comprehensive risk management documentation, described in ISO 14971. ii. Hazard analysis, should address all foreseeable hazards, including those resulting from intentional or inadvertent misuse of the IVD medical device.
3.06.02.03	**Software Requirement Specification** Under this chapter, the applicant should provide the Software Requirements Specification (SRS) documents for the software. This typically includes functional, performance, interface, design, developmental, and other requirements for the software. In effect, this document describes what the Software Device is supposed to do. For example, hardware requirements, programming language requirement, interface requirements, performance and functional requirements.
3.06.02.04	**Architecture Design Chart** Detailed depiction of functional units and software modules. May include state diagrams as well as flow charts.
3.06.02.05	**Software Design Specification** The Software Design Specification (SDS) describes the implementation of the requirements for the Software Device. The SDS describes how the

	requirements in the SRS are implemented.
3.06.02.06	**Traceability Analysis** A Traceability Analysis links together your product design requirements, design specifications, and testing requirements. It also provides a means of tying together identified hazards with the implementation and testing of the mitigations.
3.06.02.07	**Software Life Cycle Process Description** A summary describing the software development life cycle and the processes that are in place to manage the various life cycle activities.
3.06.02.08	**Software Verification and Validation** Under this subchapter the applicant should provide the following : • An overview of all verification, validation and testing performed prior to final release • For each test presented, identify the testing environment (e.g. in-house, in a simulated or actual user environment). • Discussion to support why the evidence presented is sufficient to support the application Note: i. Discussion should address all of the different hardware configurations and, where applicable, operating systems identified in the labelling. ii. In case this subchapter is not applicable, the applicant should provide a statement of why this category of non-clinical study is not applicable to this case
3.06.02.08.01	**Study description, study identifier, date of initiation, date of completion** Where applicable, the applicant should provide a separate entry for each study conducted on the device. For each study, provide: • Study description • Study identifier Date of initiation, date of completion
3.06.02.08.01.01	**Summary** The applicant should provide a summary(ies) of the specific study(ies) provided and described in the subchapter above
3.06.02.08.01.02	**Full Report**

	The applicant should include test report(s) for the study/test(s) described in the subchapter above.
3.06.02.08.01.03	**Statistical Data** Where available, the applicant should provide statistical data associated with the study(ies)/tests described in the subchapter above
3.06.02.09	**Revision Level History** Revision history log, including release version number and date.
3.06.02.10	**Unresolved Anomalies (Bugs or Defects)** All unresolved anomalies in the release version of the software should be summarized, along with a justification for acceptability (i.e. the problem, impact on safety and performance, and any plans for correction of the problems).
3.06.02.11	**Cybersecurity** Evidence to support the cybersecurity should be provided here. For example, but not limited to: • Cybersecurity risk management documentation, including traceability matrix linking cybersecurity controls to the cybersecurity vulnerabilities and risks • List of Cybersecurity control measures • Security test documentation to verify the security of the device and the effectiveness of any security controls Device's maintenance plan describing the post-market processes to ensure the continued safety and performance of the device throughout its lifecycle
3.06.02.12	**Interoperability** Evidence to support the interoperability should be provided, If the IVD medical device can communicate with other devices
3.06.03	**Cleaning and Disinfection Validation** Contains information on the validation of cleaning and disinfection instructions for reusable devices, including evidence to support maintenance of performance when subject to this procedure over a number of cycles that is representative of the IVD medical device's expected useful life. Information to be included in this section includes:

	• If applicable, a discussion of how the number of cycles that is representative of the IVD medical device's expected useful life has been determined. • A justification of the selection of the studies performed. • A summary of the evidence that falls within this category • A discussion and a conclusion to support why the evidence presented is sufficient to support the application. Notes: i. This applies most typically to devices intended for Point of care and/or home use (near patient testing) involving whole blood. ii. In case this subchapter is not applicable, the applicant should provide a statement of why this category of non-clinical study is not applicable to this case
3.06.03.01	**Study description, study identifier, date of initiation, date of completion** Where applicable, the applicant should provide a separate entry for each study conducted on the device. For each study, provide: • Study description • Study identifier Date of initiation, date of completion
3.06.03.01.01	**Summary** The applicant should provide a summary(ies) of the specific study(ies) provided and described in the subchapter above
3.06.03.01.02	**Full Report** The applicant should include test report(s) for the study/test(s) described in the subchapter above.
3.06.03.01.03	**Statistical Data** Where available, the applicant should provide statistical data associated with the study(ies)/tests described in the subchapter above
3.06.04	**Usability/Human Factors** Studies specifically assessing the instructions and/or IVD medical device design in terms of impact of human behavior, abilities, limitations, and other characteristics on the ability of the IVD medical device to perform as intended should be included here. This should include: • State the test environment and relation to the intended use environment

	• A justification of the selection of the studies performed. • A summary of the evidence that falls within this category • A discussion and conclusion to support why the evidence presented is sufficient to support the application. **Notes:** i. If a clinical study has been conducted that includes usability/human factors endpoints, **reference to the studies and endpoints should be made, but full results do not need to be repeated and should be included in Chapter 4 – Clinical Evidence.** ii. In case this subchapter is not applicable, the applicant should provide a statement of why this category of non-clinical study is not applicable to this case
3.06.04.01	**Study description, study identifier, date of initiation, date of completion** Where applicable, the applicant should provide a separate entry for each study conducted on the device. For each study, provide: • Study description • Study identifier Date of initiation, date of completion
3.06.04.01.01	**Summary** The applicant should provide a summary(ies) of the specific study(ies) provided and described in the subchapter above
3.06.04.01.02	**Full Report** The applicant should include test report(s) for the study/test(s) described in the subchapter above.
3.06.04.01.03	**Statistical Data** Where available, the applicant should provide statistical data associated with the study(ies)/tests described in the subchapter above
3.06.05	**Stability of the IVD** The information under this subchapter should be provided in the subchapters below
3.06.05.01	**Claimed Shelf-life**

	The applicant should provide evidence supporting the claimed shelf-life of the IVD medical device components (e.g. reagents, calibrators/reference materials, control material, any other components susceptible to degradation). Information provided in this section should include: • A description of recommended environmental conditions for storage of the IVD medical IVD medical device (e.g. temperature, pressure, humidity, light conditions). • A statement of the claimed shelf-life indicated as a period of time or any other means of appropriate quantification. • An indication of the packaging used in any studies conducted in support of the shelf-life. If the packaging used in the studies differs from the final device packaging, a discussion of why the evidence can be consider valid in support of the claimed shelf-life. • A description of the simulated transport conditions that the IVD was exposed to before the start of shelf-life studies. • A justification of the selection of the studies performed. • A summary of the evidence that falls within this category • A discussion and a conclusion to support why the evidence presented is sufficient to support the claimed shelf-life. **Note:** In case the above is not provided, the applicant should provide a rationale that, for an indefinite period, the storage conditions could not affect IVD medical device safety or performance.
3.06.05.01.01	**Study description, study identifier, date of initiation, date of completion** Where applicable, the applicant should provide a separate entry for each study conducted on the device. For each study, provide: • Study description • Study identifier Date of initiation, date of completion
3.06.05.01.01.01	**Summary** The applicant should provide a summary(ies) of the specific study(ies) provided and described in the subchapter above
3.06.05.01.01.02	**Full Report** The applicant should include test report(s) for the study/test(s) described in the subchapter above.
3.06.05.01.01.03	**Statistical Data** Where available, the applicant should provide statistical data associated with

	the study(ies)/tests described in the subchapter above
3.06.05.02	**In Use Stability** Contains details and evidence supporting the stability during actual routine use of the IVD medical device (real or simulated), including all applicable components (e.g. reagents, reaction cartridges). This may include open vial stability and/or, for automated instruments, onboard stability. Information provided in this section should include: • A description of recommended environmental conditions for use of the IVD medical device (e.g. temperature, pressure, humidity, light conditions). • A justification of the selection of the studies performed. • A summary of the evidence, covering shelf-life period when stored at the proposed storage condition, that falls within this category • A discussion and a conclusion to support why the evidence presented is sufficient to support the application. **Note:** In case the above is not provided, the applicant should provide a rationale that, for an indefinite period, the storage conditions could not affect IVD medical device safety or performance.
3.06.05.02.01	**Study description, study identifier, date of initiation, date of completion** Where applicable, the applicant should provide a separate entry for each study conducted on the device. For each study, provide: • Study description • Study identifier Date of initiation, date of completion
3.06.05.02.01.01	**Summary** The applicant should provide a summary(ies) of the specific study(ies) provided and described in the subchapter above
3.06.05.02.01.02	**Full Report** The applicant should include test report(s) for the study/test(s) described in the subchapter above.
3.06.05.02.01.03	**Statistical Data** Where available, the applicant should provide statistical data associated with the study(ies)/tests described in the subchapter above

3.06.05.03	**Shipping Stability** The applicant should provide evidence supporting the tolerance of IVD medical device, or if provided separately, the components (e.g. reagents, calibrators/reference materials) to the specified or expected shipping conditions. Information provided in this section should include: • An indication of environmental conditions for correct shipment of the IVD medical device (temperature, pressure, humidity, light conditions, mechanical protection etc.). • A justification of the selection of the studies performed. • A summary of the evidence, covering shelf-life period, that falls within this category • A discussion and a conclusion to support why the evidence presented is sufficient to support the application. **Note:** In case the above is not provided, the applicant should provide a rationale that, for an indefinite period, the storage conditions could not affect IVD medical device safety or performance.
3.06.05.03.01	**Study description, study identifier, date of initiation, date of completion** Where applicable, the applicant should provide a separate entry for each study conducted on the device. For each study, provide: • Study description • Study identifier Date of initiation, date of completion
3.06.05.03.01.01	**Summary** The applicant should provide a summary(ies) of the specific study(ies) provided and described in the subchapter above
3.06.05.03.01.02	**Full Report** The applicant should include test report(s) for the study/test(s) described in the subchapter above.
3.06.05.03.01.03	**Statistical Data** Where available, the applicant should provide statistical data associated with the study(ies)/tests described in the subchapter above
3.07	**Analytical Performance and Other Evidence Bibliography**

	The applicant should provide the following: • A listing of published studies relevant to the context of this Chapter that involve this specific IVD medical device (e.g. analytical specificity, analytical sensitivity) • A legible copy of key articles, including translation where applicable to meet the regulators language requirements. • A discussion and a conclusion to support why the evidence presented is sufficient to support the application.
3.08	**Other Evidence** The applicant should provide heading for other information that may be important to the submission but that does not fit in any of the other headings of this chapter. For example, for tests performed to ensure the safety and/or performance of the IVD medical device that are not delineated in the rest of the Chapter 3. In addition a) Describe the purpose of the test, the risk/safety issue the test is addressing; the test methods and results of the test b) A justification of the selection of the studies performed. c) A summary of the evidence that is being submitted under this heading d) A discussion and a conclusion to support why the evidence presented is sufficient to support the application.
3.08.01	**Study description, study identifier, date of initiation, date of completion** Where applicable, the applicant should provide a separate entry for each study conducted on the device. For each study, provide: • Study description • Study identifier Date of initiation, date of completion
3.08.01.01	**Summary** The applicant should provide a summary(ies) of the specific study(ies) provided and described in the subchapter above
3.08.01.02	**Full Report** The applicant should include test report(s) for the study/test(s) described in the subchapter above.
3.08.01.03	**Statistical Data** Where available, the applicant should provide statistical data associated with

	the study(ies)/tests described in the subchapter above
CHAPTER 4 – CLINICAL EVIDENCE	
4.01	**Chapter Table of Contents** Under this chapter, the applicant should include the following: -All headings and sub-headings for chapter 4 -Specify the page number for each item referred to in the table.
4.02	**Overall Clinical Evidence Summary** In case clinical studies have been conducted, The applicant should provide the following: • A brief (1-2 page) summary of the available clinical evidence being presented in support of the submission. The document should list the evidence presented, its characteristics (e.g. well-controlled studies, partially controlled studies, studies and objective trials without matched controls, well-documented case histories conducted by qualified experts, literature review, post market data from another jurisdiction or from a marketed device)) and provide a discussion of how this is considered sufficient to support request for marketing for the requested indications. A tabular listing of clinical studies may be included in this section. • If any of the study IVD medical devices differ from the IVD medical devices to be marketed, including competitors' IVD medical devices, a description of these differences and their impact on the validity of the evidence in terms of support for the application. This may include a detailed comparison of the clinical, technical and biological characteristics of the two devices, with a detailed critical analysis demonstrating the devices to be similar to such an extent that there would be no clinically significant difference in safety or performance. • A discussion of the clinical evidence considered for the IVD medical device and support for their selection (i.e. what type of evidence was considered and why they were or were not used) • Discussion to support why the evidence presented is sufficient to support the application. Note: Human factors testing that include patients should be included here
4.02.01	**Expected Values/Reference Ranges** Under this section the applicant should include information on what values to expect in healthy normal patients versus affected patients.

4.02.02	**Clinical Evidence Evaluation Report** The applicant should provide the following information: • A clinical evidence evaluation report reviewed and signed by an expert in the relevant field that contains an objective critical evaluation of all of the clinical data submitted in relation to the IVD medical device. • A complete curriculum vitae, or similar documentation, to justify the manufacturer's choice of the clinical expert.
4.02.03	**IVD medical Device Specific Clinical Studies** In case clinical studies have been conducted Clinical study information under this heading should be provided and grouped by study
4.02.03.01	**Study description, protocol #, date of initiation, date of completion** Where applicable, the applicant should provide a separate entry for each study conducted on the device. For each study, provide: • Study description • Protocol number • Date of initiation, date of completion
4.02.03.01.01	**Clinical Study Summary** A summary of the specific study described in the custom heading above that includes: • The key characteristics of the study (e.g. title of study, investigators, sites, study period (date of enrollment/date of last completed), objectives, methods, statistical design, interpretation of design, # patients, inclusion/exclusion criteria) and • Summary of the results of the analysis • Summary of conclusions related to the endpoints Note: The sponsor/applicant should explicitly state whether the data are sex-, gender-, age-, race-, and ethnicity- disaggregated. If the data are not disaggregated, the sponsor/applicant should provide a rationale why.
4.02.03.01.02	**Clinical Study Report** A clinical study report of the specific study described in the custom heading above. Note: The clinical study report should include elements such as the

	investigational plan/study protocol, protocol changes and deviations, description of patients, data quality assurance, analysis/results.
4.02.02.01.03	**Clinical Study Data** The information under this subchapter may not be provided. However, where deemed necessary the Authority may request clinical study (s) raw data
4.02.03	**Clinical Literature Review and Other Reasonable Known Information** Where available, the applicant should provide the following details: • Clinical literature review that critically reviews available information that is published, available, or reasonably known to the applicant/sponsor that describes safety and/or performance of the IVD medical device • A legible copy of key articles, including translation where applicable to meet the regulators language requirements. **Note:** If the above is not available, the applicant should provide a statement that no literature related to the IVD medical device was found.
4.03	**Informed Consent Information** Any information related to informed consent in the collection of the clinical information used to support the submission, such as copies of Institutional Review Board-approved informed consent forms, is to be provided here.
4.04	**Investigators Sites and IRB contact information** Where applicable, the applicant should provide a list the clinical study sites including the name, description, and address.
4.05	**Other Clinical Evidence** Heading for other information that may be important to the submission but that does not fit in any of the other headings of this chapter
CHAPTER 5 – LABELLING AND PROMOTIONAL MATERIAL	
5.01	**Chapter Table of Contents**

	Under this chapter, the applicant should include the following: -All headings and sub-headings for chapter 5 -Specify the page number for each item referred to in the table.
5.02	**Product/Package Labels** The applicant should provide legible copies of the primary and secondary packaging labels. shipping labels should not be included under this subchapter
5.03	**Package Insert/Instructions for Use** The applicant should provide the Package Insert/Instructions for Use included in the package, when required or provide support for why this element is not applicable.
5.04	**e-labelling** where applicable, the applicant should provide the e-labelling itself, additionally, the following should be provided: • For eligible IVD medical devices and stand-alone software, the applicant needs to identify which form of e-labelling is being used in case of e-labelling (e.g. electronic storage system or built-in system, website). • Provide details of risk management in relation to e-labelling. If this is part of the overall risk management, refer to it here • A description of the procedure and operations on providing IFU's when requested • Provide written information for user Information on webpage where IFU and further information can be found in relevant languages. • Description on how the requirements detailed for the website have been met. • If a video/App is available to demonstrate how the test is to be performed and interpreted, provide a link as well as details about how it is maintained and updated throughout the life cycle of the device.
5.05	**Patient Labelling** Labelling directed at the patient other than the package insert, such as informational material written to be comprehended by the patient or lay caregiver

5.06	**Technical and/or Operators Manuals** Labelling directed to the technical users and operators of IVD medical devices focusing on the proper use and maintenance of the IVD medical device
5.07	**Product Brochures** The applicant should provide product brochures, catalogues containing devices (including claims) available for the user or available at the time of application
5.08	**Other Labelling and Promotional Material** The applicant is requested to provide other information that may be important to the submission but that does not fit in any of the other subchapters of this chapter.
CHAPTER 6 – QUALITY MANAGEMENT SYSTEM	
6.01	**Cover Letter** Under this subchapter, a cover Letter is only required when the submission includes quality system information.
6.02	**Chapter Table of Contents** Under this chapter, the applicant should include the following: -All headings and sub-headings for chapter 6 -Specify the page number for each item referred to in the table.
6.03	**Product Descriptive Information** The applicant should provide an abbreviated description of the device, operating principles and overall manufacturing methods. This section includes general information such as: • A description of the device, including pictures, and where possible, the proprietary name, common name, model number(s), product code, and intended use; and • A description of how the device works

	Note: Product Descriptive Information is only provided under this chapter when the submission includes quality system information and Chapter 2.04 "Device Description" is not provided as part of the submission.
6.04	**General Manufacturing Information** The following information should be provided: • Name, address, scope/role, and contact information for all sites where the device or its components are manufactured. • Description of any relationship between the facilities to the applicant when there is more than one involved in the manufacturing process for the applicable device. • Where applicable, addresses for all critical subcontractors, such as outsourced production, critical component, or raw material production (e.g. animal tissue, drugs), and sterilisation.
6.05	**Required Forms** Where applicable, an application form associated with Quality management Systems in the premarket review process should be filled out.
6.06	**Quality Management System** The applicant should provide high level quality management system documents, including procedures for establishing and maintaining the quality management system such as the quality manual, quality policy, quality objectives, and control of documents and records, as well as records providing evidence of conformance to requirements, and of the effective operation of the quality management system (when applicable). • ISO 13485 Elements– SOPs and device specific documentation to satisfy clause 4
6.07	**Management Responsibilities** The applicant should provide documents, including procedures that provide evidence of the management commitment to the establishment and maintenance of the QMS by addressing quality policy, planning, responsibilities/authority/communication and management review, as well as records providing evidence of conformance to requirements, and of the effective operation of the quality management system (when applicable).

	• ISO 13485 Elements – SOPs and device specific documentation to satisfy clause 5
6.08	**Resource Management** The applicant should provide documents, including procedures that provide evidence of the adequate provision of resources to implement and maintain the QMS including human resources, infrastructure, and work environment, as well as records providing evidence of conformance to requirements, and of the effective operation of the quality management system (when applicable). • ISO 13485 Elements – SOPs and device specific documentation to satisfy clause 6
6.09	**Planning of Product Realization and Customer Related Processes** High level product realization documents should be provided, including procedures such as those addressing planning and customer related processes, as well as records providing evidence of conformance to requirements, and of the effective operation of the quality management system (when applicable). Records demonstrating conformance to requirements are only provided under this chapter when the submission includes quality system information, and these records were not provided within the submission as part of a previous subchapter (e.g. as part of "Biocompatibility and Toxicology Evaluation" Chapter 3.05.06). • ISO 13485 Elements – SOPs and device specific documentation implementing sub clause 7.1 and 7.2
6.10	**Design and Development** The applicant should provide documents, including procedures that provide evidence of the systematic and controlled development of the device design from initiation of the project to transfer to production, as well as records providing evidence of conformance to requirements, and of the effective operation of the quality management system (when applicable). Records demonstrating conformance to requirements are only provided under this chapter when the submission includes quality system information, and these records were not provided within the submission as part of a previous subchapter (e.g. as part of "Biocompatibility and Toxicology Evaluation" Chapter 3.05.06). • ISO 13485 Elements – SOPs and device specific documentation

	implementing sub clause 7.3
6.11	**Purchasing** Documents, including procedures that provide evidence that purchased products/services conform to established quality and/or product specifications, as well as records providing evidence of conformance to requirements, and of the effective operation of the quality management system (when applicable). • ISO 13485 Elements – SOPs and device specific documentation implementing sub clause 7.4
6.12	**Production and Service Controls** The applicant should provide the manufacturing process for the IVD medical device should be provided in the form of a list of resources and activities that transform inputs to the desired output. • Information should include the appropriate manufacturing methods and procedures, manufacturing environment or condition, and the facilities and controls used for the manufacturing, processing, packaging, labeling, and storage. • Information on the manufacturing process should be provided in sufficient detail to allow a general understanding of the manufacturing processes and enable judgement of the appropriateness of the controls in place. Detailed proprietary information on the manufacturing process is not required. The information may be presented in the form of a process flow chart showing an overview of production, controls, assembly, final product testing and packaging of the finished medical device. If multiple facilities are involved in the manufacture of IVD medical device, • Applicable information for each facility must be submitted • Manufacturing activities carried out at each site should be clearly identified ISO 13485 Elements - SOPs and device specific documentation implementing sub clause 7.5
6.13	**Control of Monitoring and Measuring Equipment** The applicant should provide documents, including procedures that provide evidence of monitoring and measuring equipment used in the QMS is controlled and continuously performing per the established requirements, as

	well as records providing evidence of conformance to requirements, and of the effective operation of the quality management system (when applicable). • ISO 13485 Element - SOPs and device specific documentation for implementing sub clause 7.6
6.14	**QMS Measurement, Analysis and Improvement** The applicant should provide documents, including procedures that provide evidence of how monitoring, measurement, analysis and improvement to ensure the conformity of the product and QMS, and to maintain the effectiveness of the QMS, as well as records providing evidence of conformance to requirements, and of the effective operation of the quality management system (when applicable). • ISO 13485 Element - SOPs and device specific documentation for implementing clause 8
6.15	**Device Specific Quality Plan** The applicant should provide a quality plan. This plan should specify "which processes, procedures and associated resources will be applied by whom and when to meet the requirements of a specific project, product, process or contract". This information may be provided in an application in the form of a flow chart. Note: The review requirement for a quality plan is not met by the ISO 13485 certificate alone, instead refer to ISO 10005.
6.16	**Quality management system verification document** According to the above procedures of the quality management system, applicants shall form documents and records related to the quality management system. The following materials shall be submitted for inspection during the inspection on the quality management system. • Basic information form of applicant. • Organizational chart of the applicant. • General layout of the enterprise and the distribution map of production areas. • Where there are requirements for purification in the production process, a copy of the environmental testing report (with the layout

	plan attached) issued by a qualified testing institution shall be provided. • The flow chart of the product production process, which shall indicate the main control points and items, main raw materials and sources of purchased parts and the quality control methods. • Catalogue of main production equipment and inspection equipment (including the equipment required for incoming inspection, process inspection and final factory inspection; environmental monitoring equipment shall also be provided for the production conducted under the purification conditions). • Self-inspection report of the quality management system. • Where applicable, the explanation on the comparison of the product to be inspected and products previously passing the inspection in terms of production conditions and production process shall be provided.
6.17	**Other Quality System Information** Heading for other information that may be important to the submission but that does not fit in any of the other headings.

1.5. Classification Rules

Rule 1:	IVDs intended for the following purposes are classified as Class D: ● Devices intended to be used to detect the presence of, or exposure to, a transmissible agent in blood, blood components, cells, tissues or organs or any of their derivatives, in order to assess their suitability for transfusion, transplantation or cell administration. ● Devices intended to be used to detect the presence of, or exposure to, a transmissible agent that causes a life-threatening, disease with a high or suspected risk of propagation; Rationale: The application of this rule as defined above should be in accordance with the rationale that follows: Devices in this Class are intended to be used to ensure the safety of blood and blood components for transfusion and/or cells, tissues and organs for transplantation. In most cases, the result of the test is the major determinant as to whether the donation/product will be used. Serious diseases are those that result in death or long-term disability, that are often incurable or require major therapeutic interventions and where an accurate diagnosis is vital to mitigate the public health impact of the condition. Examples: Tests to detect infection by HIV, HCV, HBV, HTLV; HIV blood donor screening and HIV blood diagnostics. This rule applies to first-line assays, confirmatory assays, and supplemental assays.
Rule 2:	IVDs intended to be used for blood grouping, or to determine foetomaternal blood group incompatibility, or tissue typing to ensure the immunological compatibility of blood, blood grouping for cell administration, blood components, cells, tissue, or organs that are intended for transfusion or transplantation, are classified as Class C, except when intended to determine the presence of the antigen or antibody for any of the following markers: ABO system [A (ABO1), B (ABO2), AB (ABO3)], Rhesus system [RH1 (D), RH2 (C), RH3 (E), RH4 (c), RH5 (e), and weak or partial Rh(D)], Kell system [Kel1 (K)], Kidd system [JK1 (Jka), JK2 (Jkb)]; or Duffy system [FY1 (Fya), FY2 (Fyb)], in which case they are classified as Class D. Rationale: The application of this rule as defined above should be in accordance with the rationale for this rule, which is as follows: A high individual risk, where an erroneous result would put the patient in an imminent life-threatening situation, places the device into Class D. The rule divides blood-grouping devices into two subsets, Class C or D, depending on the nature of the blood group antigen the IVD medical device is designed to detect, and its importance in a transfusion setting. Examples: HLA, Rhesus system, Duffy system (other Duffy systems except those

	listed in the rule as Class D are in Class C).
Rule 3:	IVDs are classified as Class C if they are intended for use: ● in detecting the presence of, or exposure to, a sexually transmitted agent. Examples: Sexually transmitted diseases, such as Chlamydia trachomatis, Neisseria gonorrhoeae. ● in detecting the presence in cerebrospinal fluid or blood of an infectious agent with a risk of limited propagation. Examples: Neisseria meningitidis or Cryptococcus neoformans. ● in detecting the presence of an infectious agent, if there is a significant risk that an erroneous result would cause death or severe disability to the individual, foetus or embryo being tested or to the individual`s offspring. Examples: diagnostic assay for CMV, Chlamydia pneumoniae, Methicillin Resistant Staphylococcus aureus. ● in pre-natal screening of women in order to determine their immune status towards transmissible agents. Examples: Immune status tests for Rubella or Toxoplasmosis. ● in determining infective disease status or immune status, and where there is a risk that an erroneous result will lead to a patient management decision resulting in an imminent life-threatening situation or severe disability for the patient or for the patient`s offspring. Examples: Enteroviruses, CMV and HSV in transplant patients. ● in screening for selection of patients for selective therapy and management as companion diagnostics ● in screening, diagnosis or staging of cancer; Examples: PSA, CEA, and CA 125. **Note:** those IVDs where the therapy decision would usually be made only after further investigation and those used for monitoring would fall into class B under rule 6. ● in human genetic testing Examples: Huntington's Disease, Cystic Fibrosis. ● to monitor levels of medicines, substances or biological components, when there is a risk that an erroneous result will lead to a patient management decision resulting in an immediate life-threatening situation for the patient or for the patient`s offspring. Examples: Troponin, Cyclosporin, Prothrombin time testing. ● in the management of patients suffering from a life-threatening disease or condition. Examples: HBV monitoring marker, HCV viral load, HIV Viral Load and HIV and HCV geno- and subtyping ● in screening for congenital disorders in the foetus or embryo. Examples: Spina Bifida, Down Syndrome, Glucose-6-Phosphate Dehydrogenase Deficiency, and Tay-Sachs disease. ● in screening for congenital disorders in new-born babies where failure to detect and treat such disorders could lead to life-threatening situations or severe disabilities. Rationale: The application of this rule as defined above should be in accordance with the rationale for this rule, which is as follows: devices in this Class present a

	moderate public health risk, or a high individual risk, where an erroneous result would put the patient in an imminent life-threatening situation, or would have a major negative impact on outcome. The devices provide the critical, or sole, determinant for the correct diagnosis and monitoring. They may also present a high individual risk because of the stress and anxiety resulting from the information and the nature of the possible follow-up measures.
Rule 4:	IVDs intended for use by lay users (such as for self-testing or nearpatient testing) are classified as Class C, except: those devices from which the result is not determining a critical situation, in which case they are classified under Class B, and those devices which are classified under Class D by Rule 1 and/or Rule 2. Rationale: The application of this rule as defined above should be in accordance with the rationale for this rule, which is as follows: in general, these devices may be used by lay user. Example for self-testing class C: Blood glucose monitoring. Example for self-testing class B: Pregnancy self-test, fertility testing, and urine test strips.
Rule 5:	The following IVDs are classified as Class A: ● Reagents or other articles, which possess no critical characteristics intended by the manufacturer to make them suitable for in vitro diagnostic procedures related to a specific examination; ● Instruments intended by the manufacturer specifically to be used for in vitro diagnostic procedures. ● Specimen receptacles. **Note 1**: Any product for general laboratory use which is not specifically intended by the manufacturer to be used in in vitro diagnostic applications is not deemed to be an IVD, as defined in this document. Rationale: The application of this rule as defined above should be in accordance with the rationale for this rule which is as follows: these devices present a low individual risk and no or minimal public health risk. Examples: General culture media (excluding the dehydrated powders which are considered not to be a finished IVD), wash solutions, plain urine cup, , and microbiological specimen collection devices. **Note 2**: The performance of software or an instrument that is specifically required to perform a particular test will be assessed at the same time as the respective reagent(s).
Rule 6:	IVDs not covered in Rules 1 through 5 are classified as Class B. Rationale: The application of this rule as defined above should be in accordance with the rationale for this rule which is as follows: These devices present a moderate

	individual risk as they are not likely to lead to an erroneous result that would cause death or severe disability, have a major negative impact on patient outcome or put the individual in immediate danger. The devices give results that are usually one of several determinants. If the test result is the sole determinant, but other information is available, such as presenting signs and symptoms or other clinical information, which may guide a physician, classification into Class B may be justified. Other appropriate controls may also be in place to validate the results. This Class also includes those devices that present a low public health risk because they detect infectious agents that are not easily propagated in a population. Examples: Blood gases, H. pylori test, physiological markers such as hormones, vitamins, and enzymes, metabolic markers, specific IgE assays and celiac disease markers, and tests for anti-nuclear antibody, sex hormone-binding globulin (SHBG), blood urea nitrogen (BUN), aspartate aminotransferase (AST), alkaline phosphatase (ALP), creatinine and HbA1c.
Rule 7:	IVDs that are controls without a quantitative or qualitative assigned value will be classified as Class B. Rationale: For such controls, the qualitative or quantitative value is assigned by the user and not the manufacturer. Examples: Urinalysis controls and chemistry controls.

References:

1. IMDRF/IVD WG/N64FINAL:2021. *Principles of In Vitro Diagnostic (IVD) Medical Devices Classification*
2. EAC/TF-MED/MER/FD/DEVICES/N2R0. *Requirements for Assessment and Market Authorization of In Vitro Diagnostic Medical Devices*
3. *WHO Global Model Regulatory Framework for Medical Devices including In Vitro Diagnostic Medical Devices*
4. WHO/BS/2020.2397. *Appendix 4: Collaborative procedure between the World Health Organization and national regulatory authorities in the assessment and accelerated national registration of WHO-prequalified in vitro diagnostics*
5. IMDRF/GRRP WG/N52 FINAL:2024 (Edition 2) *Principles of Labeling for Medical Devices and IVD Medical Devices*
6. AMDF *Guidelines on requirements on Labelling of medical devices Including in vitro diagnostic Medical devices*

ENDORSEMENT OF THE GUIDELINES

	Prepared by	**Checked by**		**Approved by**
Title	**Division manager**	**Head of Department**	**Quality Assurance Analyst**	**Director General**
Names	Steven NKUSI	Dr. Vedaste HABYALIMANA	Marie Ange UWASE	Prof. Emile BIENVENU
Date & Signature				

RWANDA FDA
Rwanda Food and Drugs Authority

Doc No: DD/HMDR/DOC.TYPE/….
Revision No:1
Effective Date: dd/mm/yyyy

APPENDIX 1:

cover letter

<Applicant>
<Address>
<Postal Code><Town>
<Date>

Rwanda FDA,
1948 Kigali-Rwanda

Dear Sir/Madam,

Subject: Submission of Application Dossier(s) for Marketing Authorization of < Medical device(s) or Change on registered/notified Medical device (s)>

We are pleased to submit our Application Dossier(s) for the registration of medical devices/In Vitro Diagnostics Devices (IVDDs) that details are as follows:

Name of the Medical device(s) /IVDD(s): ……..

Classification of the Medical Device(s)/IVDD(s): ……..

Intended use of the Medical Device(s)/IVDD(s): …….....

You will find enclosed the submission dossier as specified hereafter:

□ We confirm that the application dossier has been well checked for completion prior submission.

Type of Submission: □Full registration Application □Abridged Application □Notification Renewal Application for registration □Renewal Application for notification □ Application for change on registered/notified medical device
□ sample(s) submitted (where applicable)

 Application for QMS audit to Rwanda FDA, where applicable (as per relevant guidelines)

 I confirm that the Product Dossier information submitted is the same in all aspects as the product registered with the relevant SRA, WHO PQ and EAC (Only for Abridged Applications)

I, the undersigned certify that all the information in this form and accompanying documentation is correct, complete and true to the best of my knowledge

Yours sincerely,

<Signature>

<Name>

<Title>

<Phone number(s)>

<Email address>

RWANDA FDA
Rwanda Food and Drugs Authority

Doc No: DD/HMDR/DOC.TYPE/….
Revision No:1
Effective Date: dd/mm/yyyy

APPENDIX 2:

Application Form for Medical Devices including In Vitro Diagnostics Devices (IVDDs) Notification

Application Number	**Rwanda FDA use only**
Date of submission of dossier	**Rwanda FDA use only**
1.0 PARTICULARS OF THE MEDICAL DEVICE or IVD (**Bold or Tick** the right type of application)	
1.1	Name of the Medical Device or IVD
1.2	Type of application • New • Renewal • Change* • Notifiable change • minor change • major change * In case change (s) has(ve) been made to registered/notified medical device (s), fill in the following 2 rows
	Reason for change

<table>
<tr><td></td><td>Detailed description of the change (s)</td></tr>
<tr><td>1.3</td><td>Classification of the Medical Device or IVD and Classification rule(s) applied</td></tr>
<tr><td>1.4</td><td>Intended use of the Medical Device or IVD

Intended user:
• Professional user

• self user</td></tr>
<tr><td>1.5</td><td>Name and address (physical and postal) of Applicant
Address:
Country:
Telephone:
Telefax:
E-Mail:</td></tr>
<tr><td>1.6</td><td>Name and address (physical and postal) of legal manufacturer
Address:
Country:
Telephone:
Telefax:
E-Mail</td></tr>
<tr><td>1.7</td><td>Visual description of the Medical Device or IVD</td></tr>
<tr><td>1.8</td><td>Proposed shelf life (in months) (where applicable):</td></tr>
<tr><td>1.9</td><td>Proposed storage conditions (where applicable):</td></tr>
<tr><td>1.10</td><td>Other regulatory authority(ies) approval(s) (i.e. European conformity (CE) mark, United States Food and Drug Administration (USFDA) approval, etc)

<table><tr><td>Regulatory Authority’s (ies’) Approval(s)</td><td>Approval/Authorization number</td></tr><tr><td></td><td></td></tr><tr><td></td><td></td></tr></table></td></tr>
<tr><td>1.11</td><td>Country of origin (where the device was manufactured)</td></tr>
</table>

1.12	Name(s) and physical address(es) of the manufacturing site(s) of the Medical Device or IVD. Alternative sites should be also declared here. All manufacturing sites involved in the manufacturing process of the device, stating the role of each including quality control / in-process testing sites should be listed. Address: Country: Telephone: Telefax: E-Mail:
1.13	Name and address (physical and postal) of the Agent/Local Technical Representative (LTR) (Attach a valid appointment letter notarized from the country of origin): Address: Country: Telephone: Telefax: E-Mail:
1.14	Version of the product insert (attach a copy of relevant labeling including the Instruction For Use (IFU))
2.0 DECLARATION BY THE APPLICANT	
I, ,the undersigned certify that all the information in this form and accompanying documentation is correct, complete and true to the best of my knowledge. I further confirm that the information referred to in my application dossier is available for verification during Quality audit inspection. I also agree that I shall carry out Post marketing Surveillance to monitor the safety, quality and performance of the device on the market and provide safety, quality and performance update reports to Rwanda FDA. I further agree that I am obliged to follow the requirements of Rwanda Legislations and Regulations, which are applicable to Medical Devices including IVDs. I also consent to the processing of information provided to Rwanda FDA Signature: Date:	

RWANDA FDA
Rwanda Food and Drugs Authority

Doc No: DD/HMDR/DOC.TYPE/….
Revision No:1
Effective Date: dd/mm/yyyy

APPENDIX 3:

Application Form for Medical Devices and In Vitro Diagnostics Devices (IVDDs) registration

Application Number	**Rwanda FDA use only**
Date of submission of dossier	**Rwanda FDA use only**
1.0 PARTICULARS OF THE MEDICAL DEVICE or IVD (**Bold or Tick** the right type of application)	
1.1	Name of the Medical Device or IVD
1.2	Type of application • New • Renewal • Change* • Notifiable change • minor change • major change * In case change (s) has(ve) been made to registered/notified medical device (s), fill in the following 2 rows
	Reason for change
	Detailed description of the change (s)

1.3	Classification of the Medical Device or IVD and Classification rule(s) applied
1.4	Intended use of the Medical Device or IVD
1.5	Name and address (physical and postal) of Applicant Address: Country: Telephone: Telefax: E-Mail:
1.6	Name and address (physical and postal) of the legal manufacturer Address: Country: Telephone: Telefax: E-Mail
1.7	Name(s) and physical address(es) of the manufacturing site(s) of the Medical Device or IVD. Alternative or contract manufacturing sites should be also declared here. All manufacturing sites involved in the manufacturing process of the device, stating the role of each including quality control / in-process testing sites should be listed. Address: Country: Telephone: Telefax:

	E-Mail:
1.8	Visual description of the Medical Device or IVD
1.9	Proposed shelf life (in months) (where applicable):
1.10	Proposed storage conditions (where applicable):
1.11	Other sister/variants of the medical device (s) or IVD (s) registered or applied for registration with Rwanda FDA
1.12	list all accessories that are manufactured/ sold with the devices
1.13	Have you applied for Marketing Authorization(s) of medical device(s) or In Vitro Diagnostics Devices (IVDs) in any of the country of East African Community (EAC)? • Yes • No If yes state Medical Device name or IVD: Regulatory Authority(ies) where you have applied for registration:
1.14	Device Marketing Authorization in the country of origin (Attach Marketing Authorization of the Medical Device or IVD from the National Regulatory Authority). If not registered, state reasons

	• Authorized Country: Date of authorization: Authorization number: • Refused Country: Date of refusal: Reason of refusal:	• Withdrawn (by the applicant after authorization) Country: Date of withdrawal: Reason of withdrawal: • Suspended/revoked (by competent authority) Country: Date of suspension/revocation: Reason for suspension/revocation:
1.16	Name and address (physical and postal) of the Agent/Local Technical Representative (LTR) (Attach a valid appointment letter notarized from the country of origin): Address: Country: Telephone: Telefax: E-Mail:	
1.17	Name and address (physical and postal) of the person or company responsible for Pharmacovigilance and Post Marketing Surveillance: Address: Country: Telephone: Telefax: E-Mail:	
1.18	Qualitative and Quantitative composition of the Medical Device or IVD (If applicable)	
1.19	Name and address (physical and postal) of the Contract Research Organisation(s) where the clinical studies of the Medical Device or IVD were conducted. (If applicable) Address:	

	Country: Telephone: Telefax: E-Mail:

2.0 DECLARATION BY THE APPLICANT

I, ,the undersigned certify that all the information in this form and accompanying documentation is correct, complete and true to the best of my knowledge.

I further confirm that the information referred to in my application dossier is available for verification during Quality audit inspection. I also agree that I shall carry out Post Marketing Surveillance to monitor the safety, quality and performance of the device on the market and provide safety, quality and performance update reports to Rwanda FDA.

I further agree that I am obliged to follow the requirements of Rwanda Legislations and Regulations, which are applicable to Medical Devices. I also consent to the processing of information provided to Rwanda FDA.

Signature:

Date:

APPENDIX 4:

Essential Principle checklist of Medical Devices including IVDs

The EP checklist can be used by Regulatory Authorities, CABs and even manufacturers themselves to readily understand how the manufacturer demonstrates compliance to the essential principles for a particular device. The EP checklist also allows easy identification of relevant documents and data for conformity assessment purposes.

The contents of the checklist will vary from device to device. Very simple devices will have EP checklists of a few pages as many of the essential principles may not be applicable. In these cases, the supporting references to be included in the checklist will be minimal. More complex devices are more likely to reference a larger number of standards, test reports and documents. The EP checklist in those cases might be many pages long.

The following is a recommended template for the EP checklist. Preparation of the EP checklist as outlined below will provide a useful overview of the manufacturer's conformity to the essential principles

The manufacturer should identify the device, and when applicable the various configuration/variants covered by the checklist.

Applicable to device?

Here the answer is either "**Yes**" or "**No**". If the answer is "No", this should be briefly explained.

Example: For a device that does not incorporate biological substances, the answer to Essential principle 5.8.2 would be "No – The device does not incorporate biological substances"

Method of Conformity

The manufacturer should name the title and reference of the standard(s), industry or in- house test method(s), comparison study(ies) or other method used to demonstrate compliance. For standards, this should include the date of the standard and where appropriate, the clause(s) that demonstrates conformity with the relevant EP. Where a standard is referred to more than once in the checklist, simply the reference number and date can be repeated.

Identity of specific documents

This column should contain the reference to the actual technical documentation that demonstrates compliance to the essential principles, i.e. the certificates, test reports, study reports or other documents that resulted from the method used to demonstrate compliance.

Brand name :	**Generic name:**	**Risk class:**

Clause	**Essential Principal**	**Applicable to the device?**	**Method of Conformity**	**Identity of specific Documents**
1.	GENERAL REQUIREMENTS 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.			
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 risk(s) so that the residual risk(s) 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 is reasonably practicable the remaining risks by taking adequate protection measures, including alarms; and inform users of any residual risks.			
3.	Medical devices should achieve the performance intended by the manufacturer and be designed and manufactured in such a way that they are suitable for their intended purpose.			
4.	The characteristics and performances referred to in Clauses 1, 2 and 3 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.			
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.			
6.	Medical devices should achieve their intended performance during normal conditions of use. All known, and foreseeable risks, and any undesirable effects, should be minimized and be acceptable when weighed against the benefits of the intended performance.			
7. 7.1	ESSENTIAL PRINCIPLES APPLICABLE TO MEDICAL DEVICES OTHER THAN IVD DEVICES <u>DESIGN AND MANUFACTURING REQUIREMENTS</u> <u>Chemical, physical & biological properties</u> The devices should be designed and manufactured in such a way as to ensure the characteristics and performance referred to in clause 6. Particular attention should be paid to: the choice of materials used, particularly as regards toxicity and, where appropriate, flammability, the compatibility between the materials used and biological tissues, cells, and body fluids			

	taking account of the intended purpose of the device. the choice of materials used should reflect, where appropriate, matters such as hardness, wear and fatigue strength.;			
7.2	The 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 product. Particular attention should be paid to tissues exposed and to the duration and frequency of exposure.			
7.3	The devices should be designed and manufactured in such a way that they can be used safely with the materials, substances and gases with which they enter into contact during their normal use or during routine procedures; if the devices are intended to administer medicinal products they should be designed and manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and restrictions governing these products and that their performance is maintained in accordance with the intended use.			
7.4	The 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 device. Special attention shall be given to substances which are			

	carcinogenic, mutagenic or toxic to reproduction.			
7.5	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 device taking into account the device and the nature of the environment in which it is intended to be used.			
8. 8.1	<u>Infection & microbial contamination</u> The 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 patients, users and, where applicable, other persons. The design should: allow easy handling, and, where necessary: reduce as far as reasonably practicable and appropriate any microbial leakage from the device and/or microbial exposure during use, prevent microbial contamination of the device or specimen, where applicable, by the patient, user or other person.			
8.2	Devices labelled 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.			
8.3	Devices delivered in a sterile			

	state should be designed, manufactured and packaged in a non-reusable pack, and/or according to appropriate procedures, to ensure that they are sterile when placed on the market and remain sterile, under the transport and storage conditions indicated by the manufacturer, until the protective packaging is damaged or opened.			
8.4	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.			
8.5	Devices intended to be sterilized should be manufactured in appropriately controlled (e.g. environmental) conditions.			
8.6	Packaging systems for non-sterile devices should maintain the integrity and cleanliness of the product and, if the devices are to be sterilized prior to use, minimize the risk of microbial contamination; the packaging system should be suitable taking account of the method of sterilization indicated by the manufacturer.			
8.7	The labelling of the device should distinguish between identical or similar products placed on the market in both sterile and non-sterile condition.			
9. 9.1	Medical devices incorporating a substance considered to be a medicinal product/drug Where a device incorporates, as			

	an integral part, a substance which, if used separately, may be considered to be a medicinal product/drug as defined in the relevant legislation that applies within that jurisdiction and which is liable to act upon the body with action ancillary to that of the device, the safety, quality and performance of the device as a whole should be verified, as well as the safety, quality and efficacy of the substance in the specific application,			
10. 10.1	<u>Medical devices incorporating materials of biological origin</u> In some jurisdictions products incorporating tissues, cells and substances of animal origin may be considered medical devices. In this case, such tissues, cells and substances should originate from animals that have been subjected to veterinary controls and surveillance adapted to the intended use of the tissues. National regulations may require that the manufacturer and/or the Regulatory Authority retain information on the geographical origin of the animals. Processing, preservation, testing and handling of tissues, cells and substances of animal origin should be carried out so as to provide optimal safety for patients, users and, where applicable, other persons. 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.			
10.2	In some jurisdictions products incorporating human tissues, cells			

	and substances may be considered medical devices. In this case, 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 patients, users and, where applicable, other persons. 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.			
10.3	In some jurisdictions products incorporating cells and substances of microbial origin may be considered medical devices. In this case, processing, preservation, testing and handling of cells and substances should be carried out so as to provide optimal safety for patients, users and, where applicable, other persons. 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.			
11. 11.1	<u>Manufacturing and environmental properties</u> If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system should be safe and should not impair the specified performance of the			

	devices. Any restrictions on use applying to such combinations should be indicated on the labelling and/or in the instructions for use. Connections which the user has to handle, such as fluid, gas transfer or mechanical coupling, should be designed and constructed in such a way as to minimize all possible risks from incorrect connection.			
11.2	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 the patient, user or other persons 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 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, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, temperature or variations in pressure and acceleration; the risks associated with the use of the 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 device; the risk of incorrect identification of specimens; the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given; risks arising where maintenance or calibration are not possible (as with implants), from ageing of materials used or loss of accuracy of any measuring or control mechanism.			
11.3	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 devices whose intended use includes exposure to or use in association with flammable substances or substances which could cause combustion.			
11.4	Devices must be designed and manufactured in such a way as to facilitate the safe disposal of any waste substances.			
12. 12.1	<u>Devices with a diagnostic or measuring function.</u> Devices with a measuring function, should be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability for their intended purpose of the device, based on appropriate scientific and technical methods. The limits of accuracy should be indicated by the manufacturer.			
12.2	Diagnostic devices should be			

	designed and manufactured in such a way as to provide sufficient accuracy, precision and stability for their intended use, based on appropriate scientific and technical methods.			
12.3	Any measurement, monitoring or display scale should be designed in line with ergonomic principles, taking account of the intended purpose of the device.			
12.4	Wherever possible values expressed numerically should be in commonly accepted, standardized units, and understood by the users of the device.			
13. 13.1 13.1.1	<u>Protection against radiation</u> General Devices should be designed and manufactured and packaged in such a way that exposure of patients, users and other persons to any emitted radiation should be reduced as far as practicable and appropriate, compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.			
13.2 13.2.1	<u>Intended radiation</u> Where devices are designed to emit hazardous, or potentially hazardous, levels of visible and/or invisible radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks			

	inherent in the emission, it should be possible for the user to control the emissions. Such devices should be designed and manufactured to ensure reproducibility of relevant variable parameters within an acceptable tolerance.			
13.2.2	Where devices are intended to emit potentially hazardous, visible and/or invisible radiation, they should be fitted, where practicable, with visual displays and/or audible warnings of such emissions.			
13.3 13.3.1	<u>Unintended radiation</u> Devices should be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as practicable and appropriate.			
13.4 13.4.1	<u>Instructions</u> The operating instructions for devices emitting radiation must give detailed information as to the nature of the emitted radiation, means of protecting the patient and the user and on ways of avoiding misuse & of eliminating the risks inherent in installation.			
13.5 13.5.1	<u>Ionising radiation</u> Devices intended to emit ionizing radiation should be designed and manufactured in such a way as to ensure that, where practicable, the quantity, geometry and energy distribution (or quality) of radiation emitted can be varied			

	and controlled taking into account the intended use.			
13.5.2	Devices emitting ionizing radiation intended for diagnostic radiology should be designed and manufactured in such a way as to achieve appropriate image and/or output quality for the intended medical purpose whilst minimizing radiation exposure of the patient and user.			
13.5.3	Devices emitting ionizing radiation, intended for therapeutic radiology should be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam type and energy and where appropriate the energy distribution of the radiation beam.			
14. 14.1	Medical devices that incorporate software and standalone medical device software Devices incorporating electronic programmable systems, including software, or standalone software that are devices in themselves, should be designed to ensure repeatability, reliability and performance according to the intended use. In the event of a single fault condition, appropriate means should be adopted to eliminate or reduce as far as practicable and appropriate consequent risks.			
14.2	For devices which incorporate software or for standalone software that are 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, validation and verification.			
15. 15.1	Active medical devices and devices connected to them For active medical devices, in the event of a single fault condition, appropriate means should be adopted to eliminate or reduce as far as practicable and appropriate consequent risks.			
15.2	Devices where the safety of the patients depends on an internal power supply should be equipped with a means of determining the state of the power supply.			
15.3	Devices where the safety of the patients depends on an external power supply should include an alarm system to signal any power failure.			
15.4	Devices intended to monitor one or more clinical parameters of a patient should be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health			
15.5	Devices should be designed and manufactured in such a way as to reduce as far as 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.			
15.6	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.			
15.7	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 patient, user or any other person, both during normal use of the device and in the event of a single fault condition in the device, provided the device is installed and maintained as indicated by the manufacturer			
16.0 16.1	Protection against mechanical risks Devices should be designed and manufactured in such a way as to protect the patient and user against mechanical risks connected with, for example, resistance to movement, instability and moving parts.			
16.2	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.			
16.3	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, unless the noise emitted is part of the specified performance			
16.4	Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user has to handle should be designed and constructed in such a way as to minimize all possible risks.			
16.5	Accessible parts of the 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.			
17.0 17.1	Protection against the risks posed to the patient or user by supplied energy or substances Devices for supplying the patient with energy or substances should be designed and constructed in such a way that the delivered amount can be set and maintained accurately enough to guarantee the safety of the patient and of the user			
17.2	Devices should be fitted with the means of preventing and/or indicating any inadequacies in the delivered amount which could pose a danger. Devices should incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy or substances from an energy and/or substance source.			

17.3	The function of the controls and indicators should be clearly specified on the devices. Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information should be understandable to the user and, as appropriate, the patient.			
18.0 18.1	Protection against the risks posed by medical devices intended by the manufacturer for use by lay persons Devices for use by lay persons 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.			
18.2	Devices for use by lay persons should be designed and manufactured in such a way as to reduce as far as practicable the risk of error during use by the lay person in the handling of the device and also in the interpretation of results.			
18.3	Devices for use by lay persons 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.			
19.0 19.1	Label and Instructions for Use 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			
20.0 20.1	<u>Clinical evaluation</u> For all medical devices, the demonstration of conformity with essential principles includes a clinical evaluation in accordance with GHTF guidance. The clinical evaluation should review clinical data in the form of any: clinical investigation reports, literature reports/reviews, and clinical experience to establish that a favourable benefit-risk ratio exists for the device. **<u>Note</u>**: Further information is provided in GHTF/SG5/N2R8:2007 *Clinical Evaluation.*			
20.2	Clinical investigations[1] 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. In addition, some countries may			

[1] See GHTF/SG5/N3:2010 *Clinical Investigations*

	have specific regulatory requirements for pre-study protocol review or informed consent.			
21.0 21.1	Essential Principles applicable to IVD Devices <u>Chemical, physical and biological properties</u> The IVD devices should be designed and manufactured in such a way as to ensure the characteristics and performance referred to in Section 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) intended to be used with the device, taking account of its intended purpose.			
21.2	The IVD 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 product.			
21.3	The IVD 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 device. Special attention should be given to			

	substances which are carcinogenic, mutagenic or toxic to reproduction.			
21.4	IVD 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 device taking into account the device and the nature of the environment in which it is intended to be used.			
22.0 22.1	<u>Infection and microbial contamination</u> The IVD 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 device and/or microbial exposure during use; and prevent microbial contamination of the IVD device or specimen where applicable, by the user, professional or lay, or other person.			
22.2	IVD devices labeled 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.			
22.3	IVD devices labeled either as sterile or as having a special microbiological state should have been processed, manufactured and, if applicable, sterilized by appropriate, validated methods.			
22.4	IVD devices intended to be sterilized should be manufactured in appropriately controlled (e.g. environmental) conditions.			
22.5	Packaging systems for non-sterile IVD devices should maintain the integrity and cleanliness of the product.			
23.0 23.1	<u>IVD devices incorporating materials of biological origin</u> Where IVD devices include tissues, cells and substances originating from animals, 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 devices if the activity of the virus and other transmissible agent are integral to the intended purpose of the IVD device or when such			

	elimination or inactivation process would compromise the performance of the IVD device. National regulations may require that the manufacturer and/or the Regulatory Authority retain information on the geographical origin of the animals.			
23.2	Where IVD 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 devices if the activity of the virus and other transmissible agent are integral to the intended purpose of the IVD device or when such elimination or inactivation process would compromise the performance of the IVD device.			
23.3	Where IVD devices include cells and substances of microbial origin, 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 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 device.			
24.0 24.1	<u>Manufacturing and environmental properties</u> If the IVD 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.			
24.2	IVD 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 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 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 device; the risk of incorrect identification of specimens; and the risks of reasonably foreseeable interference with other devices such as carry over between IVD devices			
24.3	IVD 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 devices whose intended use includes exposure to or use in association with flammable substances or substances which could cause combustion.			
24.4	IVD devices must be designed and manufactured in such a way as to facilitate the safe disposal of any waste substances.			
25.0 25.1	<u>Performance characteristics</u> IVD 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 device as indicated by the manufacturer.			
25.2	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.			
25.3	Wherever possible values expressed numerically should be in commonly accepted, standardized units, and understood by the users of the device. **Note**: While SG1 generally supports convergence on the global use of internationally standardized measurement units, considerations of safety, user familiarity, and established clinical practice may justify the use of other recognized measurement units.			
26.0 26.1	Protection against radiation IVD 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 practicable and appropriate			
26.2	When IVD devices are intended to emit potentially hazardous, visible and/or invisible radiation, they should as far as 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			
27.0 27.1	<u>IVD devices that incorporate software and standalone IVD device software</u> For IVD devices which incorporate software or for standalone software that are IVD 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.			
28.0 28.1	<u>IVD devices connected to, or equipped with, an energy source</u> IVD devices where the safety of the patient depends on an internal power supply in the IVD device, should be equipped with a means of determining the state of the power supply.			
28.2	IVD devices should be designed and manufactured in such a way as to reduce as far as 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.			
28.3	IVD 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.			
28.4	IVD 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 device is installed and maintained as indicated by the manufacturer.			
29.0 29.1	<u>Protection against mechanical and thermal risks</u> IVD 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. 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.			
29.2	IVD 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.			
29.3	IVD 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.			
29.4	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.			
29.5	Accessible parts of the IVD 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.			
30.0 30.1	<u>Protection against the risks posed by IVD devices intended by the manufacturer for self-testing</u> IVD devices intended 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.			
30.2	IVD devices intended for self-testing should be designed and manufactured in such a way as to reduce as far as 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.			
30.3	IVD devices intended 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.			
31.0 31.1	Label and Instructions for Use 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. **Note**: Further information is provided in GHTF/SG1/N43:2005 *Labelling for Medical Devices*			
32.0 32.1	Performance evaluation including analytical performance and, where appropriate, clinical performance For an IVD 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 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. The depth and extent of a performance evaluation should be appropriate to the nature, intended use and risks of the IVD device, and in accordance with GHTF guidance. **Note**: Further information is provided in GHTF/SG1/N46:2008 *Principles of Conformity Assessment for IVD Medical Devices*.			
32.2	Clinical performance studies using specimens from human subjects should be carried out in accordance with the spirit of the Declaration of Helsinki. This includes every step in the clinical performance study from first consideration of the need and justification of the study to publication of the results.			

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

Name: _____

Signature: _____

Position: _____

Date: _____

APPENDIX 5:

Grouping of IVDs as a Cluster (Adopted from HSA)

IVD reagents or articles with the same product owner that only fall under risk class B. They are of a common test methodology and fall under the same IVD cluster category.

IVD Cluster grouping requirements

An IVD Cluster comprises a number of *in vitro* diagnostic reagents or articles that are:

- From the same product owner.
- Of the same risk classification (Only Applicable for Class A and Class B).
- Of a common test methodology.
- Of the same IVD Cluster category.

The IVD Cluster may include analysers that are designed for use with the reagents in the IVD Cluster.

The listing of the IVD test kits, reagents and their accessories on the SMDR upon approval may differ from the initial grouping.

Types of IVD Clusters

IVD Clusters	How to list
• Individual (Single) reagents or articles. • Test kits. • Family of reagents or articles within an IVD Cluster.	List separately on the Singapore Medical Device Register (SMDR). **Note:** The different device brand names, and common intended purpose would be key considerations for the separate listings.
• IVD Clusters which include IVD analyser. • IVD Test Kit which include IVD analyser.	Select one of the following options: • List together as an IVD system. • List the IVD analyser separately from the IVD test kit as a split listing.

Grouping limitations

The IVD Cluster grouping is only used for product registration, and will not apply as a grouping criterion for the addition of models through a Change Notification.

All devices and articles that are listed as part of a Cluster can be supplied separately but solely for the registered intended purpose.

A reagent or article that is intended for multiple usage categories, such that it can be grouped in more than one IVD Cluster, can be grouped as part of any IVD Cluster.

List of IVD Cluster Categories

This list of IVD Cluster categories only applies to Class B IVD devices. The label of each reagent or article should state clearly whether it is intended to be used alone or in combination, for the same category.

Methodology	**Cluster Category (Closed list)**	**Examples of analytes**
Clinical chemistry	Enzymes	• Acid Phosphatase • Alpha-Amylase • Creatine Kinase • Gamma-Glutamyl Transferase • Lactate Dehydrogenase • Lipase
Clinical chemistry	Substrates	• Albumin • Bilirubin • Urea/blood urea nitrogen • Cholesterol • Creatinine • Glucose
Clinical chemistry	Electrolytes Reagents	• Ammonia • Bicarbonate • Calcium • Chloride • Magnesium • Phosphate inorganic/phosphorus
Clinical chemistry	Electrolyte Electrodes	• Ammonia electrodes • Carbon dioxide (bicarbonate) electrodes • Calcium electrodes • Chloride electrodes • Magnesium electrodes • Potassium electrodes
Clinical chemistry	Substrate	• Creatinine Electrodes

Methodology	**Cluster Category (Closed list)**	**Examples of analytes**
	electrodes/biosensors	• Glucose Electrodes • Glycated Hemoglobin Electrodes • Lactate Electrodes • Urea Electrodes • Bilirubin Electrodes
Immunochemistry	Immunoglobulins (without IgE)	• Immunoglobulin A • Immunoglobulin D • Immunoglobulin G • Immunoglobulin M • Immunofixation kits
Immunochemistry	Complement components	• Complement component C1q • Complement component C1 inactivator • Complement component C3/C3c • Complement component Bb • Complement component C4 • Complement component C5a
Immunochemistry	Transport proteins	• Albumin • Ceruloplasmin • Haptoglobin • Hemopixin • Lactoferrin • Pre-albumin/Transthyretin
Immunochemistry	Lipoproteins	• Apolipoprotein A I • Apolipoprotein A II • Apolipoprotein B • Apolipoprotein E Sub-typing • Lipoprotein (a)
Immunochemistry	Other Specific Proteins	• a1-Acid Glycoprotein • a1-Antitrypsin • a1- Microglobulin

Methodology	Cluster Category (Closed list)	Examples of analytes
		• Fribonectin • Immuno Reactive Trypsin
Immunochemistry	Allergy	• Immunoglobuin E - Total • Immunoglobulin E - Screen • Immunoglobulin E - Specific, monotest/monoresult • Allergen specific IgA • Allergen specific IgG
Immunochemistry	Cancer markers	• G1- marker CA242 • p53
Immunochemistry	Thyroid function markers	• Free triiodothyronine • Free thyroxine • Thyroid stimulating hormone • T-uptake • Thyroglobulin • Neonatal thyroxine
Immunochemistry	Fertility/Pregnancy Hormones/ Proteins	• Androstenedione • Estradiol • Prolactin • Human Placental Lactogen • Estriol
Immunochemistry	Diabetes assays (hormones)	• C-peptide • Glucagon • Insulin • Glycosylated/glycated haemoglobin • Islet Cell Ab • Proinsulin
Immunochemistry	Renal metabolism assays	• Aldosterone • Angiotensin I/II • Angiotensin converting enzyme • Cortisol

Methodology	Cluster Category (Closed list)	Examples of analytes
		• Renine
Immunochemistry	Bone and mineral metabolism assays	• Bone alkaline phosphatase • Calcitonin • Cross-linked C-Telopeptides • Cross-linked N-Telopeptides • Cyclic adenosin monophosphate • Hydroxyproline
Immunochemistry	Endocrine hormones and peptides	• Adrenocorticotropic Hormone • Human Growth Hormone • Insulin-like Growth Factor I • Insulin-like Growth Factor Binding Protein 1 • Vasointestinal Peptide • Vasopressin
Immunochemistry	Neuroendocrine Function Assays	• Bombesin • 17-Hydroxy-Ketosterone • β-Endorphin • Neurotensin • Somatostatin • Substance P
Immunochemistry	Other individual and specified hormones	• Gastrin • Gonadotropin-releasing hormone • Melatonin • Pepsinogen • Adrenalin • Dopamine
Immunochemistry	Anaemia	• Erythropoietin • Ferritin • Folate • Iron • Iron binding capacity • Soluble transferrin receptor

Methodology	**Cluster Category (Closed list)**	**Examples of analytes**
Immunochemistry	Vitamins	• Vitamin B1 • Vitamin B2 • Vitamin B6 • Vitamin B12 • Vitamin D (cholecalciferol) • Intrinsic factor (blocking antibody)
Immunochemistry	Drug monitoring	• Caffeine • Benzodiazepines • Penicillins • Tetracyclines
Immunochemistry	Toxicology	• Amphetamines • Cocaine • Morphine • Phencyclidine • Acetaminophen • Catecholamines • Ethanol • Salicylate
Immunochemistry	Auto-immune diseases	• Anti-nuclear antibodies (ANAs) • Anti-topoisomerase • Organ-specific autoantibodies • Circulating Immuno-complex • TSH Receptor antibodies • Anti-Cardiolipin antibodies
Immunochemistry	Rheumatoid- Inflammatory diseases markers	• Anti-Streptococcal Hyaluronidase • Anti-Streptokinase • Anti-Streptolysin O • C-Reactive Protein • Anti-Staphylolysin • Anti-Streptococcal Screening
Immunochemistry	Liver function	• MEGX • Carbohydrate Deficient

Methodology	**Cluster Category (Closed list)**	**Examples of analytes**
		Transferrin
Immunochemistry	Cardiac markers	• Homocysteine • ST2 • Galectin-3 • Myeloperoxidase (MPO)
Immunochemistry	Bacterial Infection - Immunology	• *Bacillus subtilis* • *Pseudomonas Aeruginosa* • *Helicobacter Pylori* • *Lactobacillus casei*
Immunochemistry	Viral infection - Immunology	• Norovirus • Rotavirus • Hantavirus
Immunochemistry	Parasitic Infection - Immunology	• *Leishmania*
Immunochemistry	Fungal Infection - Immunology	• *Candida albicans* • *Aspergillus*
Haematology/histology/cytology (blood tests for transfusions excluded)	Haemoglobin testing	• Hemoglobin determinations (Total Hb) • Fractional oxyhemoglobin (FO2Hb) • Fractional carboxyhemoglobin (FCOHb) • Fractional methemoglobin (FMetHb) • Fractional deoxyhemoglobin (FHHb)
Haematology/histology/cytology (blood tests for transfusions excluded)	General coagulation tests	• Prothrombin Time • Thrombin Time • Activated Clotting Time • Activated Partial Thromboplastin Time
Haematology/histology/cytology (blood tests for transfusions excluded)	Haemostasis (coagulation)	• Fibrinogen • Protein C and Protein S reagents • C1-inhibitors

Methodology	**Cluster Category (Closed list)**	**Examples of analytes**
		• Alpha-Antiplasmin • Fibrin • Factor XIII • Platelet Factor 4 • Plasminogen
Haematology/histology/cytology (blood tests for transfusions excluded)	Other hematology tests	• Complete blood count • Hematocrit • Erythrocyte sedimentation rate
Haematology/histology/cytology (blood tests for transfusions excluded)	Cytokines (lymphokines)/ immunomodulators	• Interferons • Soluble antigens/receptors • Tumor necrosis factors • Colony stimulating factors • Tumor necrosis factors receptors
Haematology/histology/cytology (blood tests for transfusions excluded)	Histology/cytology reagents	• Cytochemical staining • Embedding, fixing, mounting media • Stain solutions • Immunohistology kits
Microbiology culture	Culture media	• Dehydrated culture media (DCM) • Additives for DCM • Prepared media (tubes, bottles, plates) • Cells, media, serum for viral culture
Microbiology culture	Susceptibility testing (Testing the susceptibility of bacteria to certain antibiotics)	• Erythromycin susceptibility test for *Staphylococcus aureus* • Tobramycin susceptibility test for *Pseudomonas aeruginosa* • Fungal susceptibility testing
Microbiology culture	Biochemical culture Identification (ID)	• Gram negative manual ID • Gram positive manual ID • Other ID kits manual -

Methodology	Cluster Category (Closed list)	Examples of analytes
		anaerobes, fastidious
Microbiology culture	Immunological culture Identification (ID)	• Streptococci grouping slide tests • Serotyping (Shigella etc.)
Microbiology culture	Nucleic Acid (NA) based culture identification (ID)	• Streptococci • Shigella
Microbiology culture	Serological identification (ID)	For Parasitology and Mycology (Fungi and Yeast)
Microbiology culture	Bacterial Infections (detection by NA reagents)	• Streptococci • Shigella
Microbiology culture	Viral infections (detection by NA reagents)	Para-influenza NA reagents
Microbiology culture	Fungal infections	• Fungi NA reagents • Candida albicans • Aspergillus

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