RWANDA FDA
Rwanda Food and Drugs Authority

GUIDELINES ON SUBMISSION OF DOCUMENTATION 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 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 In vitro Diagnostics devices in order to protect public health by increasing their access and availability.

Considering the provisions of the technical regulations N° DFAR/HMDAR/TRG/002 Rev_2 governing the registration of Medical Devices including In vitro Diagnostics, especially in its articles 6, 7, 13, 14, 16, and 35, the Authority has issued Guidelines N° DFAR/HMDAR/GDL/012 on submission of documentation for registration of In Vitro Diagnostics Devices.

These guidelines were developed in reference to the East African Medicines Regulatory Harmonization, World Health Organization (WHO) and the International Medical Devices Regulators Forum (IMDRF).

The purpose of these guidelines is to provide guidance to In Vitro Diagnostics Devices (IVDDs) importers, manufacturers, and distributors intending to market their products in Rwanda on the documentation requirements by the Authority to assess the conformity of such products to the essential principles of safety 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 device dossiers by the Authority for pre-market, marketing authorization, registration, and post-marketing review.

We wish to express our gratitude to all individuals who actively participated in the development of the guidelines.

The Authority acknowledges all the efforts of key stakeholders who participated in the development and validation of these guidelines.

Dr. Emile BIENVENU
Director General

RWANDA FOOD AND DRUGS AUTHORITY - RWANDA FDA

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17/10/2022	0	First Issue

TABLE OF CONTENTS

ACRONYMS 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
IVDD	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 Stringent Regulatory Authority (SRA) to inform the Authority's 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. **"Collaborative procedure"** a procedure for collaboration between the Authority and WHO or any regulatory authority in the assessment and accelerated national registration of IVDDs.
5. **"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.
6. **"Law"** means Law N0 003/2018 of 09/02/2018 establishing the Rwanda FDA and determining its mission, organization and function
7. **"Local Technical Representative (LTR)"** means any corporate body registered in Rwanda and authorized by Rwanda FDA to deal with Medical Devices and In Vitro Diagnostics that has received a mandate from the Applicant to act on his/her behalf with regard to matters pertaining to the registration of medical devices including IVDDs.
8. **"In vitro diagnostic device (IVDD)"** A 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. This includes reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles

   Note: IVD 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.
9. "**Accessory to an IVDD**" 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.

10. "**Label**" means any tag, brand, mark, pictorial or other descriptive matter, written, printed stenciled, marked, embossed or impressed on or attached to a container of any In Vitro Diagnostics Devices;

11. **"Labeling**" is all labels and other written, printed, or graphic matter (l) upon any article or any of its containers or wrappers, or (2) accompanying such article" at any time while a device is held for sale after shipment or delivery for shipment in interstate commerce.
    The term "accompanying" is interpreted liberally to mean more than physical association with the product. It extends to posters, tags, pamphlets, circulars, booklets, brochures, instruction books, direction sheets, and fillers (where applicable).

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

13. "**Manufacturer**" means a person or a firm that is engaged in the manufacture of an IVDD:

14. **"Medical device"** means any instrument, apparatus, implement, machine, appliance, implant, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings or animals, 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 a physiological process; supporting or sustaining life; control of conception; disinfection of medical devices; providing information by means of in vitro examination of specimens derived from the human or animal bodies, and which does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human or animal body, but which may be assisted in its intended function by such means.

15. **"Fee"** means the fee prescribed in Regulation CBD/TRG/004 related to regulatory services Tariff/Fees and fines.

16. **"Intended use/purpose"** The objective intent of the manufacturer regarding the use of a product, process or service as reflected in the specifications, instructions and information provided by the manufacturer

17. **"Batch number (or lot number)"** a distinctive combination of numbers and/or letters which specifically identifies a batch on the labels, the batch records, etc.

18. **"Packaging"** means all operations, including filling and labelling, that a medical device has to undergo.

19. **"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.

20. **"IVD test kit"** an IVD test kit is an in vitro diagnostic Device (IVDD) 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.

INTRODUCTION

1.1. Background

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

Considering the provisions of the technical regulations N° DFAR/HMDAR/TRG/002 Rev_2 Governing Registration of Medical Devices including In Vitro Diagnostics, especially in its articles 6, 7, 13, 14, 16 and 35, the authority has issued Guidelines N° DFAR/HMDAR/GDL/012 on Submission of documentation For Registration Of In Vitro Diagnostics Devices.

Manufacturers of all classes of IVDDs 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 IVDDs 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 the Authority for assessment and registration.

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 IVDD 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 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 IVDD, 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

An application for In Vitro Diagnostics Devices registration for either a locally manufactured or imported IVVD shall be made in writing via a cover letter and application form dated and signed by the applicant. If the applicant is a foreign company, the applicant shall appoint a local technical representative through whom an application shall be submitted. The local technical representative shall be any corporate body registered in Rwanda and authorized by Rwanda FDA to deal with Medical Devices including In Vitro Diagnostics Devices that has received a mandate from the Applicant to act on his/her behalf with regard to matters in the relevant area.

The application should be submitted to Rwanda FDA through the authorized local technical Representative to the following address:

Director General

Rwanda Food and Drugs Authority

P. O. Box 1948 Kigali-Rwanda

1.5. Types of IVDDs registration Applications

For the purposes of submission of an IVDD Dossier to Rwanda FDA, applications are classified into three categories as follows:

1. **New applications for registration/notification:** an application for registration/notification of In Vitro Diagnostics Devices that is intended to be placed on the Rwandan market for the first time or a device which was on the market without a certificate of registration or notification.
2. **Renewal of product registration/notification:** Applications for renewal of a registered or notified In Vitro Diagnostic Device. The application shall be made at least 3 months before the expiry of the existing registration/notification.
3. **Variation of a registered/notified IVDD:** an application for any change in the registered/notified In Vitro Diagnostic Device. All applications for variation to a registered/notified device shall be made according to requirements as stipulated in the Rwanda FDA Guidelines for Variation of Registered/notified In Vitro Diagnostics Devices.

1.6. Application Requirements

1.6.1. Application requirements for notification

a) In Vitro Diagnostics Devices falling under class A which are in a non-sterile state, a non-active and non-measuring function shall apply for notification to the Authority. Applicants shall
submit the following:

1. Signed and dated original hard copy of a cover letter (Annex I)
2. Signed and dated and duly filled in notification form (Annex III)
3. Proof of payment of notification fee at the time of submission
4. One commercial pack sample of the device or artwork (where applicable)

1.6.2. Application requirement for registration

a) An application for In Vitro Diagnostics Devices registration in Rwanda shall include the following:

1. Signed and dated original hard-copy of the cover letter (annex I)
2. Signed and dated application form for the In Vitro Diagnostic Device registration (annex II)
3. Proof of payment of registration fee at the time of submission as per regulations N^0 CBD/TRG/004 related to regulatory service tariff/fees and fines.
4. Two CD-Rom or any other external driver containing STED in a selectable PDF.
5. Two commercial samples of the IVDD and certificate of conformity (where applicable), however, additional samples might be required.

b) An application for a prequalified In Vitro Diagnostics Devices registration in Rwanda shall also include the following:

1. Consent of WHO prequalification holder for WHO to confidentially share information with Rwanda FDA under Abridged registration Procedure. Refer to WHO *Appendix 2. Consent of WHO prequalification holder for WHO to confidentially share information with the NRA under the Procedure*
2. Expression of interest to be provided to the Authority along with the application. Refer to 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*

1.7. Receiving new applications for IVDD registration

An application consists of soft and hard copies submission. The application for registration of In Vitro Diagnostics Devices is only received by the Authority when the payment of prescribed registration/notification fees is effected. After receiving a device registration application, a reference number is assigned to the application and it will be used in all subsequent correspondences relating to the application. An acknowledged receipt will be issued.

1.8. Rwanda FDA Dossier Notification Procedure

After receiving an application requesting notification, the Authority shall proceed with the screening of the dossier for completeness based on the First in First out (FIFO) rules.

An IVDD dossier is reviewed by one assessor to verify the completeness of requirements.

During the review, additional data and/or samples may be requested through an official communication letter. Once a query has been issued to the applicant, the notification process stops until the Authority receives a written response to the raised queries. Further processing of the application may only be undertaken if responses to queries issued in the official communication letter 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 thirty **(30)** calendar days 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, registration of In Vitro Diagnostics Devices 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 certificate of notification within thirty **(30)** working days.

1.9. Rwanda FDA Dossier Registration Procedure

After receiving an application requesting registration, 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 within thirty (**30)** working days and requested to comply with requirements in writing. Devices under abridged assessment shall not undergo the screening process.

In case of a positive outcome during 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 device is intended for diagnosis of rare disease conditions or in the case of an emergency situation.

An IVDD dossier is reviewed by two assessors to provide scientific and regulatory

oversight regarding the quality, safety and performance of the IVDD under assessment.

The Authority reserves the right to request any additional information to establish the quality, safety and performance of In Vitro Diagnostics Devices. During the assessment, additional data and/or samples may be requested through an official communication letter.

Samples may be analyzed in the Quality Control Laboratory in order to guide the Authority's final decision. Once a query has been raised and issued to the applicant, the assessment process stops until the Authority receives a written response to the raised queries. Further processing of the application may only be undertaken if responses to queries issued in the official communication letter contain all outstanding information requested in one submission. 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 that the responses to the queries are not submitted within ninety **(90)** calendar days/thirty **(30)** calendar days for IVVDs 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 In Vitro Diagnostics Devices may only be considered upon submission of a new application.

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

Note: The Authority may rely on assessments and audits conducted by other recognized regulatory authorities or conformity assessment bodies (CABs); An abridged assessment procedure might then be conducted.

1.10. Compliance with the Quality Management System (QMS)

The QMS audit is part of the In Vitro Diagnostics Device registration process. The Authority should conduct an inspection of the facility or use other means to verify whether the manufacturing site complies with QMS before an IVD is registered. All devices under classes C and D shall undergo a QMS audit. During the assessment, assessors may highlight QMS's issues and communicate 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.

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

1.11. Authority's Peer Review Committee for In Vitro Diagnostics Devices Registration/ notification

After a thorough dossier assessment, a final dossier assessment report shall be presented to the Authority's Peer Review Committee (PRC) before making final decisions for granting or rejecting market authorization of the IVDD.

In the event, that there are safety, quality or performance issues to be resolved as per the decision of the PRC, the application shall remain pending until the resolution of the raised issues. If the applicant fails to provide the required data within ninety (90) calendar days, the product application shall be considered as withdrawn.

The Authority will register/ notify the IVDD in the event that data on safety, quality and performance or other requirements are considered satisfactory and a certificate of registration/ certificate of notification of IVDD will be granted. The registration shall be valid for a period of five (5) years, whereas the certificate of notification validity 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.

1.12. Timelines for In Vitro Diagnostics registration/notification

In Vitro Diagnostics Device dossiers shall be scheduled for assessment according to the First in First out (FIFO) basis upon compliance with the requirements.

A new application for registration shall be processed within:

- Thirty **(30)** calendar days for the notification procedure
- Ninety **(90)** calendar days for the abridged assessment procedure
- Nine **(9)** months for the full assessment procedure

Any additional data shall be submitted within:

- Thirty **(30)** calendar days for IVDDs undergoing notification procedure
- Thirty **(30)** calendar days for IVDDs undergoing abridged assessment procedure
- Ninety **(90)** calendar days undergoing the full assessment procedure

1.13. 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 IVDDs

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 IVDD, that may or may not be from the same manufacturer, a separate submission should be made and the conformity assessments of the IVDD 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 IVDDs.

1.14. Technical Documentation Requirements

All IVDDs in classes A, B, C & D require pre-market submission of technical documentation demonstrating conformity with Essential Principles, except for those requiring notification.

1.14.1. Format and data presentation of the dossier

The information must be organized in the Summary of Technical Documentation (STED) such that it incorporates the sections described in these guidelines.

1.14.1.1. Preparation, content and compilation of the dossier

Applicants are required to arrange the application dossier in the format described below:-

i. Application form

ii. Device Details

iii. Registration status in different countries along with supporting documents (marketing authorization approval, free sale certificate, etc)

iv. Summary technical documentation (where applicable)

v. Labelling information

vi. Essential requirement checklist (where applicable)

Note: Failure to arrange the application dossier accordingly will lead to the rejection of the application.

1.14.1.2. Evidence of Compliance with QMS

For the In Vitro Diagnostics Devices with higher risks the pre-registration GMP inspection or Quality Management System audit will be conducted to verify their compliance. The audit will be conducted on a risk basis, however, in most cases, evidence of compliance with GMP or the Quality Management System for IVDD provided by the manufacturer will be adequate. For IVDDs that require evidence of compliance with the Quality Management System, a CE certificate issued by a Notified Body designated in Europe for the purposes of the In Vitro Diagnostic Medical Devices Directive (98/79/EC) (IVDD) will be accepted. (May also be referred to as an EU Certificate, an EC certificate or an EEC Certificate) ISO 13485 certificates issued by recognized Notified Bodies for the purposes of the IVDD will also be accepted.

CE and ISO 13485 certificates will only be accepted if they include acceptable evidence of good manufacturing practice (GMP) for IVDDs:

- Full legal name of the manufacturer of the goods, including trading names if appropriate.
- Street address of the manufacturing site (PO box is not acceptable)
- Date of the last audit/inspection.
- Standard of manufacture with which the manufacturer of the product(s) complies.
- Product(s) or type(s) of the product(s) in sufficient detail to determine if the scope of the certificate is relevant to the IVDD to be supplied
- Date of issue
- Period of validity or expiry date (must be current)
- Notified Body number
- Notified Body name

1.14.2. Device details

1.14.2.1. Name(s)

State the generic and brand name (where applicable) of the IVDD.

1.14.2.2. Description

Provide a general description on the design, characteristics and performance of the IVDD. The description should also include information on the device packaging.

1.14.2.3. Category/classification

State the class of the IVDD and the applicable classification rule as appended in Annex IV of these guidelines.

1.14.2.4. Intended Use/Indication

State the intended use of the IVDD and/or provide a general description of the disease or condition that the device will help diagnose, treat, prevent, or mitigate. The description of the

target patient population for which the device is intended should also be included, whether it is automated or not, whether it is qualitative or quantitative; the type of specimen it requires (serum, plasma, urine) and what the assay type is e.g. immunoassay, chemistry, cytochemistry, image analysis should be stated.

1.14.2.5. Instruction of Use

Give a concise summary of information for the safe use of the device including procedures, methods, frequency, duration, quantity and preparation to be followed.

1.14.2.6. Contraindications

State conditions under which the IVDD should not be used. For example, a limitation of an assay using specimens from patients who have received preparations of mouse monoclonal antibodies for therapy when tested with assay kits which employed mouse monoclonal antibodies. It may show either false elevated or depressed values.

1.14.2.7. Warnings

State the specific hazard alert information that a user needs to know before using the IVDD. E.g. for products containing biological material, radioactive material, explosive material and any other hazardous material, safety warnings must be included.

1.14.2.8. Precautions

State briefly the precautions to be taken and any special care necessary for the safe and effective use of the IVDD.

1.14.2.9. Adverse effects/events

Describe all adverse and side effects associated with IVDD under normal conditions of use.

1.14.2.10. Alternative Use

Describe any alternative practices or procedures for helping in the diagnosis, treatment, or mitigation of the disease or condition for which the IVDD is intended.

1.14.2.11. Storage conditions

State the storage conditions for the IVDD.

1.14.2.12. Recommended shelf-life (where applicable)

State the recommended shelf-life of the IVDD.

1.14.3. Summary of Technical Documentation (STED)

1.14.3.1. Device description and features

Provide a detailed description of the device attributes that are necessary to explain how the device functions. These details should include:

(a) Intended use of the In Vitro Diagnostic Device. This may include:

(i) What is detected

(ii) The function of the IVDD (e.g. screening, monitoring, diagnostic or aid to diagnosis, staging or aid to staging of disease);

(iii) The specific disorder, condition or risk factor of interest that is intended to detect, define or differentiate;

(iv) Whether the product is automated or not;

(v) Whether the test is qualitative or quantitative.

(vi) The type of specimen(s) required (e.g. serum, plasma, whole blood, sputum, urine)

(vii) The intended testing population (e.g. neonates, antenatal women)

(b) The intended user (laboratory professional and/or at point-of-care);

(c) A general description of the principle of the assay method or instrument principles of operation.

(d) A description of the components of the assay (e.g. reagents, assay controls and calibrators), and where appropriate, a description of the reactive ingredients of relevant components (such as antibodies, antigens, nucleic acid primers).

(e) A description of the specimen collection and transport materials provided with the product or a description of specifications recommended for use.

(f) For instruments of automated assays: a description of the appropriate assay characteristics or dedicated assays.

(g) For automated assays: a description of the appropriate instrumentation characteristics or dedicated instrumentation.

(h) If applicable, a description of any software to be used with the product.

(i) If applicable, a description or complete list of the various configurations/variants of the product that will be made available. For example, a family of pregnancy rapid tests can consist of devices available in different configurations, such as test strips or in a cassette.

(j) If applicable, a description of the accessories, and other non IVD products that are intended to be used in combination with the IVDD.

(k) Risk class and the applicable classification rule for the IVDD according to the classification rules in annex IV below

The instruction for use may be used to provide some of this information on the condition that a cross-reference to the different requirements is supplied in conjunction with the instructions-for-use.

1.14.3.2. Evidence of Conformity to Essential Principles

Provide evidence of conformity to Essential Principles of Safety and Performance (EPSP) by completing the checklist appended as Annex V.

Note:

(i) Manufacturer should identify the essential principles of safety and performance that are applicable to the device and the general methods used to demonstrate conformity to each applicable Essential Principle. The methods that may be used include:-

(a) Conformity with a recognized or another/other standard (s)

(b) Conformity with a commonly accepted industry test method (reference method)

(c) Conformity with appropriate in-house test methods that have been validated and verified;

(d) Comparison to an IVDD already available on the market.

(ii) When the manufacturer uses national, international or other standards to demonstrate conformity with the Essential Principles, the full title of the standard, identifying numbers, the date of the standard and the organization that created the standard should be provided. (Essential Principles of Safety and Performance of Medical Devices.

The IVDD, to which the Essential Principles (EP) conformity checklist is applicable, should be identified by the brand name, common name and risk class on the checklist itself. The columns of the checklist should be completed as follows:

a) Applicable to the IVDD?

Either a "Yes" or "No" answer is required. If the answer is "No" there should be a brief explanation.

b) Method of conformity

State the title and reference of the standard(s), industry or in-house test method(s), comparison study(ies) or other methods to demonstrate compliance. For standards, this should include the date of the standard and where a standard is referred to more than once in the checklist, the reference number and date can be repeated.

c) Identity of specific documents

The column should contain the reference to the actual technical documentation that demonstrates compliance to the EP, i.e. the certificate number(s), test reports, study reports or other documents that resulted from the method used to demonstrate compliance, and its location within the technical documentation or dossier.

1.14.3.3. Risk Analysis

Provide a summary of the risks identified during the risk analysis process and how such risks have been controlled to an acceptable level. Preferably, the risk analysis should be based on recognized standards and be part of the manufacturer's risk management plan.

The summary should address possible hazards for the IVDD such as the risk from false positive or false negative results, indirect risks which may lead to erroneous results, or from user-related hazards, such as reagents containing infectious agents.

The results of the risk analysis should provide a conclusion with evidence that the remaining risks are acceptable when compared to the benefits.

1.14.3.4. Design and Manufacturing Information

1.14.3.4.1. Product design

Provide information such as to give a general understanding of the design applied to the IVDD. It should include a description of the critical ingredients of an assay such as antibodies, antigens, enzymes and nucleic acid primers provided or recommended for use with the IVDD.

i. For **instruments**, include a description of major subsystems, analytical technology (e.g. operating principles, control mechanisms), dedicated computer hardware and software.

ii. For **instruments and software**, give an overview of the entire system, including an Architecture Design Chart which is typically a flowchart of the relationships among the major functional units in the software, including relationships to hardware and to data flows such as networking.

iii. For **standalone software**, include a description of the data interpretation methodology (i.e. algorithms).

iv. For self-testing IVDDs the design should include a description of the design aspects that make it suitable for lay person use.

v. If design takes place at multiple sites, a controlling site must be identified.

1.14.3.4.1.1. Formulation and composition

Provide formulation/composition for each of the ingredients;

(a) Materials

Provide complete details of material specifications, including raw materials;

(i) All components of the IVDD should be listed, chemically and biologically characterized, including antibodies, antigens, and assay controls, substrates used to detect antigen-antibody complexes, and test reagents. Appropriate references should be cited.

(ii) If synthetic peptides are used, the peptide sequence should be provided.

(iii) If components are of biological origin or recombinant, the source must be indicated and details on production must be provided. These details would include the strain of the virus, the cell line for the cultivation of the virus, sequences of relevant nucleic acids and amino acids, etc., used in the manufacturing process of viral lysate, purified proteins, recombinant and synthetic proteins.

(iv) If applicable, process validation results to be provided to substantiate that manufacturing procedures are in place to minimize biological risks, in particular, with regard to viruses and other transmissible agents. This also includes the inactivation of infectious organisms in reagents and the production of reagents.

(v) If applicable, information to be provided on irradiating components, non-ionising or ionizing (e.g. Iodide- 131 in the Radioimmunoassay kit, radio-labelled Phosphorus-32 DNA probes in Southern blots)

(vi) If applicable, information to be provided on the poison or controlled substance (e.g Buprenorphine in drug assay kit)

(vii) Give the nature and specification of the packaging material(s) including complete chemical and physical characterization of the packaging material making either direct or indirect contact with the IVDD.

Identify the sources of the materials from which the components are constructed.

(a) Biological Safety

List all biological components included in the IVDD to include material of bacterial, viral, parasitic, animal, or human origin or their derivatives where applicable. Indicate the name of the biological component, details of its use in the product and description of steps taken for the reduction of transmission or infection risk.

(b) Documentation of design change

Provide records of each design change, if any, with reasons for these changes along with associated validation/, data. Include evidence that the change achieves the desired effect, and that the product continues to comply with the Essential Principles of Safety and Performance.

1.14.3.4.2. Manufacturing Processes

1.14.3.4.2.1. Overview of Manufacturing Process

Provide information on the manufacturing process, which may be in form of a process flow chart, showing an overview of production including technologies used, assembly and packaging as well as details on each major step in the manufacturing process of the finished IVDD and Verification and validation for all stages of design and manufacturing process. Include details of any in-process and final device testing (e.g. the manufacturer's QC release program such as batch release criteria for the device, etc).

1.14.3.4.2.2. Sites of Manufacture

Provide the following information;

i. Name of site,

ii. Physical address of the site,

iii. Description of the component manufacture/stage of manufacturing process carried out at the site,

iv. A simple sight plan highlighting production areas and the number of employees at the site,

v. A description of any other manufacturing that occurs at the site;

vi. A certified QMS certificate equivalent for all sites

For all the critical manufacturing sites that are involved in the manufacture of this device (i.e. including design, warehousing and quality control stages of manufacture).

1.14.3.4.2.3. Key Suppliers

Provide a list of key suppliers of ingredients/products/services for the manufacture of the IVDD, indicating the;

i. Name of the supplier,

ii. Supplier's manufacturing site physical address

iii. A description of the ingredient/product/service supplied

iv. Evidence of purchasing and verification procedures for the ingredients/products/services sourced from these suppliers

1.14.3.5. Device Specifications

Describe functional characteristics and technical performance specifications for the device including accuracy, sensitivity, specificity of measuring and other specifications including chemical, physical, mechanical, electrical and biological.

A list of the features, dimensions and performance characteristics of the IVDD its variants and accessories should be provided in the dossier and also made available to the end user.

1.14.3.5.1. Device Verification and Validation

Summarize the results of verification and validation studies undertaken to demonstrate compliance of the IVDD with the Essential Principles that apply to it. Whenever applicable the information should cover:

i. The complete study protocol,

ii. The method of data analysis,

iii. Complete the study report,

iv. The study's conclusion,

v. Any published literature regarding the device or substantially similar devices.

vi. Summaries or reports of tests and evaluations based on other standards, manufacturer methods and tests or alternative ways of demonstrating compliance. Declarations/certificates of compliance to a recognized standard as applied by the manufacturer should be provided.

When a recognized standard exists that contains the protocol and the method of data analysis, this information can be substituted by a declaration/certificate of conformity to the recognized standard. However, a summary of the data and conclusions should be provided. Where appropriate actual test results summaries with their acceptance criteria should be provided and not just pass/fail statements.

1.14.3.5.2. Specimen type

This section should describe the different specimen types that can be used, including their stability (and storage) conditions and is typically applicable to all systems and assay types.

i. Stability includes storage and where applicable transport conditions. Storage includes elements such as duration, temperature limits and freeze/thaw cycles.

ii. Summary information for each matrix and anticoagulant when applicable, including a description of the measurement procedure for comparison or determination of measurement accuracy. This includes information such as specimen type tested, number of samples, sample range (using spiked samples as appropriate) or target concentrations tested, calculations and statistical methods, results and conclusions.

1.14.3.6. Analytical performance characteristics

1.14.3.6.1. Accuracy of measurement

Provide information to describe both trueness and precision studies.

1.14.3.6.2. Trueness of measurement

Provide information on the trueness of the measurement procedure and summarize the data used to establish the trueness measures for both quantitative and qualitative assays.

(a) Precision of measurement

Provide information to describe repeatability and reproducibility studies.

(i) Repeatability

Provide detail on repeatability estimation and information about the studies used to estimate, as appropriate, within-run variability. Repeatability data is obtained for instrumentation in conjunction with an appropriate assay.

(ii) Reproducibility

Provide information on reproducibility estimates and information about the studies used to estimate, as appropriate, variability between days, runs, sites, lots, operators and instruments. Such variability is also known as "Intermediate Precision".

1.14.3.6.3. Analytical sensitivity

Provide information about the study design and results. Give a detailed description of specimen type and preparation including matrix, analyte (measured) levels, and how levels were established. The number of replicates tested at each concentration should also be provided as well as a description of the calculation used to determine assay sensitivity. For example:

(i) Number of standard deviations above the mean value of the sample without analyte (measurand), commonly referred to as 'limit of blank' (LoB).

(ii) Lowest concentration distinguishable from zero, based on measurements of samples containing the analyte (measurand), commonly referred to as 'limit of detection, (LoD).

(iii) Lowest concentration at which precision and/or trueness are within specified criteria, commonly referred to as the 'limit of quantitation' (LoQ).

1.14.3.6.4. Analytical specificity

Give information to describe interference and cross-reactivity studies to determine the analytical specificity, defined as the ability of a measurement procedure to detect or measure only the analyte (measurand) to be detected, in the presence of other substances/agents in the sample.

Provide information on the evaluation of potentially interfering and cross-reacting substances/agents on the assay. Information should be provided on the substance/agent type and concentration tested, sample type, analyte (measurand) test concentration, and results.

Interferents and cross-reacting substances/agents, which vary greatly depending on the assay type and design, could derive from exogenous or endogenous sources such as:

Substances used for patient treatment (e.g. therapeutic drugs, alcohol, vitamins, foods, etc.), substances added during sample preparation (e.g. preservatives, stabilizers), substances encountered in specific specimen types (e.g. haemoglobin, lipids, bilirubin, proteins), and; analytes of similar structure (e.g. precursors, metabolites) or medical conditions unrelated to the test condition including specimens negative for the assay but positive for a condition that may mimic the test condition (e.g. for a hepatitis A assay: test specimens negative for hepatitis A virus, but positive for hepatitis B virus)

1.14.3.6.5. Metrological traceability of calibrator and control material values

The applicant shall summarize the information about the metrological traceability of values assigned to calibrators and trueness control materials. Include, for reference materials and/or reference measurement procedures and a description of value assignment and validation.

1.14.3.6.5.1. Measuring the range of the assay

Provide a summary of studies which define the measuring range (linear and non-linear measuring systems) including the limit of detection and describe information on how these were established. The summary should include a description of specimen type, number of samples, number of replicates, and preparation including information on matrix, analyte (measurand) levels and how levels were established. If applicable, add a description of the high dose hook effect and the data supporting the mitigation (e.g. dilution) steps.

1.14.3.6.5.2. Validation of assay cut-off

Provide a summary of analytical data with a description of the study design including methods for determining the assay cut-off, including the population (s) studied, method or mode of characterization of specimens and statistical methods e.g. Receiver Operator Characteristic (ROC) to generate results and if applicable, define grey-zone/equivocal zone.

1.14.3.7. Stability (excluding specimen stability)

Describe claimed shelf life, in-use stability and shipping studies.

1.14.3.7.1. Claimed shelf life

Provide information on stability testing studies, to support the claimed shelf life, performed on at least three different lots manufactured under conditions that are essentially equivalent to routine production conditions (these lots do not need to be consecutive lots). The summary should include:

i. The study report (i.e. protocol, number of lots, acceptance criteria and testing intervals),

ii. When accelerated studies have been performed in anticipation of the real time studies, the method used for accelerated studies;

iii. Conclusion and claimed shelf life.

Note:
Shelf life can be derived from the lot with the longest real time stability data as long as accelerated or extrapolated data from all three lots are comparable.

1.14.3.7.2. In use stability

Provide information on in use stability studies for one lot reflecting actual routine use of the device (real or simulated). This may include open vial stability and/or, for automated instruments, on board stability.

In case of automated instrumentation if calibration stability is claimed, supporting data should be included sufficient to describe: the study protocol (i.e. protocol, acceptance criteria and testing intervals), conclusions and claimed in use stability.

1.14.3.7.3. Shipping stability

Provide information on shipping stability studies for one lot to evaluate the tolerance of products to the anticipated shipping conditions, describing the study report (i.e. protocol, acceptance criteria), a method used for simulated conditions, conclusion and recommended shipping conditions.

Shipping studies can be done under real and/or simulated conditions and should include variable shipping conditions such as extreme heat and/or cold.

1.14.3.8. Software Verification and Validation

Provide information on the software design and development process and evidence of the validation of the software, as used in the finished device. This information should typically include the summary results of all verification, validation protocol and report and testing

performed both in-house and in a simulated or actual user environment prior to final release. It should also address all of the different hardware configurations and, where applicable, operating systems identified in the labelling.

1.14.3.9. Clinical Performance

Provide evidence of assessment and analysis of data generated from the clinical use of the product sufficient enough to verify the clinical safety of the IVDD. Include claims for clinical/diagnostic sensitivity and specificity. All claims should be supported by well-designed performance evaluations which should include:

(a) A detailed written plan and protocol for the evaluation study

(b) Dates on which the study was performed and by which site

(c) A written report on the outcome of the study; all anomalous results should be explained and justified. The report outline should contain,

i. The technology on which the device is based, the intended use of the device and any claims made about the device's clinical performance or safety.

ii. The nature and extent of the clinical data that has been evaluated; and,

iii. How does the referenced information (recognized standards and/or clinical data) demonstrate the clinical performance and safety of the device in question.

(d) Details of the IVDD lots/batches used for the evaluation including lot number, date of expiry, and storage conditions of the product prior to and during the study.
(e) The clinical evaluation report should be signed and dated by the evaluator(s) and accompanied by the manufacturer's justification of the choice of an evaluator.

The clinical evaluation report should be summarized as per the required information elaborated above.

1.14.4. Labelling Requirements

Labelling information shall be in English, French and/or Kinyarwanda and shall be expressed in a legible, permanent and prominent manner that can be easily understood by the intended user.
Provide a complete set of labeling associated with the IVDD including immediate and outer container labels on the IVDD, and instructions for use.
The labeling should contain the final content as determined by the manufacturer.

Depending on the type of device, the following minimum information should be provided on the label:

(a) The name of the IVDD shall be indicated. If the name does not uniquely identify the IVDD, an additional means of identification shall also be provided.
Examples: Catalogue number, commodity number

(b) the name and address of the manufacturer

(c) the identifier of the device, including the identifier of a device that is part of a system, test kit, or device class.

(d) batch or lot number

(e) Contents: if the contents are not readily apparent, an indication of what the package contains, expressed in terms appropriate to the device, such as size, net weight, length, volume or number of units, volume after reconstitution shall be indicated

(f) the words "Sterile" if the manufacturer intends to sell the IVDD in a sterile condition

(g) the word "For Single Use Only" shall be included if the IVDD is intended for single use

(h) In vitro diagnostics use: The In vitro diagnostics use of the device shall be indicated e.g. "For In vitro diagnostics use" or graphical symbol: "In vitro diagnostic device".

(i) The Expiry date: An expiry date based upon the storage instructions shall be indicated and shall follow the requirements of ISO 8601. Expiry dates shall be expressed as the year, the month and where relevant, the day. E.g. "YYYY-MM-DD" or "YYYY-MM".

(j) Unless self-evident to the intended user, the medical conditions, purposes and uses for which the device is manufactured, sold or represented, including the performance specifications of the device if those specifications are necessary for proper use

(k) the directions for use, unless directions are not required for the device to be used safely and effectively

(l) Warning and precautions: If an IVDD is considered hazardous, the outer container label shall include the appropriate danger wording or symbol(s) e.g. chemical, radioactive and biological hazards

(m) Storage and Handling conditions: The storage conditions necessary to maintain the stability of the reagents, calibrators, control materials in the unopened state and other IVDDs shall be indicated. If there are any other conditions that may affect the handling or storage of the reagents, calibrators, control materials and other IVDDs shall be specified e.g. Fragile

(n) Intended use: If the intended use is not indicated by the name of the IVDD, then an abbreviated intended use statement shall be given or included in the instruction for use. e.g. For measurement of plasma glucose concentration
In case the device is intended to be sold to the general public, labeling information:-

i. Shall be set out on the outside of the package that contains the device, and be visible under normal conditions of sale
ii. where a package that contains a device is too small to display all the information in accordance with (a-k) above, the directions for use shall accompany the device but need not be set out on the outside of the package or be visible under normal conditions of sale.

Specimen label(s), promotional material(s) and user manual(s) should be provided.

Note:
Requirements that have been described in a respective standard should also be followed when labelling a device.

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. *Annex 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*

ENDORSEMENT OF THE GUIDELINES

	Author	Checked by		Approved by
Title	**Division Manager of Human Medicines and Devices Assessment And Registration**	**Head of Drugs and Food Assessment and Registration Department**	**Quality Assurance Analyst**	**Director General**
Names	Mrs Clarisse IRASABWA	Dr. Védaste HABYALIMANA	Théogène NDAYAMBAJE	Dr. Emile BIENVENU
Signature				
Date	19/10/2022	20/10/2022	21/10/2022	24/10/2022

APPENDICES

Annex I: cover letter

QMS Nº: DFAR/HMDAR/FMT/001
Revision No: 1
Effective Date: 16/06/2022

Cover Letter

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

<Applicant's reference>
<Rwanda FDA>
<P.O.Box:1948><Kigali_Rwanda>

Dear Sir/Madam,

Subject: Submission of Application Dossier(s) for Marketing Authorization of < 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:

- ☐ Two (2) CD rom/external driver that contains the summary of technical documentation (STED) in selectable PDF format
- ☐ The proof of payment.

- ☐ We confirm that the electronic submission has been checked with up-to-date and state-of-the-art antivirus software.

- ☐ Type of Submission: ☐Full registration Application ☐Abridged Application ☐notification

- ☐ sample(s) submitted
- ☐ Application for QMS audit/GMP inspection has been made to Rwanda FDA (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>

Annex II: Application form

Format: QMS/FMT/002 Revision No: 1 Effective Date: 20 June 202	Department/Division/Office/Unit	DFAR Department/HMDAR Division
Document Type: **Form**		Doc. No :DFAR/HMDAR/FOM/022
RWANDA FDA Rwanda Food and Drugs Authority	Title: **Application Form for Medical Devices and In Vitro Diagnostics Devices (IVDDs) for registration**	Revision Number : 2 Revision Date: : 17/10/2022 Effective Date : 31/10/2022 Review Due Date : 30/10/2025 Ref Doc. :
Application Number	**Rwanda FDA use only**	
Date of submission of dossier	**Rwanda FDA use only**	

1.0 PARTICULARS OF THE MEDICAL DEVICE or IVDD (**Bold or Tick** the right type of application)

1.1	Type of application • New • full registration • abridged registration • Renewal • Variation* * If variation has been made, information supporting the changes should be submitted.
1.2	Name of the Medical Device or IVDD
1.3	Classification of the Medical Device or IVDD

1.4	Intended use of the Medical Device or IVDD
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 manufacturer Address: Country: Telephone: Telefax: E-Mail
1.7	Visual description of the Medical Device or IVDD
1.8	Proposed shelf life (in months) (where applicable):
1.9	Proposed storage conditions (where applicable):
1.10	Other sister/variants of the medical device (s) or IVD (s) registered or applied for registration

1.11	list all accessories that are manufactured/ sold with the devices
1.12	Do you hold Marketing Authorization(s) for another/ other medical device(s) or In Vitro Diagnostics Devices (IVDDs) in any of the East African Community (EAC)? • Yes • No If yes state Medical Device(s) or IVDD(s) name: Regulatory Authority(ies) where the product is authorized: Marketing authorization number(s): Indication(s):
1.13	Have you applied for Marketing Authorization(s) of medical device(s) or In Vitro Diagnostics Devices (IVDs) in any of the countries of the East African Community (EAC)? • Yes • No If yes state Medical Device name or IVDD: Regulatory Authority(ies) where you have applied for registration: Indication(s):
1.14	Country of origin (where the device was manufactured)

<table>
<tr><td></td><td></td></tr>
<tr><td>1.15</td><td>Device Marketing Authorization in the country of origin (Attach Marketing Authorization of the Medical Device or IVDD from the National Regulatory Authority). If not registered, state the reasons
<table>
<tr><td>• Authorized Country:
Date of authorization:
Authorization number:

• Refused Country:
Date of refusal:
Reason for refusal:</td><td>• Withdrawn (by the applicant after authorization) Country:
Date of withdrawal:
Reason for withdrawal:

• Suspended/revoked (by competent authority) Country:
Date of suspension/revocation:
Reason for suspension/revocation:</td></tr>
</table></td></tr>
<tr><td>1.16</td><td>Name(s) and physical address(es) of the manufacturing site(s) of the Medical Device or IVDD. Alternative sites should be also declared here.

All manufacturing sites involved in the manufacturing process of the device, stating the role of each including the quality control / in-process testing sites should be listed.

Address:

Country:

Telephone:

Telefax:

E-Mail:</td></tr>
<tr><td>1.17</td><td>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:</td></tr>
</table>

1.18	Name and address (physical and postal) of the person or company responsible for Pharmacovigilance and Post Marketing Surveillance: Address: Country: Telephone: Telefax: E-Mail:
1.19	Declaration of Conformity specifying all standards used in the manufacturing of the Medical Device or IVDD
1.20	Qualitative and Quantitative composition of the Medical Device or IVDD (If applicable)
1.21	Name and address (physical and postal) of the Contract Research Organisation(s) where the clinical studies of the Medical Device or IVDD 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 the Quality audit inspection. I also agree that I shall carry out pharmacovigilance and 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's Legislation and Regulations, which are applicable to Medical Devices and IVDDs. I also consent to the processing of information provided to Rwanda FDA. It is hereby confirmed that fees will be paid/have been paid according to the authority's rules*

Signature:

Date:

* **Note**: If fees have been paid, attach proof of payment

Annex III: Notification Form

Format: QMS/FMT/002 Revision No: 1 Effective Date: 20 June 2022	Department/Division/Office/Unit	DFAR Department/HMDAR Division
Document Type: **Form**		Doc. No :DFAR/HMDAR/FOM/023
RWANDA FDA Rwanda Food and Drugs Authority	Title: **Application Form for Medical Devices and In Vitro Diagnostics Devices (IVDDs) for notification**	Revision Number : 0 Revision Date: : 17/10/2022 Effective Date : 31/10/2022 Review Due Date : 30/10/2025 Ref Doc. :
Application Number	**Rwanda FDA use only**	
Date of submission of dossier	**Rwanda FDA use only**	

1.0 PARTICULARS OF THE MEDICAL DEVICE or IVDD (**Bold or Tick** the right type of application)	
1.1	Type of application • New • Renewal • Variation* * If variation has been made, information supporting the changes should be submitted.
1.2	Name of the Medical Device or IVDD
1.3	Classification of the Medical Device or IVDD
1.4	Intended use of the Medical Device or IVDD Intended user: ☐ Professional ☐ self user
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 manufacturer Address: Country: Telephone: Telefax: E-Mail
1.7	Visual description of the Medical Device or IVDD
1.8	Proposed shelf life (in months) (where applicable):
1.9	Proposed storage conditions (where applicable):
1.10	Other regulatory authority(ies) approval(s) (i.e. European conformity (CE) mark, United States Food and Drug Administration (USFDA) approval, etc)
1.11	Country of origin (where the device was manufactured)
1.12	Name(s) and physical address(es) of the manufacturing site(s) of the Medical Device or IVDD. 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	Declaration of Conformity specifying all standards used in the manufacturing of the Medical Device or IVDD
1.15	Global Medical Device Nomenclature (GMDN) Name GMDN Code

1.16	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 the Quality audit inspection. I also agree that I shall carry out pharmacovigilance and 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's Legislations and Regulations, which are applicable to Medical Devices and IVDDs. I also consent to the processing of information provided to Rwanda FDA. It is hereby confirmed that fees will be paid/have been paid according to the authority's rules*

Signature:

Date:

* **Note**: If fees have been paid, attach proof of payment

Annex IV : Classification rules of Invitro Diagnostics Devices (IVDDs)

Rule 1:	IVDDs 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:	IVDDs 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:	IVDDs 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, and 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 pneumonia, Methicillin Resistant Staphylococcus aureus. ● in a 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 IVDDs 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, and 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 the 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:	IVDDs intended for use by lay users (such as for self-testing or near patient 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 the lay user. Example for self-testing class C: Blood glucose monitoring. Examples of self-testing class B: Pregnancy self-test, fertility testing, and urine test strips.
Rule 5:	The following IVDDs 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 IVDD, 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 IVDD), wash solutions, plain urine cups, , and microbiological specimen collection devices. Note 2: The performance of the 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:	IVDDs 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 the 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:	IVDDs 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.

Annex V: Essential Principle checklist of Medical Devices including IVDDs

Format: QMS/FMT/002 Revision No: 1 Effective Date: 20 June 2022	Department/Division/Office/Unit	DFAR Department/HMDAR Division
Document Type: **Checklist**		Doc. No :DFAR/HMDAR/CKL/004
RWANDA FDA Rwanda Food and Drugs Authority	Title: **Essential Principle checklist of Medical Devices including IVDDs**	Revision Number :1 Revision Date: :17/10/2022 Effective Date :31/10/2022 Review Due Date :30/10/2025 Ref Doc. :

ESSENTIAL REQUIREMENTS CHECK LIST		
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 into account 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 another person / other people.			
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 conditions.			
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 the 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 the 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 the 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 an 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 is 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 into account 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 the 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	Unintended radiation 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	Instructions 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	Ionising radiation 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 the appropriate image and/or output quality for the intended medical purpose whilst minimizing radiation exposure to 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.	Medical devices that incorporate			

14.1	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 the 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	Label and Instructions for Use			

19.1	Users should be provided with the information needed to identify the manufacturer, use the device safely and ensure the intended performance, taking account of their training and knowledge. This information should be easily understood			
20.0 20.1	Clinical evaluation 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. **Note**: 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 have specific regulatory requirements for pre-study protocol review or informed consent.			
21.0 21.1	Essential Principles applicable to IVD Devices Chemical, physical and biological properties 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			

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

	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			

	a user, professional or lay, or, where applicable, another person or other people. 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 another person or other people.			
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 agents are integral to the intended purpose of the IVD device or when such an 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 the user, professional or lay, or other person. In particular safety with regard to viruses and other transmissible agents should be addressed by the 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 agents 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	<u>Label and Instructions for Use</u> Users should be provided with the information needed to identify the manufacturer, use the device safely and ensure the intended performance, taking account of their training and knowledge. This information should be easily understood. **<u>Note</u>**: Further information is provided in GHTF/SG1/N43:2005 *Labelling for Medical Devices*			
32.0				

32.1	<u>Performance evaluation including analytical performance and, where appropriate, clinical performance</u> 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. **<u>Note</u>**: 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 the first consideration of the need and justification of the study to the 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: _____

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