RWANDA FDA
Rwanda Food and Drugs Authority

GUIDELINES ON SUBMISSION OF DOCUMENTATION FOR REGISTRATION OF MEDICAL DEVICES

AUGUST 2022

Doc. No.: DHT/GDL/024	Revision Date: 18/08/2022	Review Due Date: 04/05/2023
Revision No.: 1	Effective Date: 04/05/2020	

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 medical 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, and 14, the Authority has issued Guidelines No DHT/GDL/024 on submission of documentation for registration of medical devices.

These guidelines were developed in reference to the Regulation Harmonization in the East African Community (EAC), World Health Organization (WHO) and the International Medical Device Regulators/STED.

The purpose of these guidelines is to provide guidance to medical devices importers, manufacturers and distributors intending to market their products in Rwanda on the documentation requirements by the Authority to assess 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 devices by the Authority for marketing authorization.

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

GUIDELINES DEVELOPMENT HISTORY

DRAFT ZERO BY COUNSULTANTS	27 June 2019, 18 August 2022
ADOPTION BY RWANDA FDA	13 February 2020, 15 September 2022
STAKEHOLDERS CONSULTATION	18 February 2020, …./…./2022
ADOPTION OF STAKEHOLDERS COMMENTS	02 March 2020, …./…/2022
DATE FOR COMING INTO EFFECT	05 May 2020, …/…/2022

TABLE OF CONTENT (to be revised)

FOREWORD 2

GUIDELINES DEVELOPMENT HISTORY 3

TABLE OF CONTENT 4

ABBREVIATIONS AND ACRONYMS 6

DEFINITIONS 7

INTRODUCTION 11

1.1 BACKGROUND 11
1.2 SCOPE 11
1.3 GENERAL PRINCIPLES 11
1.4 SUBMISSION OF APPLICATION 12
1.5 TYPES OF PRODUCT REGISTRATION APPLICATIONS 13
1.6 APPLICATION REQUIREMENTS 13
1.7 RECEIVING OF NEW APPLICATIONS FOR PRODUCT REGISTRATION 13
1.8 RWANDA FDA DOSSIER ASSESSMENT PROCEDURES 14
1.9 COMPLIANCE TO THE CURRENT GOOD MANUFACTURING PRACTICES (CGMP) 15
1.10 AUTHORITY"S PEER REVIEW COMMITTEE FOR MEDICAL DEVICE REGISTRATION 15
1.11 TIMELINES FOR MEDICAL DEVICE REGISTRATION 16
1.12 CLASSIFICATION OF MEDICAL DEVICES 16

1.13.1.1 Medical Device Description and Specification, Including Variants and Accessories 17

A. DEVICE DESCRIPTION 17
B. MEDICAL DEVICE SPECIFICATION 18

1.13.1.2 Label 18
1.13.1.3 Design and Manufacturing Information 19

A. DEVICE DESIGN 20
B. MANUFACTURING PROCESSES 20
C. DESIGN AND MANUFACTURING SITES 20

1.13.1.4 Essential Principles (EP) Checklist 20
1.13.1.5 Risk Analysis and Control 21
1.13.1.6 Product Verification and Validation 21

A. General 21
B. Biocompatibility 22
C. Medicinal substances 22
D. Biological safety 22
E. Sterilization 22

F. Software Verification and Validation *23*
G. Animal Studies *23*
H. Clinical Evidence *23*
1.13.1.7 Declaration of conformity *24*
INITIAL CLASSIFICATION RULES 25

ABBREVIATIONS AND ACRONYMS:

DAWO	Dossier Assessment Workshop
PRC	Peer Review Committee
Rwanda FDA	Rwanda Food and Drugs Authority
EP	Essential Principles
EAC	East African Community
FIFO	First In First Out
STED	Summary of Technical Documentation
ISO:	International Organization for Standardization
IVD	In Vitro Diagnostics
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
IFU	Instruction for Use
CE	Conformite Europeene (European Conformity)

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°. 003/2018 of 09/02/2018;
2. **"Active diagnostic medical device**" means an active device that whether used alone or in combination with another medical device, is intended for the use of detecting, monitoring or treating a physiological condition, state of health, illness or congenital deformity;
3. **"Active medical device"** means any medical device which depends on a source of electrical energy or any source of power other than that directly generated by the human body or gravity and which acts by converting this energy. Medical devices intended to transmit energy, substances or other elements between an active medical device and the patient, without any significant change, are not considered to be active medical devices. Standalone software is considered to be an active medical device;
4. **"Active therapeutic medical device"** means an active device that whether used alone or in combination with another medical device, is intended to support, modify, replace or restore a biological function or structure for the purpose of treating or mitigating an illness or injury or symptom of an illness or injury;
5. **"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";
6. **"Certificate of Notification"** means a certificate issued by the authority after its approval to be marketed; applicable to some devices falling under class a, depending on their extremely low risk- to the user or health care providers;
7. **"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;
8. **"Documentation"** a compilation of required information for registration including samples and any other additional information requested for registration;
9. **"Law"** means Law N° 003/2018 of 09/02/2018 establishing the Rwanda FDA and determining its mission, organization and functioning;
10. **"Local Technical Representative (LTR)"** Any applicant who is not resident in Rwanda shall appoint a local technical representative who must be a company incorporated in Rwanda and authorized by Rwanda FDA to deal with medical devices and must hold an operating license. The appointment shall be notified to the Authority by submitting a letter of appointment supported by original copy of power of attorney duly notarised in country of origin;
11. **"Medical device family"** means a group of medical devices that are made by the same manufacturer, that differ only in shape, colour, flavour or size, that have the same design and manufacturing process and that have the same intended use;
12. **"Medical device group"** means group of devices comprising a collection of medical devices, such as a procedure pack or tray, that is sold under a single name;
13. **"Medical device group family"** means a collection of medical device groups that are made by the same manufacturer, that have the same generic name specifying their intended use and that

differ only in the number and combination of products that comprise each group;

14. **"Medical Device System"** A medical device comprising a number of components or parts intended to be used together to fulfill some or the entire device's intended functions and that is sold under a single name;
15. **"Active implantable medical device"** Any active medical device, together with any accessories for its proper functioning, which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure;
16. **"Implantable device"** means any device which is intended:

    - to be totally introduced into the human body or,
    - to replace an epithelial surface or the surface of the eye, by surgical intervention which is intended to remain in place after the procedure. Any device intended to be partially introduced into the human body through surgical intervention and intended to remain in place after the procedure for at least 30 days is also considered an implantable device;

17. **"Invasive device"** A device, which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body. Body orifice means any natural opening in the body, as well as the external surface of the eyeball, or any permanent artificial opening, such as a stoma or permanent tracheotomy;
18. **"In vitro diagnostic device (IVD)"** a medical device is an *in vitro* diagnostic device (IVD) if it is a reagent, calibrator, control material, kit, specimen receptacle, software, instrument, apparatus, equipment or system, whether used alone or in combination with other diagnostic goods for *in vitro* use. It must be intended by the manufacturer to be used *in vitro* for the examination of specimens derived from the human body, solely or principally for the purpose of giving information about a physiological or pathological state, a congenital abnormality or to determine safety and compatibility with a potential recipient, or to monitor therapeutic measures;
19. "**Accessory to an IVD**" means an article intended specifically by its manufacturer to be used together with a particular IVD device to enable or assist that device to be used in accordance with its intended use;
20. "**Label**" means any tag, brand, mark, pictorial, or other descriptive matter, written, printed, stenciled, marked, embossed or impressed on, or attached to a medical device;
21. "**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). ";
22. "**manufacture**" means all operations that involve preparation, processing, filling transforming, packaging, repackaging and labeling of medical devices;
23. "**manufacturer**" means a person or a firm that is engaged in the manufacture of medical devices
24. **"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; or compensation for an injury; investigation, replacement, modification or support of the anatomy or of a physiological process; supporting or sustaining life; control of conception; 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;

25. **"Accessory to a medical device"** means an article intended specifically by its manufacturer to be used together with a particular medical device to enable or assist that device to be used in accordance with its intended use;
26. **"Fee"** means the fee prescribed in Regulation **CBD/TRG/004** related to regulatory services and fines;
27. **"Batch number (or lot number)"** a distinctive combination of numbers and/or letters that specifically identifies a batch on the labels, the batch records, etc;
28. **"Packaging"** means all operations, including filling and labeling, that a medical device has to undergo;
29. **"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.

INTRODUCTION

1.1 Background

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

Considering the provisions of the technical regulations No DFAR/HMDAR/TRG/002 Rev_2 Governing Registration of Medical Devices including In Vitro Diagnostics especially in its articles 6, 7, 13, 14 , the Authority has issued Guidelines N° DHT/GDL/024 on Submission of Documentation for registration of Medical Devices.

Manufacturers of all classes of medical devices are expected to demonstrate conformity to the Essential Principles of Safety, quality and Performance, through the preparation and holding of technical documentation that shows how each medical 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 the medical device through normal application of the manufacturer's Quality Management System (QMS).

1.2 Scope

These guidelines shall apply to all medical devices, other than In Vitro Diagnostics intended to be marketed in Rwanda. They provide guidance on the documentation to be submitted to the Authority for assessment and registration or notification

1.3 General principles

For the purpose of conformity assessment, the manufacturer should assemble information from existing technical documentation to provide evidence that the subject medical device is in conformity with the Essential Principles. The information submitted shall reflect the status of the medical device 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 sections including the Essential Principles checklist - EP checklist**.**

All information should be submitted in English, French or Kinyarwanda languages and may also include, for example: abstracts, high level summaries, or existing controlled documents sufficient to communicate key relevant information and allow an assessor 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 medical device, 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 applications

An application for registration of either a locally manufactured or imported medical device shall be made in writing via a cover letter and application form dated and signed by the applicant, along with application requirements. If the applicant is a foreign company, they shall appoint a local technical representative (LTR) through whom an application shall be submitted. The local technical representative shall be a registered wholesale company or an accredited manufacturer's representative**.** The application should be submitted to Rwanda FDA through the authorized local technical Representative to the following address:

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

1.5 Types of product registration applications

For the purposes of submission of product dossier to Rwanda FDA, applications are classified into three categories as follows:

1. **New applications for registration/notification:** an application for registration or notification of a medical device that is intended to be placed on the Rwandan market for the first time or a medical device which was on the market without a registration certificate or notification certificate.
2. **Renewal of a medical device registration/notification:** Applications for renewal of a registered or notified medical device. The application shall be made at least 3 months before the existing certificate expiry.
3. **Variation of a registered/notified medical device:** an application for any change in the registered or notified medical device. All applications for variation to a registered or notified medical device shall be made according to requirements as stipulated in the relevant guidelines

1.6 Application Requirements

1.6.1 Application Requirements for Registration

a) An application for medical devices registration shall include the following:

1. Signed and dated original hard copy of the cover letter (**Annex I**)
2. Signed and dated application form for medical device registration (**Annex II**)
3. Two CD-Rom or any other external drive containing relevant technical documentation (Summary of Technical Documentation (STED)) in a selectable PDF.
4. Two commercial samples of the medical device Please note that where required, additional samples might be requested.
5. Proof of payment of non-refundable prescribed registration fees
6. Proof of QMS audit application or QMS audit certificate issued by the Authority (where applicable).

b) For medical devices where the STED is prepared on request, the manufacturer should be able to assemble and submit it in the timeframe indicated by such notification as may be given by the Authority.

c) The manufacturer should submit the STED in the prescribed format.

d) A copy of any submitted information to the Authority should be held by the manufacturer for future reference.

1.6.2 Application Requirements for Notification

1. Signed and dated original hard-copy of the cover letter (**Annex I**)
2. Signed and dated and duly filled in notification form (**Annex III**)
3. Manual, Catalogue of IFU, art work of immediate package, outer package, product information leaflet or any other related document of the device.
4. A copy of a free sale certificate a QMS certificate, and a Certificate of conformity of the device.
5. Two commercial samples of the medical device. please note that where required, additional samples might be requested.
6. Proof of payment of prescribed non-refundable registration fees

1.7 Rwanda FDA Dossier Notification Procedure

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

A medical device dossier is reviewed by one assessor to verify 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 for extension of deadline to the Authority.

Thereafter, notification of the medical device may only be considered upon submission of a new application. In case the dossier is complete, the application will be scheduled for peer review. After which, the applicant shall receive a certificate of notification within thirty **(30)** working days.

1.8 Rwanda FDA Dossier Registration Procedure

After receiving an application requesting registration, the Authority shall proceed with screening of the dossier for completeness. In the event 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 assessement shall not undergo the screening process.
In case of a positive outcome during screening the applicant will be notified through an official communication letter and 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, treatment or prevention of rare disease conditions in the case of an emergency situation.

A medical device dossier is reviewed by two assessors to provide scientific and regulatory oversight regarding the quality, safety and performance of the device under assessment.

The Authority reserves the right to request any additional information to establish the quality, safety and performance of a medical device. 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 contains all outstanding information requested in one submission. Failure to comply with this condition or if the queries have been reissued for a **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 for medical devices undergoing full assessment and thirty **(30)** calendar days for medical devices 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 Medical 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. After which, the applicant shall receive a certificate of registration.

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.

1.9 Compliance with Quality Management System (QMS)

The QMS audit is part of the Medical 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 a Medical Device 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 is detailed in relevant guidelines.

1.10 Authority's Peer Review Committee for medical device 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 medical device.

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 calendar days **(90)**, the application shall be considered as withdrawn.

The Authority will register/ notify the medical device in the event that data on safety, quality and performance is considered satisfactory and a certificate of registration/ certificate of notification of medical device (***Refer to document n^{O}DHT/FMT/042)*** 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 made to the applicant.

1.11 Timelines for medical device registration

Medical Devices dossiers shall be scheduled for assessment according to the First in First out (FIFO) basis upon compliance of 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 full assessment procedure

Any additional data shall be submitted within:

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

1.12 Classification of Medical Devices

Medical devices are classified into four classes, based on a risk assessment. Class A represents the group with the lowest risk and Class D represents the group with the highest risk to the individual and/or to public health) *Table 1*

Table 1: Classification examples for Medical Devices

CLASS	RISK LEVELS
A	Low (examination gloves, tongue depressors…)
B	Low-Moderate(electronic thermometers, tubes for blood transfusion…)
C	Moderate-High (condoms, infusion pumps…)
D	High (cardiac pacemakers, implants, IUDs….)

Where a medical device can be classified into more than one class, the class representing the higher class shall apply.

Where one medical device is intended to be used together with a different medical device, that may or may not be from the same manufacturer, a separate submission should be made and the conformity assessment of the medical device 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 medical device.

1.13 Technical Documentation Requirements

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

1.13.2 Format and data presentation

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

1.13.2.1 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. STED (where applicable)
v. Labelling information
vi. Essential requirement checklist (where applicable)

Note: Failure to arrange the application dossier accordingly will lead to delay in the application process.

1.13.2.2 Evidence of compliance with QMS

For Medical Devices that require evidence of compliance to Quality Management System, an ISO 13485 certificates issued by recognized notified bodies must be provided. A CE certificate issued by a Notified Body designated in Europe will be also accepted. (May also be referred to as an EU Certificate, an CE certificate or an EEC Certificate).

CE and ISO 13485 certificates will only be accepted if they include acceptable information on the medical device:

- Full legal name of the manufacturer of the goods, including trading names if appropriate.
- Street address of the manufacturing site

- Date of the last audit/inspection.
- Standard of manufacture with which the manufacturer of the product(s) complies.
- Product(s) or type(s) of product(s) in sufficient detail to determine if the scope of the certificate is relevant to the medical device to be supplied
- Date of issue
- Period of validity or expiry date (must be current)
- Notified Body number
- Notified Body name

1.14.2. Content of the Summary of Technical Documentation (STED)

1.14.2.1. Device description and features

A. Device Description

The following descriptive information for the device should be submitted:

a) A general description including its intended use/purpose.

b) The intended patient population and medical condition to be diagnosed and/or treated and other considerations such as patient selection criteria.

c) Principles of operation.

d) Risk class and the applicable classification rule according to the Regulations for Classification and Registration of Medical Devices.

e) An explanation of any novel features.

f) A description of the accessories, other medical devices and other products that are not medical devices, which are intended to be used in combination with it.

g) A description or complete list of the various configurations/variants of the device that will be made available.

h) A general description of the key functional elements, e.g. its parts/components (including software if appropriate), its formulation, its composition, its functionality. Where appropriate, this will include: labelled pictorial representations (e.g.diagrams, photographs, and drawings), clearly indicating key parts/components, including sufficient explanation to understand the drawings and diagrams.

i) A description of the materials incorporated into key functional elements and those making either direct contact with a human body or indirect contact with the body, e.g., during extracorporeal circulation of body fluids.

B. Medical device Specification

Information under product specification should contain a list of the features, dimensions and performance attributes of the medical device, its variants and accessories, that would typically

appear in the product specification made available to the end user, e.g. in brochures, catalogues and the like.

Where relevant to demonstrating conformity to the Essential Principles, and to provide general background information, the STED should provide an overview of:

- the manufacturer's previous generation(s) of the device, if such exist; and
- similar devices available on the market.

1.14.2.2. Label

-A complete label associated with the device should be submitted. The labelling information shall include the following:

-the name of the device, both "proprietary" and "common".

-the name and address of the manufacturer

-the manufacturing site address

-the identifier of the medical device (serial number or batch number) that is part of a system, test kit, medical device group, medical device family or medical device group family

-the control number, otherwise the batch or lot number in the case of Class C & D

-an indication of what the package contains, expressed in terms appropriate to the medical device, such as size, net weight, length, volume or number of units

-the word "Sterile" if the manufacturer intends to sell the medical device in a sterile condition

-the words "For single use only" if the medical device is intended for that purpose, the expiry date of the medical device expressed in day, month and year.

-unless self-evident to the intended user, the medical conditions, purpose and uses for which the medical device is manufactured, sold or represented, including the performance specifications of the medical devices if those specifications are necessary for proper use;

-the directions for use; unless directions are not required for the safe and effective use of the device

-warnings, precautions and limitations of the device.

-The labelling design shall not bear close resemblance to other devices already registered by the Authority

-where a package that contains a device is too small to display all the information as specified in 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.

-Promotional material (brochures, catalogues and others)

-In addition to the above stated requirements in where the device is for sale to the general public, the labelling information shall be set out on the outside of the package that contains the device and must be visible under normal conditions of sale. Where a package that contains a device is too small to display all the information as specified above, the directions for use shall accompany the device but need not be set on the outside of the package or be visible under normal conditions of sale.

-Any special information, required by a relevant and applicable standard must be provided.

1.14.2.3 Design and Manufacturing Information

The processes for the design and manufacture should ensure that the medical device when used according to the intended purpose and meeting the conditions of technical knowledge and training of the user is safe and does not compromise the clinical condition of the patient or the health of the user. Performance and safety should not be affected during the lifetime of a medical device in such a way that it affects the safety of the patient or the user. Performance and safety should not be affected by transport or packaging or storage provided the instructions for transportation, packaging and storage are followed.

A. Device design

Device design should contain information to allow a reviewer to obtain a general understanding of the design stages applied to the device. The information may take the form of a flow chart. Such information may include product needs, design, verification, examination, test, review plan, and records.

B. Manufacturing processes

Information to allow a reviewer to obtain a general understanding of the manufacturing processes. The information may take the form of a process flow chart showing, for example, an overview of production, assembly, any final device testing, and packaging of the finished medical device.

C. Design and Manufacturing Sites

If multiple facilities are involved in the design and manufacture of a device, the overview of activities for each facility should be included in the STED. If the information is identical for a number of sites, this should be noted. This does not include identification of sub- contractors supplying components incorporated into the device.

1.14.2.4. Essential Principles (EP) Checklist

Information to be submitted include:

1. the Essential Principles;
2. whether each Essential Principle applies to the device and if not, why not;
3. the method(s) used to demonstrate conformity with each Essential Principle that applies;
4. a reference for the method(s) employed (e.g., standard), and
5. the precise identity of the controlled document(s) that offers evidence of conformity with each method used.

The method used to demonstrate conformity may include one or more of the following:

1. conformity with international or other standards;
2. conformity with a commonly accepted industry test method;

The EP checklist should incorporate a cross-reference to the location of such evidence both within the full technical documentation held by the manufacturer **(*Refer: Annex 1 Essential Principle Checklist*)**

1.14.2.5. Risk Analysis and Control

Provide a summary of the risks identified during the risk analysis process and how these risks have been controlled to an acceptable level. The manufacturer should perform a risk assessment to identify known and foreseeable risks and to mitigate these risks in the design, production and use of the medical device. Preferably, this risk analysis should be based on international standards and be part of the manufacturer's risk management plan.

1.14.2.6. Product Verification and Validation

A. General

Product verification and validation documentation should be submitted in a summary of results of verification and validation studies undertaken to demonstrate conformity of the device with the Essential Principles that apply to it. Such information would typically cover:

1. engineering tests;
2. laboratory tests;
3. simulated use testing;
4. any animal tests for demonstrating feasibility or proof of concept of the finished device;
5. any published literature regarding the device or substantially similar devices.

Detailed information will describe test design, complete test or study protocols, methods of data analysis, in addition to data summaries and test conclusions. Where no new testing has been undertaken, a rationale for that decision should be included. E.g. biocompatibility testing on the identical materials was conducted when these were incorporated in a previous, legally marketed version of the device

B. Biocompatibility

List of all materials in direct or indirect contact with the patient or user. where biocompatibility testing has been undertaken to characterize the physical, chemical, toxicological and biological response of a material, detailed information should be included on the tests conducted, standards applied, test protocols, the analysis of data and the summary of results. At a minimum, tests should be conducted on samples from the finished, sterilized (when supplied sterile) device.

C. Medicinal substances

Where the medical device incorporates a medicinal substance(s), detailed information concerning that medicinal substance, its identity and source, the intended reason for its presence, and its safety and performance in the intended application should be submitted

D. Biological safety

List of all materials of animal or human origin used in the device. For these materials, detailed information should be provided concerning the selection of sources/donors; the harvesting, processing, preservation, testing and handling of tissues, cells and substances of such origin should also be provided.

Process validation results should be included to substantiate that manufacturing procedures are in place to minimize biological risks, in particular, with regard to viruses and other transmissible agents. The system for record-keeping to allow traceability from sources to the finished device should be fully described.

E. Sterilization

Where the device is supplied sterile, detailed information of the initial sterilization validation including BIOBURDEN (microbial limit) testing, PYROGEN testing, testing for sterility residues (if applicable) and packaging validation should be submitted.

Typically, the detailed validation information should include the method used, sterility assurance level attained, standards applied, the sterilization protocol developed in accordance with those standards, and a summary of results.

Evidence of the ongoing revalidation of the process should also be provided. Typically this would consist of arrangements for, or evidence of, revalidation of the packaging and sterilization processes.

F. Software Verification and Validation

Information on the software design and development process and evidence of the validation of the software should be submitted; This information should typically include the summary results of all verification, validation 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 labeling.

G. Animal Studies

Where studies in an animal model have been undertaken to provide evidence of conformity with the Essential Principles related to functional safety and performance, detailed information should be contained in the documnents submitted.

Description of the study objectives, methodology, results, analysis and conclusions and document conformity with Good Laboratory Practices. The rationale (and limitations) of selecting the particular animal model should be discussed.

H. Clinical Evidence

Clinical evidence that demonstrates conformity of the device with the Essential Principles that apply to it. Some technologies have been available for many years and their clinical safety and performance have been well characterized. Many devices, however, utilize new technology that has had little prior application in the diagnosis or treatment of humans and for which safety and clinical performance have not yet been established. For long- established technologies, clinical investigation data that might be required for novel technologies may not be necessary. The available clinical data in the form of literature, reports of clinical experience, post-market reports and adverse event data for previous versions of the device, may, in principle, be adequate to establish the safety and performance of the device, provided that new risks have not been identified, and that the intended use(s)/purpose(s) has/have not changed.

The manufacturer should perform a documented, comprehensive evaluation of all the available clinical evidence under the control of its Quality Management System(QMS). That clinical evaluation report should become part of the technical documentation for the device and may serve as the basis for determining whether a new clinical device is appropriate.

1.14.2.7. Declaration of conformity

The manufacturer attests that its medical device complies fully with all applicable Essential Principles for Safety and Performance and draws up a written „Declaration of Conformity". As a minimum, this declaration should contain the following information:

- An attestation that each device that is subject to the declaration complies with the applicable Essential Principles for Safety and Performance, has been classified according to the classification rules, and has met all the applicable conformity assessment elements.
- Information sufficient to identify the device (s) to which the Declaration of Conformity applies.
- The Global Medical Device Nomenclature (GMDN) code and term for the device.
- The risk class allocated to the device(s) after following the guidance found in Initial Classification rules.
- Which of the conformity assessment elements described in Section 5 have been applied.
- The date from which the Declaration of Conformity is valid.
- The name and address of the device manufacturer.
- The name, position and signature of the responsible person who has been authorized to complete the Declaration of Conformity upon the manufacturer's behalf.

REFERENCES

1. The Common Submission Dossier Template (CSDT) of the Asian Harmonization Working Party (AHWP)
2. WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices
3. GHTF/SG1/N12:2000 *Role of Standards in the Assessment of Medical Devices*
4. GHTF/SG1/N15:2006 -*Principles of Medical Devices Classification*
5. GHTF/SG1/N40:2006 *Principles of Conformity Assessment for Medical Devices*
6. GHTF/SG1/N41:2005 *Essential Principles of Safety and Performance of Medical Devices*
7. GHTF/SG1/N43:2005 *Labelling for Medical Devices*
8. GHTF/SG1/NO11:2008 *Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices*

ENDORSEMENT OF THE GUIDELINES

	Author	**Authorized by**	**Approved by**
Title	Division Manager of Human Medicines and Medical Devices Assessment And Registration	Head of Drugs and Food Assessment and Registration Department	Director General
Names	**IRASABWA Clarisse**	**Dr. Vedaste HABYALIMANA**	**Dr. Emile BIENVENU**
Signature			
Date			

ANNEXES

Annex I: cover letter

QMS Nº: DAR/FMT/031
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 a 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 Application)

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

Document Type: **FORM**	Department/Division/ Directorate	Food and Drugs Assessment and Registration/ HMDAR Division
RWANDA FDA Rwanda Food and Drugs Authority	Title: **Application Form for Medical Devices and In Vitro Diagnostics Devices (IVDDs) registration**	Doc. No :DAR/FOM/050 Revision Number : 2 Revision Date: : 09/05/2022 Effective Date : 16/06/2022 Review Due Date : 16/06/2025 Ref Doc. :DHT/GDL/024

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 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) of 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 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 country of 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 reasons
<table>
<tr><td>• Authorized Country:
Date of authorization:
Authorization number:

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

• Suspended/revoked (by competent authority) Country:
Date of suspension/revocation:
Reason for suspension/revocation:</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 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>
<tr><td>1.18</td><td>Name and address (physical and postal) of the person or company responsible for Pharmacovigilance and Post Marketing Surveillance:
Address:
Country:
Telephone:
Telefax:
E-Mail:</td></tr>
<tr><td>1.19</td><td>Declaration of Conformity specifying all standards used in the manufacturing of the Medical Device or IVDD</td></tr>
</table>

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 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 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 III: Notification form

Document Type: **FORM**	Department/Division/ Directorate	Food and Drugs Assessment and Registration/ HMDAR Division
RWANDA FDA Rwanda Food and Drugs Authority	Title: **Application Form for Medical Devices and In Vitro Diagnostics Devices (IVDDs) notification**	Doc. No :DAR/FOM/187 Revision Number : 0 Revision Date: : 09/05/2022 Effective Date :16/06/2022 Review Due Date :16/06/2025 Ref Doc. :DHT/GDL/024

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 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 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.

The actual classification of each device depends on the claims made by the manufacturer and on its intended use. While the provision of illustrative examples in the table that follows is helpful when interpreting the purpose of each rule, it must be emphasised that the actual classification of a particular device must be considered individually, taking account of its design and intended use (**GHTF/SG1/N15:2006: *The Global Harmonization Task Force-****Principles of Medical Devices Classification*)

Duration of use.

Transient: Normally intended for continuous use for less than 60 minutes.

Short term: Normally intended for continuous use for between 60 minutes and 30 days.

Long term: Normally intended for continuous use for more than 30 days.

NON-INVASIVE DEVICES	
RULES	ILLUSTRATIVE EXAMPLES
Rule 1. All non-invasive devices which come into contact with injured skin:	Devices covered by this rule are extremely claim sensitive.
are in Class A if they are intended to be used as a mechanical barrier, forcompression or for absorption of exudates only, i.e. they heal by primary intent;	**Examples:** bandages; cotton wool.
are in Class B if they are intended to be used principally with wounds which have breached the dermis, including devices principally intended to manage the microenvironment of a wound.	**Example**: non-medicated impregnated gauze dressings.

unless they are intended to be used principally with wounds which have breached the dermis and can only heal by secondary intent, in which case they are in Class C.	Devices used to treat wounds where the subcutaneous tissue is at least partially exposed and the edges of the wound are not sufficiently close to be pulled together. To close the wound, new tissue must be formed within the wound prior to external closure. The device manufacturer claims that they promote healing through physical methods other than „primary intent". **Examples**: dressings for chronic ulcerated wounds; dressings for severe burns.
Rule 2(i). All non-invasive devices intended for channelling or storing • liquids, or • gases for the purpose of eventual infusion, administration or introduction into the body are in Class A,	Such devices are „indirectly invasive" in that they channel or store liquids that will eventually be delivered into the body. **Examples:** administration sets for gravity infusion; syringes without needles.
unless they may be connected to an active medical device in Class B or a higher class, in which case they are Class B;	**Examples**: syringes and administration sets for infusion pumps; anaesthesia breathing circuits. **Note:** "Connection" to an active device covers those circumstances where the safety and performance of the active device is influenced by the non-active device and *vice versa*.
Rule 2(ii). All non-invasive devices intended to be used for • channeling blood, or • storing or channeling other body liquids, or • storing organs, parts of organs or body tissues, for the purpose of eventual infusion, administration or introduction into the body are Class B.	**Examples:** tubes used for blood transfusion, organ storage containers
unless they are blood bags, in which case they are Class C.	**Examples:** Blood bags that do not incorporate an anti-coagulant. **Note:** In some jurisdictions, blood bags have a special rule that places them within a

	different class.
Rule 3. All non-invasive devices intended for modifying the biological or chemical composition of • blood, • other body liquids, or • other liquids, intended for infusion into the body are in Class C,	Such devices are „indirectly invasive" in that they treat or modify substances that will eventually be delivered into the body. They are normally used in conjunction with an active device within the scope of either Rule 9 or 11. **Examples:** hemodialyzers **Note:** For the purpose of this part of the rule, „modification" does not include simple, mechanical filtration or centrifuging which are covered below.
unless the treatment consists of filtration, centrifuging or exchanges of gas or of heat, in which case they are in Class B.	**Examples**: Devices to remove carbon Dioxide particulate filters in an extracorporeal circulation system.
Rule 4. All other non-invasive devices are in Class A.	These devices either do not touch the patient or contact intact skin only. **Examples:** urine collection bottles; compression hosiery; non-invasive electrodes, hospital beds.
INVASIVE DEVICES	
RULE	**ILLUSTRATIVE EXAMPLES**
Rule 5. All invasive devices with respect to body orifices? (other than those which are surgically invasive) and which: • are not intended for connection to an active medical device, or • are intended for connection to a Class A medical device only.	Such devices are invasive in body orifices and are not surgically invasive (refer to definition in Section 4). Devices tend to be diagnostic and therapeutic instruments used in ENT, ophthalmology, dentistry, proctology, urology and gynaecology. Classification depends on the duration of use and the sensitivity (or vulnerability) of the orifice to such invasion.
• are in Class A if they are intended for transient use;	**Examples**: examination gloves; enema devices.
• are in Class B if they are intended for short-term use;	**Examples**: urinary catheters, tracheal tubes.
unless they are intended for short-term use in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in a nasal cavity, in which case they are in Class A,	**Examples**: dressings for nose bleeds**.**

• are in Class C if they are intended for long-term use;	**Example:** urethral stent; contact lenses for long-term continuous use (for this device, removal of the lens for cleaning is considered as part of the continuous use).
unless they are intended for long-term use in the oral cavity as far as the pharynx, inan ear canal up to the ear-drum or in a nasal cavity and are not liable to be absorbed by the mucous membrane, in which case they are in Class B.	**Examples:** orthodontic materials, removable dental prosthesis.
All invasive devices with respect to body orifices (other than those which are surgically invasive) that are intended to be connected to an active medical device in Class B or a higher class, are in Class B.	**Examples**: tracheal tubes connected to a ventilator; suction catheters for stomach drainage; dental aspirator tips. **Note**: Independent of the time for which they are invasive.
Rule 6. All surgically invasive devices intended for **transient use** are in Class B,	A majority of such devices fall into several major groups: those that create a conduit through the skin (e.g. syringe needles; lancets), surgical instruments (e.g. single-use scalpels; surgical staplers; single-use aortic punch); surgical gloves; and various types of catheter/sucker etc.
unless they are reusable surgical instruments, in which case they are in Class A; or	**Examples**: Manually operated surgical drill bits and saws. **Note**: A surgical instrument connected to an active device is in a higher class than
unless intended to supply energy in the form of ionizing radiation, in which case they are in Class C; or	**Example:** catheter containing sealed radioisotopes.
unless intended to have a biological effect or be wholly or mainly absorbed, in which case they are in Class C; or	**Notes**: (a) The „biological effect“ referred to is an intended one rather than unintentional. The term „absorption“ refers to the degradation of a material within the body and the metabolic elimination of the resulting degradation products from the body. (b) This part of the rule does not apply to those substances that are excreted without modification from the body. **Example:** Insufflation gases for the abdominal cavity.

unless intended to administer medicinal products by means of a delivery system, if this is done in a manner that is potentially hazardous taking account of the mode of application, in which they are in Class C; or	**Example:** insulin pen for self- administration. **Note**: The term „administration of medicines" implies storage and/or influencing the rate/volume of medicine delivered not just channeling. The term „potentially hazardous manner" refers to the characteristics of the device and not the competence of the user.
unless they are intended specifically for use in direct contact with the central nervous system in which case they are in Class D; or	**Example:** spinal needle.
unless intended specifically to diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class D.	**Examples:** angioplasty balloon catheters and related guide wires; dedicated disposable cardiovascular surgical instruments.
Rule 7. All surgically invasive devices intended for **short-term use** are in Class B,	Such devices are mostly used in the context of surgery or post-operative care, or are infusion devices, or are catheters of various types. **Examples:** infusion cannulae; temporary filling materials; non-absorbable skin closure devices; tissue stabilizers used in cardiac surgery. **Note:** Includes devices that are used during cardiac surgery but do not monitor or correct a defect.
unless they are intended to administer medicinal products, in which case they are in Class C; or	**Note**: The term „administration of medicines" implies storage and/or influencing the rate/volume of medicine delivered not just channeling.
unless they are intended to undergo chemical change in the body (except if the devices are placed in the teeth), in which case they are in Class C; or	**Example:** surgical adhesive.
unless they are intended to supply energy in the form of ionizing radiation, in which case they are in Class C; or	**Example:** brachytherapy device.
unless they are intended to have a biological effect or to be wholly or mainly absorbed, in which case they are in Class D; or	**Example:** absorbable suture; biological adhesive. **Note**: The „biological effect" referred to is an

	intended one rather than unintentional. The term „absorption" refers to the degradation of a material within the body and the metabolic elimination of the resulting degradation products from the body.
unless they are intended specifically for use in direct contact with the central nervous system in which case they are in Class D;	**Example**: neurological catheter.
unless they are intended specifically to diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class D.	**Examples:**cardiovascular catheters; temporary pacemaker leads; carotid artery shunts
Rule 8. All implantable devices, and long- term surgically invasive devices, are in Class C,	Most of the devices covered by this rule are implants used in the orthopaedic, dental, ophthalmic, and cardiovascular fields. **Example:** maxilla-facial implants; bone plates and screws; bone cement; non- absorbable internal sutures; posts to secure teeth to the mandibula bone (without a bioactive coating).
unless they are intended to be placed into the teeth or on prepared tooth structure, in which case they are in Class B; or	**Examples:** materials for inlays, crowns, and bridges; dental filling materials.
unless they are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in Class D; or	**Examples:** prosthetic heart valves; cardiovascular stents; pacemaker leads and electrodes; deep brain stimulation electrodes; cerebrospinal catheter.
unless they are intended to be life supporting or life sustaining, in which case they are in Class D; or	
unless they are intended to be active implantable medical devices, in which case they are Class D; or	**Example**: pacemakers; implantable defibrillators.
unless they are intended to have a biological effect or to be wholly or mainly	**Example:** implants claimed to be bioactive.

absorbed, in which case they are in Class D; or	**Note**: Hydroxy-apatite is considered as having biological effect only if so claimed and demonstrated by the manufacturer.
unless they are intended to administer medicinal products, in which case they are in Class D; or	**Example:** subcutaneous infusion ports for long-term use.
unless they are intended to undergo chemical change in the body (except if the devices are placed in the teeth), in which case they are in Class D; or	**Example:** surgical adhesives intended for long term use. **Note**: Bone cement is not within the scope of the term „chemical change in the body" since any change takes place in the short rather than long term.
unless they are breast implants, in which case they are in Class D.	
ACTIVE DEVICES	
Rule 9(i). All active therapeutic devices intended to administer or exchange energy are in Class B,	Such devices are mostly electrically powered equipment used in surgery; devices for specialised treatment and some stimulators. **Examples:** muscle stimulators; powered dental hand pieces; hearing aids; neonatal phototherapy equipment; ultrasound equipment for physiotherapy.
unless their characteristics are such that they may administer or exchange energy to or from the human body in a potentially hazardous way, including ionizing radiation, taking account of the nature, the density and site of application of the energy, in which case they are in Class C.	**Examples:** lung ventilators; baby incubators; electrosurgical generators; external pacemakers and defibrillators; surgical lasers; lithotriptors; therapeutic X-ray and other sources of ionizing radiation. **Note**: The term „potentially hazardous" refers to the type of technology involved and the intended application.
Rule 9(ii). All active devices intended to control or monitor the performance of active therapeutic devices in Class C, or intended directly to influence the performance of such devices, are in Class C.	**Examples:** external feedback systems for active therapeutic devices.
Rule 10(i). Active devices intended for diagnosis are in Class B:	Such devices include equipment for ultrasonic diagnosis/imaging, capture of physiological signals.

- if they are intended to supply energy which will be absorbed by the human body (except for devices used solely to illuminate the patient's body, with light in the visible or near infra-red spectrum, in which case they are Class A), or	**Examples:** magnetic resonance equipment; diagnostic ultrasound in non- critical applications; evoked response stimulators.
-if they are intended to image *in vivo* distribution of radiopharmaceuticals, or	**Example:** gamma/nuclear cameras.
-if they are intended to allow direct diagnosis or monitoring of vital physiological processes,	**Example:** electronic thermometers, stethoscopes and blood pressure monitors; electrocardiographs.
unless they are specifically intended for: a) monitoring of vital physiological parameters, where the nature of variations is such that it could result in immediate danger to the patient, for instance variations in cardiac performance, respiration, activity of central nervous system, or b) diagnosing in clinical situations where the patient is in immediate danger, in which case they are in Class C.	**Example:** monitors/alarms for intensive care; biological sensors; oxygen saturation monitors; apnoea monitors. **Example:** ultrasound equipment for use in interventional cardiac procedures.
Rule 10. Active devices intended to emit ionizing radiation and intended for diagnostic and/or interventional radiology, including devices which control or monitor such devices, or those which directly influence their performance, are in Class C.	**Example:** devices for the control, monitoring or influencing of the emission of ionizing radiation.
Rule 11. All active devices intended to administer and/or remove medicinal products, body liquids or other substances to or from the body are in Class B,	Such devices are mostly drug delivery systems or anaesthesia equipment. **Examples:** suction equipment; feeding pumps; jet injectors for vaccination; nebuliser to be used on conscious and spontaneously breathing patients where failure to deliver the appropriate dosage characteristics is not potentially hazardous.
unless this is done in a manner that is potentially hazardous, taking account of the nature of the substances involved, of the part of the body concerned and of the mode and route of administration, in which case they are in Class C.	**Examples:** infusion pumps; anaesthesia equipment; dialysis equipment; hyperbaric chambers; nebuliser where the failure to deliver the appropriate dosage characteristics could be hazardous.
Rule 12. All other active devices are in Class A.	**Examples:** examination lamps; surgical microscopes; powered hospital beds & wheelchairs; powered equipment for the

	recording, processing, viewing of diagnostic images; dental curing lights.
ADDITIONAL RULES	
Rule 13. All devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, and which is liable to act on the human body with action ancillary to that of the devices, are in Class D.	These medical devices incorporate medicinal substances in an ancillary role. **Examples:** antibiotic bone cements; heparin-coated catheters; wound dressings incorporating antimicrobial agents to provide ancillary action on the wound; blood bags incorporating an anti-coagulant.
Rule 14. All devices manufactured from or incorporating animal or human cells/tissues/derivatives thereof, whether viable or non-viable, are in Class D,	**Example:** porcine heart valves.
unless such devices are manufactured from or incorporate non-viable animal tissues or their derivatives that come in contact with intact skin only in which case they are in Class A.	**Examples:** leather components of orthopaedic appliances.
Rule 15. All devices intended specifically to be used for sterilising or disinfecting medical devices are in Class B.	**Example:** desk-top sterilisers for use with dental instruments.
unless they are disinfectant solutions or washer-disinfectors intended specifically for invasive medical devices, as the end point of processing, in which case they are in Class C; or	**Examples:** solutions intended to be used for the disinfection of medical devices without further processing (for example in a sterilizer) including those where the infective agent is a prion; washer-disinfector equipment specifically for disinfecting an endoscope or another invasive device.
unless they are intended to clean medical devices by means of physical action only, in which case they are in Class A.	

Rule 16. All devices that are intended specifically to be used for disinfecting, cleaning, rinsing or, when appropriate, hydrating contact lenses are in Class C.	**Note:** In some jurisdictions such products: are considered to be outside the scope of the medical device definition; may be subject to different controls.
Rule 17. All devices used for contraception or the prevention of the transmission of sexually transmitted diseases are in Class C,	**Examples**: contraceptive diaphragms. condoms;
unless they are implantable or long-term invasive devices, in which case they are in Class D.	**Example**: contraceptive intrauterine device.

Annex V: Essential Principles Checklist

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

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

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

How to fill in the checklist

Device

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

Applicable to device?

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

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

Method of Conformity

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

standard is referred to more than once in the checklist, simply the reference number and date can be repeated.

Identity of Specific Documents

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

Document Type: **CHECKLIST**	Department/Division/ Directorate	Food and Drugs Assessment and Registration/ HMDAR Division
RWANDA FDA Rwanda Food and Drugs Authority	Title: **checklist for Medical Devices Essential Principle**	Doc. No :DAR/CKL/077 Revision Number : 1 Revision Date: : Effective Date :16/06/2022 Review Due Dat :16/06/2025 Ref Doc. • : DHT/GDL/024

Essential Principles Checklist			
Device:			
Essential Principle	**Applicable to the device?**	**Method of Conformity**	**Identity of Specific Documents**
General Requirements			
5.1 Medical devices should be designed and manufactured in such a way that, when used under the conditions and for the purposes intended and, where applicable, by virtue of the technical knowledge, experience, education or training of intended users, they will 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.			

5.2 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, ▪ inform users of any residual risks.			
5.3 Devices should achieve the performance intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions within the scope of the definition of a medical device applicable in each jurisdiction.			

5.4 The characteristics and performances referred to in Clauses 5.1, 5.2 and 5.3 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.			
5.5 The devices should be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected under transport and storage conditions (for example,fluctuations of temperature and humidity) taking account of the instructions and information provided by the manufacturer.			
5.6 The benefits must be determined to outweigh any undesirable side effects for the performances intended.			
Design and Manufacturing Requirements			
5.7 Chemical, physical and biological properties			

• The devices should be designed and manufactured in such a way as to ensure the characteristics and performance referred to in Clauses 5.1 to 5.6 of the 'General Requirements'. 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, body fluids, and specimens, taking account of the intended purpose of the device, ▪ the choice of materials used should reflect, where appropriate, matters such as hardness, wear and fatigue strength.			
• The devices should be designed, manufactured and packed 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.			

• 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 asto 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.			
• 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 usefulness of the substance should be verified, taking account of the intended purpose of the device.			
• 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.			

• 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 ingression 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.			
5.8 Infection and microbial contamination			
The devices and manufacturing processes should be designed in such a way as to eliminate or to reduce as far as reasonably practicable and appropriate the risk of infection to patients, users and, where applicable, other persons. The design should: ▪ allow easy handling, and, where necessary: ▪ reduce as far as reasonably practicable and appropriate any microbial leakage from the device and/or microbial exposure during use, ▪ prevent microbial contamination of the device, or specimen where applicable, by the patient, user or other person.			

Where a device incorporates substances of biological origin, the risk of infection must be reduced as far as reasonably practicable and appropriate by selecting appropriate sources, donors and substances and by using, as appropriate, validated inactivation, conservation, test and control procedures.			
In some jurisdictions products incorporating tissues, cells and substances of non-human origin may be considered medical devices. In this case, such tissues, cells andsubstances 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. 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.			

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. 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.			
Devices labelled as having a special microbiological state should be designed, manufactured and packed to ensure they remain so when placed on the market and remain so under the transport and storage conditions specified by the manufacturer.			
Devices delivered in a sterile state should be designed, manufactured and packed 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.			

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.			
Devices intended to be sterilized should be manufactured in appropriately controlled (e.g. environmental) conditions.			
Packaging systems for non-sterile devices should keep the product without deterioration at the level of cleanliness stipulated 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.			
The packaging and/or label of the device should distinguish between identical or similar products placed on the market in both sterile and non-sterile condition.			
5.9 Manufacturing and environmental properties			
• 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 label and/or in the instructions for use.			

• 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, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features; ▪ 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 in pressure and acceleration; ▪ the risks connected to their use in conjunction with materials, substances and gases with which they may come into contact during normal conditions of use; ▪ the risks of accidental penetration of substances into the device; ▪ the risk of incorrect identification of specimens; ▪ the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given; ▪ risks arising where maintenance or calibration are not possible (as with implants), from ageing of materials used or loss of accuracy of any measuring or control mechanism.			

• 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.			
• Devices must be designed and manufactured in such a way as to facilitate the safe disposal of any waste substances.			
5.10 Devices with a diagnostic or measuring function			
• Devices with a measuring function where inaccuracy could have a significant adverse effect on the patient, should be designed and manufactured in such a way as to provide sufficient accuracy,precision and stability for their intended purpose of the device. The limits of accuracy should be indicated by the manufacturer.			

• 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. In particular the design should address sensitivity, specificity, trueness, repeatability, reproducibility, control of known relevant interference and limits of detection, as appropriate.			
• 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 a quality management system.			
• Any measurement, monitoring or display scale should be designed in line with ergonomic principles, taking account of the intended purpose of the device.			
• Wherever possible values expressed numerically should be in commonly accepted, standardised units, and understood by the users of thedevice **Note:** While SG1 generally supports convergence on the global use of internationally standardised measurement units, considerations of safety, user familiarity, and established clinical practice may justify the use of other recognised measurement units.			
5.11 Protection against radiation			
General			

5.11.1.1 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 andappropriate, compatible with the intended purpose, whilst not restricting the application ofappropriate specified levels for therapeutic and diagnostic purposes.			
Intended radiation			
5.11.2.1 Where devices are designed to emit hazardous, or potentially hazardous, levels of visible and/or invisible radiation necessary for a specific medical purpose thebenefit of which is considered tooutweigh the risks inherent in the emission, it should be possible for the user to control the emissions.Such devices should be designed and manufactured to ensure reproducibility of relevant variable parameters within an acceptable tolerance.			
5.11.2.2 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.			
Unintended radiation			

5.11.3.1 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.			
Instructions for use			
5.11.4.1 The operating instructions for devices emitting radiation should 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 and of eliminating the risks inherent in installation.			
Ionizing radiation			
5.11.5.1 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.			
5.11.5.2 Devices emitting ionizing radiation intended for diagnostic radiology should be designed and manufactured in such a way as to achieve appropriate image and/or output quality for the intended medical purpose whilst minimising radiation exposure of the patient and user.			

5.11.5.3 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.			
5.12 Requirements for medical devices connected to or equipped with an energy source			
5.12.1 Devices incorporating electronic programmable systems, including software, should be designed to ensure the repeatability, reliability and performance of these systems according to the intended use. In the event of a single fault condition in the system, appropriate means should be adopted to eliminate or reduce as far as practicable and appropriate consequent risks.			
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.			
Devices where the safety of the patients depends on an external power supply should include an alarm system to signal any power failure.			

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			
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.			
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.			
Protection against electrical risks Devices should be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks during normal use and in single fault condition, provided the devices are installed and maintained as indicated by the manufacturer.			
5.13 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.			

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.			
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.			
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.			
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.			
5.14 Protection against the risks posed to the patient by supplied energy or substances			

Devices for supplying the patient with energy or substances should be designed and constructed in such away that the delivered amount can be set and maintained accurately enough to guarantee the safety of the patient and of the user.			
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 from an energy and/or substance source.			
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.			
5.15 Protection against the risks posed to the patient for devices for self-testing or self-administration			

Such devices 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 users and the influence resulting from variation that can reasonably beanticipated in user"s technique and environment. The information and instructions provided by the manufacturer should be easy for the user to understand and apply.			
Such devices should be designed and manufactured in such a way as to reduce as far as practicable the risk of use error in the handling of the device and, if applicable, the specimen, and also in the interpretation of results.			
Such devices should, where reasonably possible, include a procedure by which the user can verify that, at the time of use, that the product will perform as intended by the manufacturer.			
5.16 Information supplied by the manufacturer			
5.16.1 Users should be provided with the information needed to identify the manufacturer, to use the device safely and to ensure the intended performance, taking account of their training and knowledge. This information should be easily understood. **Note:** Further information is provided in *SG1/N009 Labelling for Medical Devices* and in SG1/N043 *Labelling for Medical Devices (revised).*			

5.17 Performance evaluation including, where appropriate, clinical evaluation			
All data generated in support of performance evaluation should be obtained in accordance with therelevant requirements applicable in each jurisdiction.			
Clinical investigations on human subjects should be carried out in accordance with the spirit of the Helsinki Declaration. This includes every step in the clinical investigation from first consideration of the need and justification of the study to publication of the results. In addition, some countries may have specific regulatory requirements for pre-study protocol review or informed consent.			

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: _____

End of document