RWANDA FDA
Rwanda Food and Drugs Authority

GUIDELINES ON SUBMISSION OF DOCUMENTATION FOR REGISTRATION OF MEDICAL DEVICES

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FOREWORD

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

Considering the provisions of the technical regulations Governing Registration of Medical Devices including In Vitro Diagnostics in its article which gives the power to issue guidelines, the Authority has issued Guidelines on submission of technical documentation for registration of medical devices.

Rwanda FDA adopted the Guidelines 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), Africa Medical Devices Forum (AMDF), World Health Organization (WHO) and the International Medical Device Regulators Forum (IMDRF).

The purpose of these guidelines is to provide guidance to medical devices importers, manufacturers and distributors intending to market or manufacture their devices in Rwanda, on the documentation requirements by the Authority to assess conformity of such devices to the essential principles of safety, quality and performance before market authorization can be issued.
These guidelines are hereby promulgated for information, guidance and strict compliance by all concerned.

Adherence to the guidelines by the manufacturers/applicants will facilitate timely assessments and approvals of medical devices dossiers by the Authority for pre-market authorization/ registration.
We wish to acknowledge all the efforts of key stakeholders and express our gratitude to all individuals who actively participated in the development and validation of these guidelines.

Dr. Emile BIENVENU
Director General

GUIDELINES DEVELOPMENT HISTORY

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1	-Revision of the definitions -Amendment of the technical file sections -The STED mode of submission has been superseded by the Table of Content (ToC) -Inclusion of the notification procedure for class A medical devices -inclusion of the renewal process -Revision of timelines -Revision and inclusion of forms and cover letter as appendices -Editorial changes

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ACCRONYMES AND ABBREVIATIONS

CAB	Conformity Assessment Body
DOC	Declaration of Conformity
EAC	East African Community
EEC	European Economic Community
EP	Essential Principles
FIFO	First In First Out
GMP	Good Manufacturing Practice
IMDRF	International Medical Devices Regulators Forum
ISO	International Organization for Standardization
IRB	Institutional Review Board
ISRC	Internal Scientific Review Committee
IVD	In Vitro Diagnostic
STED	Summary of Technical Documentation
QMS	Quality Management Systems
LTR	Local Technical Representative
RWANDA FDA	Rwanda Food and Drugs Authority
TOC	Table of Content
MA	Marketing Authorization

GLOSSARY / Definitions

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

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

2. **"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. Stand-alone software is considered to be an active medical device;

3. **"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;

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 a person who applies for registration of a product to Rwanda FDA, who must be the owner of the product. He may be a manufacturer or a person to whose order and specifications, the product is manufactured. After the product is registered, the applicant shall be the "Marketing Authorization Holder"

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

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

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

9. **"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;

10. **"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;

11. **"Medical Device System"** means 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 are sold under a single name;

12. **"Active implantable medical device"** means 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;

13. **"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;

14. **"Invasive device"** means 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;

15. **"In vitro diagnostic device (IVD)**" means a device, whether used alone or in combination, intended by the manufacturer for the in vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes. This includes reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles

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

16. "**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 the device to be used in accordance with its intended use;

17. "**Label**" means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stenciled, marked, embossed or impressed on, or attached to a container or any medical device;

18. "**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, fillers (where applicable). ";

19. "**Manufacture**" means all operations that involve preparation, processing, filling transforming, packaging, repackaging and labelling of a medical device;

20. "**Manufacturer**" means any natural or legal person with responsibility for design and/or manufacture of a medical device with the intention of making the medical device available for use, under his name; whether or not such a medical device is designed and / or manufactured by that person himself or on his behalf by another person (s);

21. "Medical device" means any instrument, apparatus, implement, machine, appliance, implant, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings or animals, for one or more of the specific medical purpose(s) of diagnosis, prevention, monitoring, treatment or alleviation of disease; diagnosis, monitoring, treatment, alleviation of or compensation for an injury; investigation, replacement, modification or support of the anatomy or a physiological process; supporting or sustaining life; control of conception; disinfection of medical devices; providing information by means of in vitro examination of specimens derived from the human or animal bodies, and which does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human or animal body, but which may be assisted in its intended function by such means;

22. "Fee" means the fee prescribed in Regulation related to regulatory services and fines;

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

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

25. "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;

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

27. "Dossier" means a file that contains detailed information on the device description, manufacturing, quality control and biomedical studies that demonstrates quality, safety and performance of the finished medical device;

28. "Quality Management System" means a management system to direct and control an organization with regard to quality, from establishing quality policy, quality objectives and implementing and maintaining quality system;

29. "Technical Documentation" means documented evidence, normally an output of the Quality Management System that demonstrates compliance of a device to the Essential Principles of Safety and Performance of Medical Devices;

30. **"Medical Devices with Measuring Function"** a device has a measuring function if;
    a. The device is intended by the manufacturer to measure: - quantitatively a physiological or anatomical parameter, or - a quantity or a qualifiable characteristic of energy or of substances delivered to or removed from the human body,
    b. The result of the measurement - is displayed in legal units or other internationally acceptable units or - is compared to at least one point of reference indicated in legal units or other acceptable units.
    c. The intended purpose implies accuracy, claimed explicitly or implicitly, where a non-compliance with the implied accuracy could result in a significant adverse effect on the patient's health and safety.

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

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

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

INTRODUCTION

1.1 Background

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

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

1.2. Scope

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

1.3. General principles

For the purpose of conformity assessment, the manufacturer should assemble information from existing technical documentation to provide evidence that the subject medical device is in conformity with the Essential Principles (EP). 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 should 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 (any document not provided in the languages above should be translated)and may also include, abstracts, high level summaries, or existing controlled documents sufficient to communicate key relevant information and allow a reviewer to understand the subject and assess the validity of that information.

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

An application for medical devices registration for either locally manufactured or imported shall be made in writing via a cover letter and application form dated and signed by the applicant. If the applicant is a foreign company, the applicant shall appoint a local technical representative (LTR); The local technical representative shall be a registered wholesale company or an accredited manufacturer's representative**.**

The application should be submitted to Rwanda FDA by the applicant via Rwanda FDA Online portal. Only samples can be submitted along with the cover letter (Annex 1) together with a printed email notification bearing an application reference number generated at the time of application submission at Rwanda FDA head Quarters reception to the following address:

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

1.5. Application requirements

1.5.1. Requirements for notification of new applications

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

1. Signed and dated original hard copy of a cover letter (**Appendix 1**)
2. Signed and dated and duly filled in application form for notification (**Appendix 2**)
3. Certificate of compliance to ISO 13485 standard or its equivalent from the manufacturer(s) of the device
4. Declaration of Conformity (DoC)
5. Instruction for Use (IFU) (where applicable)
6. Device artworks/ mock ups
7. One device commercial pack sample (where applicable)

1.5.2. Requirements for registration of new applications

Other medical devices not eligible for notification shall apply (online) for registration and their applications shall include the following:

1. Signed and dated original hard-copy of cover letter (**Appendix 1**)
2. Signed and dated application form for device registration (**Appendix 3**)
3. Technical documentation (Table of Content (ToC))
4. Declaration of Conformity (DoC)

5. Copies of referenced literature and other supporting documents
6. Two commercial samples of medical devices and certificate of conformity (where applicable), however additional samples might be required
7. Rwanda FDA QMS audit certificate or Proof of QMS audit application (for class C and class D medical devices)

1.5.3. Requirements for renewal of notified/registered devices applications

An application for renewal of medical devices registration shall include the following:

1. Signed and dated original hard-copy of cover letter **(Appendix 1)**
2. Signed and dated application form for notified devices **(Appendix 2)**, for registered devices **(Appendix 3)**
3. Current artworks/ mock ups of the device
4. One (notification)/ two (registration) commercial pack samples (where applicable)
5. Specifications of the device along with batch certificates of analysis
6. Payment of renewal fee and proof of QMS audit (where applicable)

1.6. Receiving applications for Medical Devices registration/notification

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

1.7. Dossier Assessment Procedures

1.7.1. Dossier Notification Procedure

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

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

In the event that the responses to the queries are not submitted within the specified time, from the date they were issued, it will be considered that the applicant has withdrawn the application unless the applicant has requested an extension of the deadline to the Authority. Thereafter, notification of the 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.

The applicant shall receive a certificate of notification within thirty (**30**) calendar days.

1.7.2. Rwanda FDA Dossier Registration Procedure

After receiving an application requesting registration via the online platform, the Authority shall proceed with the screening of the dossier for completeness. In the event that the dossier is incomplete, it will not be scheduled for assessment and the applicant will be notified via the platform within thirty (**30)** calendar days and requested to comply with requirements.
In case of a positive outcome from the screening, the application will be scheduled for assessment according to the First in First out (FIFO) rules. Priority assessment may be granted where the device is intended for diagnosis of rare disease conditions or in the case of an emergency situation.

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

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

In the event the responses to the queries are not submitted within the specified timeline for 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 deemed complete after the assessment, the application will be scheduled for peer review.

The applicant shall receive a certificate of registration within a maximum period of nine (**9**) months.

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.

1.8. Compliance with The Quality Management System (QMS)

The QMS audit is part of a Medical Device registration process. The Authority should conduct an inspection of the manufacturing facility or use other means to verify whether the manufacturing site complies with QMS before the 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 them to the department that has the mandate of inspection and compliance.
QMS audit compliance of the manufacturing site of devices under the abridged assessment procedure shall be confirmed through desk review; however, if deemed necessary the Authority may conduct an onsite inspection.
More information on QMS requirements and application for QMS audit/GMP inspection is detailed in relevant guidelines.

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

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

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

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

1.10. Timelines for Medical Device Registration/Notification

1.10.1. Timelines for registration/notification of new applications

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

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

Any additional data shall be submitted within:

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

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

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

1.10.2. Timelines for renewal of notified/registered devices applications

Marketing authorisation holders must apply for renewal of notification/registration to the Authority at least ninety (**90**) calendar days before the expiry of the Marketing Authorization.

Applications for renewal of notified/ registered medical devices shall be processed within:
- Thirty **(30)** calendar days for notified Medical Devices
- Thirty **(90)** calendar days for registered Medical Devices

Any additional data shall be submitted within:
- Fifteen **(15)** calendar days for notified Medical Devices
- Thirty **(30)** calendar days for registered Medical Devices

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

1.11. Classification of Medical Devices

Medical devices are classified into four (4) classes (A, B, C, D) based on the level of risk to the end user and their intended purpose. Class A represents the group with the lowest risk and Class D represents the group with the highest risk.

CLASS	RISK LEVELS
A	Low (examination gloves, tongue depressors…)
B	Low-Moderate(electronic thermometers, tubes for blood transfusion, Hypodermic needles…)
C	Moderate-High (lung ventilators, 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 risk applies.

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 assessments of the medical devices 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 devices.

Each submitted application shall contain only one of the following:

a. A single medical device
b. One medical device family
c. One medical device system
d. One medical device group

1.12. Technical Documentation Format and data Presentation of the Dossier

All medical devices in classes A, B, C & D require pre-market submission of technical

documentation demonstrating conformity with Essential Principles except for those requiring notification.

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

1.13. Content of the technical documentation (ToC)

Prior submission, the following **6 chapters** as well as **subchapters** shall be compiled in a well-organized structure within the technical documentation as one file or one folder. Files shall be presented in a searchable format so as to avoid unnecessary delays during the registration process.

CHAPTER 1: Administrative information

1.1. Cover letter

The cover letter should be written dated and signed by the applicant. This letter should state the name of the device requesting for registration, classification, intended use as well as other relevant information included in **Appendix 1.**

1.2. Application form for registration

The application form should be filled in dated and signed by the applicant. This application form should contain information on the device name, type of application, manufacturing site address, as well as other relevant information included in **Appendix 3.**

1.3. Declaration of Conformity

Within the DoC, the manufacturer attests that the medical device complies fully with all applicable Essential Principles for Safety and Performance. It should contain the following information:

- The name of the device
- The applicable provisions of the Essential Principles/Requirements
- The name and address of the device manufacturer.
- The name, position and signature of the responsible person who has been authorised to complete the Declaration of Conformity upon the manufacturer's behalf.

1.4. Letter of appointment to the LTR

A letter provided to the LTR by a foreign manufacturer to act on his/her behalf and deal with regard to matters pertaining to the registration of medical devices including IVDDs.

1.5. QMS certificate

A valid certificate confirming the implementation of good quality management system in the device's production process. The applicant shall provide one of the following ISO 13485 certificate, CE full quality system certificate or their equivalents.

1.6. Evidence of Registration in other NRAs

Under this subchapter, If available, the device's valid registration certificate(s)/ Marketing Authorization should be submitted.

CHAPTER 2: submission content

2.1 Device description

2.1.1. General Description and Principles of Operation

2.1.1.1. General description

i. A statement of the device name and Principle of operation
ii. What the device does?
iii. Who uses it and for what? (high level statement)
iv. Where to use it? (places/environment where the device is intended to be used)
v. How it works? Including theory surrounding feature/variants/operating modes that enable the device to be used for indications/intended use (principle of operation/mechanism of action).
vi. If applicable, labelled pictorial representation (diagrams, photos, drawings).
vii. If system, how the components relate?
viii. If applicable, identify if the device incorporates software/firmware and its role

2.1.1.2. Product specification:

i. Physical characteristics or relevance to the end user (dimensions, weight)
ii. Features and operating modes
iii. Input specifications (e.g. electrical power requirements, settings and associated allowable ranges/limits)
iv. Output and performance characteristics (e.g. range and type of energy delivered, resolution of images)
v. If applicable, an indication of the variants/models of the devices and a summary of the differences in specifications of the variants (comparison table and/or pictures/diagrams with supporting text).

2.1.1.3. Engineering diagrams:

All engineering /prints/schematics of the device.

2.1.1.4. List of accessories:

List of all accessories intended to be used in combination with the devices.

2.1.1.5. Indication of any other medical devices:

Indication of other devices or general product intended to be used in combination with the medical device (e.g. infusion sets and infusion pumps, bipolar electrode and RF equipment).

2.1.1.6. Components or accessories:

All accessories or components that can be sold separately should be identified.

2.1.1.7. Sterilized devices:

If the device is to be sterilized, an indication of who is to perform the sterilization and by what method (e.g. EtO, gamma irradiation, dry heat) OR an affirmative statement that the device is non-sterile when used.

Note: The validation report is not expected be presented at this point, only the device sterility condition shall be indicated here. If appropriate, for the validation report, see Chapter 3 – Non-Clinical Studies.

2.1.1.8. Device composition:

Summary of the composition of the device including, at minimum, the material specification and/or chemical composition of the materials that have direct or indirect contact with the user and/or patient. When required, full details to support how these specifications are met are to be provided in chapter 3 of this guideline required under "Chemical/Material Characterization".
Note: If applicable, chemicals may be identified using either the IUPAC (International Union of Pure and Applied Chemistry) or the CAS (Chemical Abstract Service) Registry number. Reference to applicable material standards may also be useful in this description.

2.1.1.9. Devices incorporating Biological materials

If applicable, indication of biological material or derivate used in the medical device, including: origin (human, animal, recombinant or fermentation products or any other biological material), source (e.g. blood, bone, heart, any other tissue or cells), and the intended reason for its presence and, if applicable, its primary mode of action.

2.1.1.10. Devices incorporating medicines:

If the device contains an active pharmaceutical ingredient (API) or drug, an indication of the substance, should be provided. This should include its identity and source, and the intended reason for its presence and its primary mode of action.

2.1.2 Description of Device Packaging

2.1.2.1. Packaging information of the device:

Information regarding the packaging of the devices, including, when applicable, primary packaging, secondary and any other packaging associated;

2.1.2.2. Packaging of accessories:

Specific packaging of accessories marketed together with the medical devices shall also be described;

2.1.2.3. Other packaging information:

If the user needs to package the medical device or its accessories before they perform sterilization, information about the correct packaging (e.g. material, composition, dimension) should be provided.

2.1.3 History of Development

For any device versions/prototypes referenced in the evidence presented in the submission, a table describing the version/name, with 4 columns (Device Name and/or Version; Description of changes from previous row; motivation for the change; list of verification/validation activities, including clinical studies, conducted using this version). For any design verification or validation activities presented in this submission (including clinical studies) performed on any earlier versions of the subject device, include a justification for why the changes do not impact the validity of the data collected under those activities in supporting the safety and effectiveness of the final device design.

2.1.4 Reference and Comparison to Similar and/or Previous Generations of the Device

2.1.4.1. Similar devices:

A list of similar devices (available on local and international market) and/or previous generation of the devices (if existent) relevant to the submission. This should include any similar/previous generation devices that were previously reviewed and refused by the Authority. And the description of why they were selected.

2.1.4.2. Specification comparison:

A key specification comparison, preferably in a table, between the references (similar and/or previous generation) considered and the device.

2.1.5 Substantial Equivalence Discussion

Where applicable,

a) identify the predicate device(s), and optionally reference devices

i. trade name and model number

ii. Ensure the identified predicate device(s) is consistent throughout the submission

b) Include a comparison of indications for use and the technology (including features materials and principles of operation) between the predicate device(s) and subject device(s).

c) Include an analysis of why any differences between the subject device(s) and the predicate device(s) do not render the subject device(s) Not Substantially Equivalent, affect safety or effectiveness or raise different questions of safety and effectiveness.

2.2 Indications for Use and/or Intended Use and Contraindications

2.2.1. Intended Use; Intended Purpose; Intended User; Indications for Use

a) Intended Use: The statement of intended use should specify the therapeutic or diagnostic function provided by the device and may describe the medical procedure in which the device is to be used (e.g. Diagnosis *in vivo* or *in vitro,* treatment monitoring rehabilitation, contraception, disinfection).
b) Intended Purpose: What is expected with the use of this medical device? Which results are expected?
c) Intended user and skills/knowledge/training that the user should have to operate or use the device.
d) Identify if the device is intended for single or multiple use
e) Indications for Use: Disease or medical condition that the device will diagnose, treat, prevent, mitigate, or cure, parameters to be monitored and other considerations related to indication for use.

   ii. If applicable, information about patient selection criteria.

iii. If applicable, information about intended patient population (e.g. adults, pediatrics or newborn) or a statement that no subpopulations exist for the disease or condition for which the device is intended.

Notes:

i. The statements of intended use and purpose and the intended user and indications for use must be as presented in the labelling.

ii. If more than one device is included, the information should be provided for each device.

2.2.2. Intended Environment/Setting for use:

a) The setting where the device is intended to be used (e.g. domestic use, hospitals, medical/clinical laboratories, ambulances, medical/dental offices). Multiple options can be indicated.

b) If applicable, environmental conditions that can affect the device's safety and/or performance (e.g. temperature, humidity, power, pressure, movement).

2.2.3. Pediatric Use:

a) Description of any pediatric subpopulations that suffer from the disease or condition that the device is intended to treat, diagnose or cure,

b) The number of affected pediatric patients, as a whole and within each pediatric subpopulation, or

c) Statement that no pediatric subpopulation exists for the disease or condition for which the device is intended.

2.2.4. Contraindications for Use:

If applicable, specify the disease or medical conditions that would make use of the device inadvisable due to unfavorable risk/benefit profile

2.2.5. For amendments/supplements or changes to existing approvals:

Identify any changes to the previously approved intended use/intended purpose/intended user/indications. If there are no changes, this should be stated and a reference should be made to the precise regional regulatory tracking number associated with the previous submission/approval.

2.3 Global Market History

2.3.1. Global Market History

a) Up to date indication of the markets (all countries or jurisdictions) where the device is approved for marketing, including any marketing under compassionate use regulations. As an evidence, the list shall be supported by copies of Marketing Authorization, free sale certificates or any other supporting certificates issued by the National Regulatory Authorities of the listed Countries.

b) Should include history of the marketing of the device by any other entity in as much detail as possible, acknowledging that detailed information may not be available in all cases.

c) If the subject device is different in any way (e.g. design, labeling, specifications) from those approved or marketed in other jurisdiction, the differences should be described.
d) The month and year of market approval in each country or jurisdiction where the device is marketed. If the device has been marketed for greater than 10 years, a statement of greater than 10 years can be made.
e) For each of the markets listed in (a) above, and statement of the commercial names used in those markets or a clear statement that the commercial names are the same in all jurisdictions.
f) State the date of data capture for the market history data.
g) If the subject device has been the subject of any previous compassionate use and/or clinical trials this should be identified and, if applicable, relevant reference numbers provided.

2.3.2. Global Incident Reports and Recalls

a) List adverse events/incidents associated with the device and a statement of the period associated with this data.
b) If the number of adverse events is voluminous, provide a summary by event type that state the number of reported events for each event type.
c) List of the medical device recalls and/or advisory notice, and a discussion of the handling and solution given by the manufacturer in each case.
d) A description of any analysis and/or corrective actions undertaken in response to items listed above.

2.3.3. Sales, Incident and Recall Rates

a) A summary of the number of units sold in each country/region and a statement of the period associated with this data.
b) Provide the rates calculated for each country/region, for example:
i. Incident rate = number of adverse events/incidents divided by number of units sold x 100
ii. Recall rate = number of recalls divided by number of units sold x 100
Rates may be presented in other appropriate units such as per patient year of use or per use. In this case, methods for determining these rates should be presented and any assumptions supported.
c) Critical analysis of the rates calculated (e.g. why are they acceptable? How do they break down in terms of incidents? Is there some outlier data that has driven the rates up? Are there any trends associated with any sub-groups of the devices that are subject of the submission (e.g. size, version).

Notes:

i. Sales in this context should be reported as the number of units sold.
ii. The summary of sales should be broken down by components when appropriate.

2.3.4. Evaluation/Inspection Reports (where applicable)

Where applicable Copies of Evaluation/Inspection Reports from other parties (e.g. Notified Body inspection reports) should be provided.

CHAPTER 3: non clinical evidence

3.1 Risk Management:

a) A summary of the risks identified during the risk analysis process and how these risks have been controlled to an acceptable level.
b) The results of the risk analysis should provide a conclusion with evidence that remaining risks are acceptable when compared to the benefits.
c) Where a standard is followed, identify the standard.

3.2 Essential Principles (EP) Checklist:

a) An EP checklist (**Appendix 5**) must be appropriately filled and submitted.
b) An EP checklist established for the medical devices, information about method(s) used to demonstrate conformity with each EP that applies, references for the method adopted and identification of the controlled document with evidence of conformity with each method used.
c) For the controlled documents indicated which are required for inclusion in the submission: a cross-reference of the location of such evidence within the submission.
d) If any EP indicated in the checklist does not apply to the device: a documented rationale of the non-application of each EP that does not apply.

Note:

Methods used to demonstrate conformity may include one or more of the following:
Conformity with recognized or other standards; Conformity with a commonly accepted industry test method(s); Conformity with an in-house test method(s); The evaluation of pre-clinical and clinical evidence; Comparison to a similar device already available on the market.

3.3 Standards used:

a) List the standards that have been complied with in full or in part in the design and manufacture of the device,
b) At a minimum should include the standard organization, standard number, standard title, year/version, and if full or partial compliance.

3.4 Non-clinical Studies:

3.4.1 Physical and Mechanical Characterization

Evidence that support the physical or mechanical properties of the subject device is to be included in this section. This should include:
a) A summary of the non-clinical evidence that falls within this category
b) A discussion of the non-clinical testing considered for the device and support for their selection or omission from the verification and validation studies conducted in this category (i.e. what tests were considered and why they were or were not performed)
c) Discussion to support why the evidence presented is sufficient to support the application. or

d) A statement of why this category of non-clinical laboratory study is not applicable to this case.
A summary of the specific study and the test report for the study described in the physical and mechanical characterization must be provided.

3.4.2 Chemical/Material Characterization

Tests that describe the chemical or structural composition of the device and its components are to be included in this section. This should include:
a) A summary of the non-clinical evidence that falls within this category
b) A discussion of the non-clinical testing considered for the device and support for their selection or omission from the verification and validation studies conducted in this category (i.e. what tests were considered and why they were or were not performed)
c) Discussion to support why the evidence presented is sufficient to support the application. or
d) A statement of why this category of non-clinical laboratory study is not applicable to this case.
A summary of the specific study and the test report for the study described in the chemical/material characterization must be provided.

3.4.3 Electrical Systems: Safety, Mechanical and Environmental Protection, and Electromagnetic Compatibility

Evidence supporting electrical safety, mechanical and environmental protection, and electromagnetic compatibility are to be included in this section. This should include:
a) A summary of the non-clinical evidence that falls within this category,
b) A discussion of the non-clinical testing considered for the device and support for their selection or omission from the verification and validation studies conducted in this category (i.e. what tests were considered and why they were or were not performed)
c) Discussion to support why the evidence presented is sufficient to support the application. or
d) A statement of why this category of study is not applicable to this case.
A summary of the specific study and the test report for the study described in the electrical systems must be provided.

3.4.4 Radiation Safety

Studies supporting radiation safety, where the device emits radiation or where the device is exposed to radiation are to be included in this section. This should include:
a) A summary of the non-clinical evidence that falls within this category
b) A discussion of the non-clinical testing considered for the device and support for their selection or omission from the verification and validation studies conducted in this category (i.e. what tests were considered and why they were or were not performed)
c) Discussion to support why the evidence presented is sufficient to support the application. or
d) A statement of why this category of non-clinical laboratory study is not applicable to this case.
A summary of the specific study and the test report for the study described in the radiation safety must be provided.

3.4.5 Software/Firmware

3.4.5.1 Software/Firmware Description

a) Specify the name of the software
b) Specify the version of the software - The version tested must be clearly identified and should

match the release version of the software, otherwise justification must be provided.
c) Provide a description of the software including the identification of the device features that are controlled by the software, the programming language, hardware platform, operating system (if applicable), use of Off-the-shelf software (if applicable), a description of the realization process.
d) Provide a statement about software version naming rules, specify all fields and their meanings of software version, and determine the complete version of software and its identification version used for release.

3.4.5.2 Hazard Analysis

The Hazard Analysis should take into account all device hazards associated with the device's intended use, including both hardware and software hazards.
Note:
i. This document can be in the form of an extract of the software-related items from comprehensive risk management documentation, described in ISO 14971.
ii. Hazard analysis, should address all foreseeable hazards, including those resulting from intentional or inadvertent misuse of the device.

3.4.5.3 Software Requirement Specification

The Software Requirements Specification (SRS) documents the requirements for the software. This typically includes functional, performance, interface, design, developmental, and other requirements for the software. In effect, this document describes what the Software Device is supposed to do. For example, hardware requirements, programming language requirement, interface requirements, performance and functional requirements.

3.4.5.4 Architecture Design Chart

Detailed depiction of functional units and software modules. May include state diagrams as well as flow charts.

3.4.5.5 Software Design Specification

The Software Design Specification (SDS) describes the implementation of the requirements for the Software Device. The SDS describes how the requirements in the SRS are implemented.

3.4.5.6 Traceability Analysis

A Traceability Analysis links together your product design requirements, design specifications, and testing requirements. It also provides a means of tying together identified hazards with the implementation and testing of the mitigations.

3.4.5.7 Software Life Cycle Process Description

A summary describing the software development life cycle and the processes that are in place to manage the various life cycle activities.

3.4.5.8 Software Verification and Validation

This should include:
a) An overview of all verification, validation and testing performed both in-house and in a simulated or actual user environment prior to final release.

b) Discussion to support why the evidence presented is sufficient to support the application. or
c) A statement of why this category of non-clinical laboratory study is not applicable to this case.

Note:

Discussion should address all of the different hardware configurations and, where applicable, operating systems identified in the labelling.

A summary of the specific study and the test report for the study described in the Software Verification and Validation must be provided.

3.4.5.9 Revision Level History

Revision history log, including release version number and date.

3.4.5.10 Unresolved Anomalies (Bugs or Defects)

All unresolved anomalies in the release version of the software should be summarized, along with a justification for acceptability (i.e. the problem, impact on safety and effectiveness, and any plans for correction of the problems).

3.4.5.11 Cyber-security

Evidence to support the cyber-security should be provided here. For example, but not limited to:
a) Cyber-security vulnerabilities and risks analysis
b) Cyber-security controls measures
c) Traceability matrix linking cyber-security controls to the cyber-security vulnerabilities and risks.

3.4.5.12 Interoperability

If the device can communicate with other devices. Evidence to support the interoperability should be provided.

3.4.6 Biocompatibility and Toxicology Evaluation

Studies supporting biocompatibility and assessing toxicology are to be included in this section. Studies to assess the immunological response to animal or human tissues, tissue components or derivatives are to be included in this section. This should include:
a) A list of all materials in direct or indirect contact with the patient or user.
b) State conducted tests, applied standards, test protocols, the analysis of data and the summary of results
c) A discussion of the non-clinical testing considered for the device and support for their selection or omission from the verification and validation studies conducted in this category (i.e. what tests were considered and why they were or were not performed)
d) Discussion to support why the evidence presented is sufficient to support the application.
OR
e) A statement of why this category of non-clinical laboratory study is not applicable to this case.

Note:

Tests should be conducted on samples from the finished, sterilized (when supplied sterile) device.

A summary of the specific study and the test report for the study described in the Biocompatibility and Toxicology Evaluation must be provided.

3.4.7 Non-Material-Mediated Pyrogenicity

Studies to support Pyrogenicity evaluation of final release are to be included in this section. This should include:

a) A summary of the non-clinical evidence that falls within this category

b) A discussion of the non-clinical testing considered for the device and support for their selection or omission from the verification and validation studies conducted in this category (i.e. what tests were considered and why they were or were not performed)

c) Discussion to support why the evidence presented is sufficient to support the application. or

d) A statement of why this category of non-clinical laboratory study is not applicable to this case.

Note:

The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the non-clinical study results provided in this section regarding the subject device.

A summary of the specific study and the test report for the study described in the Non-Material-Mediated Pyrogenicity must be provided.

3.4.8 Safety of Materials of Biological Origin (human/animal)

Evaluations performed to demonstrate the safety of materials of biological origin (e.g. animal sourced, human sourced material) are to be included in this section. This should include:

a) A description of biological material or derivate

b) State the harvesting, processing, preservation, testing and handling of tissues, cells and substances

c) If applicable, discussion of infectious agents/transmissible agents known to infect the source animal

d) Clarify the origin (including details of donor screening and source country), and describe the tests on validation of removal or inactivation methods of viruses and other pathogens in the manufacturing process.

e) A brief summary of process validation should be included to substantiate that manufacturing and screening procedures are in place to minimize biological risks, in particular, with regard to viruses and other transmissible agents.

f) The system for recordkeeping to allow traceability from sources to the finished device should be fully described

g) Discussion to support why the evidence presented is sufficient to support the application. or

h) A statement of why this category of non-clinical laboratory study is not applicable to this case.

3.4.8.1 Certificates

Certificates that support the safety of materials of biological origin.

A summary of the specific study and the test report for the study described in the Safety of Materials of Biological Origin (human/animal) must be provided.

3.4.9 Sterilization Validation

3.4.9.1 End-User Sterilization

Information and validation of end-user sterilization where it is necessary for the end-user to sterilize the device. This should include:

a) A description of the sterilization process (method, parameters)

b) A summary of the non-clinical evidence that falls within this category
c) A discussion of the non-clinical testing considered for the device and support for their selection or omission from the verification and validation studies conducted in this category (i.e. what tests were considered and why they were or were not performed)
d) If applicable, state the rationale on the durability of the product against two or more sterilization.
e) Discussion to support why the evidence presented is sufficient to support the application. or
f) A statement of why this category of non-clinical laboratory study is not applicable to this case.

3.4.9.2 Manufacturer Sterilization

Information and validation of manufacturer sterilization where the device is provided sterile. This should include:
a) A description of the sterilization process (method, parameters) and Sterility Assurance Level (SAL)
b) State if parametric release is used
c) A summary of the non-clinical evidence that falls within this category
d) Information on the ongoing revalidation of the process. Typically, this would consist of arrangements for, or evidence of, revalidation of the packaging and sterilization processes.
e) A discussion of the non-clinical testing considered for the device and support for their selection or omission from the verification and validation studies conducted in this category (i.e. what tests were considered and why they were or were not performed)
f) Discussion to support why the evidence presented is sufficient to support the application. Or
g) A statement of why this category of non-clinical laboratory study is not applicable to this case.

3.4.9.3 Residual Toxicity

Contain the information on the testing for sterilant residues, where the device is supplied sterile and sterilized using a method susceptible to residues. This should include:
a) A summary of the non-clinical evidence that falls within this category
b) A discussion of the non-clinical testing considered for the device and support for their selection or omission from the verification and validation studies conducted in this category (i.e. what tests were considered and why they were or were not performed)
c) Discussion to support why the evidence presented is sufficient to support the application. or
d) A statement of why this category of non-clinical laboratory study is not applicable to this case.
A summary of the specific study and the test report for the study described in the Residual Toxicity must be provided.

3.4.9.4 Cleaning and Disinfection Validation

Contains information on the validation of cleaning and disinfection instructions for reusable devices. This should include:
a) A summary of the non-clinical evidence that falls within this category
b) A discussion of the non-clinical testing considered for the device and support for their selection or omission from the verification and validation studies conducted in this category (i.e. what tests were considered and why they were or were not performed)
c) Discussion to support why the evidence presented is sufficient to support the application. or

d) A statement of why this category of non-clinical laboratory study is not applicable to this case.

3.4.9.5 Reprocessing of Single Use Devices, Validation Data

The required validation data including cleaning and sterilization data, and functional performance data demonstrating that each single use device (SUD) will continue to meet specifications after the maximum number of times the device is reprocessed as intended by the person submitting the premarket application.

3.4.10 Animal Testing

Contains information about any animal studies conducted to support the submission. This should include:

a) A summary of the non-clinical evidence that falls within this category

b) A discussion of the non-clinical testing considered for the device and support for their selection or omission from the verification and validation studies conducted in this category (i.e. what tests were considered and why they were or were not performed)

c) Discussion to support why the evidence presented is sufficient to support the application. or

d) A statement of why this category of non-clinical laboratory study is not applicable to this case.

A summary of the specific study and the test report for the study described in the Animal Testing must be provided.

3.4.11 Usability/Human factors

Studies specifically assessing the instructions and/or device design in terms of impact of human behavior, abilities, limitations, and other characteristics on the ability of the device to perform as intended should be included here. This should include:

a) A summary of the non-clinical evidence that falls within this category

b) A statement of the test environment and relation to the intended use environment

c) A discussion of the non-clinical testing considered for the device and support for their selection or omission from the verification and validation studies conducted in this category (i.e. what tests were considered and why they were or were not performed)

d) If a clinical study has been conducted that includes human factors/usability endpoints, reference to the studies and endpoints should be made, but full results do not need to be repeated.

e) Discussion to support why the evidence presented is sufficient to support the application. or

f) A statement of why this category of non-clinical laboratory study is not applicable to this case.

Note:

If a clinical study has been conducted that includes usability/human factors endpoints, reference to the studies and endpoints should be made, but full results do not need to be repeated and should be included in Chapter 4 – Clinical Evidence.

3.5 Non clinical bibliography

This section should include:

a) A listing of published non-clinical studies involving this specific device (e.g. cadaveric evaluations, biomechanical assessments)

b) A legible copy of key articles, including translation where applicable to meet the regulators language requirements

c) Discussion to support why the evidence presented is sufficient to support the application. or

d) A statement that no literature related to the device was found.

3.6 Expiration Period and Package Validation

This section should include:
a) An indication of environmental conditions for correct storage of the device (e.g. temperature, pressure, humidity, luminosity).
b) A statement of the expiration period considering the materials and sterilization (when applicable), indicated as a period of time or any other means of appropriate quantification. or
b) A rationale that storage conditions could not affect device safety or effectiveness.

3.6.1. Product stability

Contains details relating to product stability under specified storage conditions and in final packaging or simulated conditions. This should include:
a) A summary of the non-clinical evidence that falls within this category
b) A discussion of the non-clinical testing considered for the device and support for their selection or omission from the verification and validation studies conducted in this category (i.e. what tests were considered and why they were or were not performed)
c) Discussion to support why the evidence presented is sufficient to support the application. or
d) A statement of why this category of non-clinical laboratory study is not applicable to this case.
This section should provide information on stability testing studies to support the claimed shelf life. Testing should be performed on at least three different lots manufactured under conditions that are essentially equivalent to routine production conditions (these do not need to be consecutive lots). Accelerated studies or extrapolated data from real time data are acceptable for initial shelf life claim but need to be followed up with real time stability studies.
If applicable, product stability shall also include:
a) **In use stability**, containing details and evidence supporting the stability during actual routine use of the device (real or simulated);
b) **Shipping stability** containing details and evidence supporting the tolerance of device components to the anticipated shipping conditions.
A summary of the specific study and the test report for the study described in the Product Stability Testing must be provided.
c) **Use by date**: A use by date is required where a safety-related characteristic or claimed performance is likely to deteriorate over time. It is not a lifetime determination, as described above.
In deciding whether there is such a safety-related deterioration, the manufacturer must provide proper risk analysis and measures taken to manage risk:

e. The risk analysis will identify those performances and characteristics necessary for the safe use of the particular device. For example, the risk analysis may indicate that sterility is necessary for safe use. Equally, the risk analysis would not cover the color of the device if this is purely aesthetic, but it might cover the color of the device if that color has a purpose related to safe use of the device (e. g., the color signifies the size of the device).

f. The risk analysis and measures taken to manage risk will also identify the level or extent of performance or characteristic but only in so far as they are relevant to safe use of the device. For example, the level of resistance to gas flow or rate of leakage from a breathing system, or the probability of non-sterility.

g. The risk analysis and measures taken to manage risk will also identify the period over which

the relevant performance or characteristic would be expected to be maintained for safe use, including the shelf life and intended period of use. For example, the period over which a pacemaker battery maintains sufficient energy to function after implantation as long as intended by the manufacturer.

3.6.2. Package validation

Contains details relating to package integrity over the claimed shelf-life and in the packaging and distribution environment (transport and packaging validation) and when applicable, following exposure to the sterilization process. This should include:

a) A summary of the non-clinical evidence that falls within this category

b) A discussion of the non-clinical testing considered for the device and support for their selection or omission from the verification and validation studies conducted in this category (i.e. what tests were considered and why they were or were not performed)

c) Discussion to support why the evidence presented is sufficient to support the application. or

d) A statement of why this category of non-clinical laboratory study is not applicable to this case.

CHAPTER 4: clinical evidence

4.1. Overall Clinical Evidence Summary

a) This should be a brief summary of the available clinical evidence being presented in support of the submission. The document should list the evidence presented, its characteristics (RCT, case study, literature review) and provide a discussion of how this is considered sufficient to support request for marketing for the requested indications. A tabular listing of clinical studies may be included in this section,

b) If any of the study devices differ from the devices to be marketed, including competitors devices, a description of these differences and their impact on the validity of the evidence in terms of support for the application,

c) A discussion of the clinical evidence considered for the device and support for their selection (i.e. what type of evidence was considered and why they were or were not used)

d) Discussion to support why the evidence presented is sufficient to support the application.

Note:

Human factors testing that include patients should be included here.

4.1.1. Clinical Evaluation Report

a) A clinical evaluation report reviewed and signed by an expert in the relevant field that contains an objective critical evaluation of all of the clinical data submitted in relation to the device.

b) A complete CV, or similar documentation, to justify the manufacturer's choice of the clinical expert.

4.1.2. Device Specific Clinical Trials

Clinical trial information under this heading should be grouped by trial.

4.1.2.1. Trial description, protocol number, date of initiation

The applicant should submit the following subsections. It is important to note that this subsection should be customized based on the the study details.

4.1.2.1.1. Clinical Trial Synopsis

a) A summary of the specific study described in the custom heading above.
b) A document summarizing the information below should be presented:
i. The key characteristics of the study (e.g. title of study, investigators, sites, study period (date of enrollment/date of last completed), objectives, methods, # patients, inclusion/exclusion criteria) and
ii. Summary of the results of the analysis
iii. Summary of conclusions related to the endpoints

4.1.2.1.2. Clinical Trial Report

A clinical trial report of the specific study described in the custom heading above.
Notes:
The clinical study report should include elements such as the investigational plan/study protocol, protocol changes and deviations, description of patients, data quality assurance, analysis/results.

4.1.2.1.3. Clinical Trial Data

The applicant should meet Rwanda FDA applicable clinical trial guidelines/ guidance or any recognized standard related to the clinical study and data provided in this section regarding the subject device.

4.1.3. Clinical Literature Review and Other Reasonable Known Information

a) Clinical literature review that critically reviews available information that is published, available, or reasonably known to the applicant/sponsor that describes safety and/or effectiveness of the device.
b) A legible copy of key articles, including translation where applicable to meet the regulators language requirements. Or
c) A statement that no literature related to the device was found.

4.2. IRB Approved Informed Consent Forms

Copies of IRB approved informed consent forms are to be provided here (if any).

4.3. Investigators Sites and IRB Contact Information

Investigators and study administrative structure information should be provided, including (as appropriate):
a) Investigators (who signed the Investigator agreement)-name, address, telephone number (contact info), CV
b) Sites- Site number as reflected in the study report in reference to the investigator, address if different from the above
c) Sponsor- address and regulatory contact information
d) Contract Research Organization (CRO), if applicable-name, address, and contact information and Laboratory facilities (central lab and/or local lab that participated in the study)-name, address, contact information.

CHAPTER 5: labelling and promotional material

5.1. Product/Package Labels

Samples of the primary and secondary packaging labels but exclusive of labels for shipping.

5.2. Contents of medical devices labelling

Irrespective of the class of the device, the labeling of any medical device should bear the following information:

a) Name or trade name of the device;

b) Manufacturer's/Manufacturing site(s) address(es):

Name and complete address of the actual manufacturer of the device (street name, number, telephone, fax, e-mail, website);

c) Instruction for Use (IFU)

Date of issue or latest revision of the instructions for use and, where appropriate, an identification number;

d) Information for the end user

Sufficient details for the user to identify the device and, where these are not obvious, its intended purpose, user, and patient population of the device, and, where relevant, the contents of any packaging;

e) batch code/lot number:

An indication of either the batch code/lot number (e.g., on single-use disposable devices or reagents) or model, or the serial number (e.g., on electrically-powered medical devices), where relevant, to allow appropriate actions to trace and recall the devices.

f) Shelf life and validity:

An unambiguous indication of the date until when the device may be used safely, expressed at least as the year and month (e.g., on devices supplied sterile, single-use disposable devices or reagents), where this is relevant. Where relevant, the storage conditions and shelf life following the first opening of the primary container, together with the storage conditions and stability of working solutions.

For devices other than those covered by (f) above, and as appropriate to the type of device, an indication of the dates of manufacture and expiration. This indication may be included in the batch code/lot number or serial number;

g) Installation of the device:

Where applicable, the information needed to verify whether the device is properly installed and can operate correctly and safely, plus details of the nature and frequency of preventative and regular maintenance and, where relevant, any quality control, replacement of consumable components, and calibration needed to ensure that the device operates properly and safely during its intended life;

h) Warnings and precautions and special storage:

Any warnings, precautions, limitations, or contra-indications should be submitted, as well as the performance intended by the manufacturer and, where relevant, any undesirable side effects;
An indication on the external packaging of any special storage and /or handling conditions that apply;
Details of any further treatment or handling needed before the device can be used (e.g., sterilization, final assembly, calibration, preparation of reagents and/or control materials, etc.) where relevant;

i) Sterile medical devices:

If the device is sterile, an indication of that condition and necessary instructions in the event of damage to the sterile packaging and, where appropriate, description of methods for re-sterilization;

j) Other labeling contents:

- If the device has been specified by the manufacturer as intended for single-use only, an indication of that state;
- If the device is intended for premarket clinical investigation, or for in vitro diagnostic medical devices, or for performance evaluation only, an indication of that situation;
- If the device is intended for presentation or demonstration purposes only, an indication of that situation;
- If the device is to be installed with or connected to other medical devices or equipment, or with dedicated software in order to operate as required for its intended use, sufficient details of its characteristics to identify the correct devices or equipment to use in order to obtain a safe combination;
- If the device is implantable, information regarding any particular risks in connection with its implantation;
- Information regarding the risks of reciprocal interference posed by the reasonably foreseeable presence of the device during specific investigations, evaluations, treatment, or use (e.g., electromagnetic interference from other equipment);
- If the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging, and, where appropriate, the method of re-sterilization, and any restriction on the number of reuses. Where a device is supplied with the intention that it is sterilized before use, the instructions for cleaning and sterilization should be such that, if correctly followed, the device will still perform as intended by the manufacturer and comply with the Essential Principles of Safety and Performance of Medical Devices;
- If the device emits radiation for medical purposes, details of the nature, type, and where appropriate, the intensity and distribution of this radiation,
- Precautions and/or measures to be taken in the event of changes in the performance, or malfunction, of the device including a contact telephone number, if appropriate;
- Precautions and/or measures to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, temperature, humidity, acceleration, thermal ignition sources, proximity to other devices, etc.;
- If the device administers medicinal products, adequate information regarding any medicinal product(s) that the device in question is designed to administer, including any limitations in the choice of substances to be delivered;
- Any medicinal substances or biological material incorporated into the device as an integral part of the device;

- Any requirement for special facilities, or special training, or particular qualifications of the device user and/or third parties;

Note:

i)Any precautions to be taken related to the disposal of the device and/or its accessories (e.g., lancets), to any consumables used with it (e.g., batteries or reagents), or to any potentially infectious substances of human or animal origin;

ii) Where relevant, for devices intended for lay persons, a statement clearly directing the user not to make any decision of medical relevance without first consulting his or her health care provider.

5.3. E-labelling

The following should be provided:

a) For eligible medical devices and stand-alone software, the applicant needs to identify which form of e-labelling is being used in case of e-labelling (e.g. electronic storage system or built-in system, website).

b) Details of risk management in relation to e-labelling. If this is part of the overall risk management, refer to it here

c) A description of the procedure and operations on providing IFU's when requested

d) Written information for user Information on webpage where IFU and further information can be found in relevant languages.

e) A description on how the requirements detailed for the website have been met.

f) If a video/App is available to demonstrate how the test is to be performed and interpreted, provide a link as well as details about how it is maintained and updated throughout the life cycle of the device.

5.4. Physician Labelling

Where applicable, Labelling directed at the physician other than the package insert, such as the surgical manual should be submitted.

5.5. Patient Labelling

Where applicable, Labelling directed at the patient other than the package insert, such as informational material written to be comprehended by the patient or lay caregiver should be submitted.

5.6. Technical Operators Manual

Where applicable, the applicant should submit the labelling directed the technical users and operators of medical devices focusing on the proper use and maintenance of the device

5.7. Product Brochures

If available, Draft product brochures available at the time of application

1.14. Other medical devices

1.14.1. Repairs

Where a registered device is "repaired" and returned to its original owner after the repair the components used in the repair would not require registration. The device should not be „placed on the market" but returned to its owner. If the repaired device was not registered, then registration process will be required.

1.14.2. Second-hand and fully refurbished devices

Second-hand medical devices are those which are already on the market and have been „pre-owned" and used and that are subsequently „sold on" for the same continued use. These products are considered to be already registered and do not require second registration by their new owner.

A medical device that has been fully refurbished is not the same as one that has been repaired or undergone maintenance. Therefore, it requires to be registered as a new medical device.

They will be considered to be the „manufacturer" under the regulations and are required to place the product on the market under their own name. "Fully refurbished" is considered to mean that a device has been completely rebuilt / made as new from used devices and is assigned a new „useful life". It would also be considered as a new device if a new intended purpose was assigned.

1.14.3. Medical devices that require final processing

Some devices may not be supplied in their final state (i.e. may not be immediately available for use) once placed on the market. They may require some further processing prior to being „usable", for example processing, preparation, installation, assembly or fitting. These activities are not usually undertaken by the manufacturer but are carried out by the healthcare professional or the final user.

Examples of such activities are:

- sterilization of medical devices supplied non-sterile;
- assembly of systems;
- configuration of electronic equipment;
- preparation of dental fillings
- fitting of contact lenses;
- adaptation of a prosthesis to the needs of the individual patient.

Note:

The type of documentation for registration and application process for borderlines medical devices shall depend on the declared intended use and risk class declared by the manufacturer.

Majority of border line medical devices especially from item 6.1 to 6.3 falls under the list of exempted medical devices and therefore do not require registration. However, applicants must confirm the status before importation is initiated.

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 emphasized 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.

Note:
For the purpose of this document, continuous use means:

i) The entire duration of use of the device without regard to temporary interruption of use during a procedure or, temporary removal for purposes such as cleaning or disinfection of the device.
ii) The accumulated use of a device that is intended by the manufacturer to be replaced immediately with another of the same type.

1. Non-invasive Devices

Rule	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, for compression 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	**Examples:** tubes used for blood transfusion, organ storage containers
unless they are blood bags, in which case they are Class C.	**Example:** 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**: haemodializers **Note:** For the purpose of this part of the rule, „modification" does not include simple, mechanical filtration or
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 extracorporial 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.

2. Invasive device

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	**Examples**: dressings for nose bleeds**.**

cavity, in which case they are in Class A,	
• 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, in an 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 channelling. 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 stabilisers 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 channelling.
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 absorbed, in which case they are in Class D; or	**Example:** implants claimed to be bioactive. **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.	

3. Active devices

Rule	Illustrative Examples
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(ii). 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

4. Additional Rule

Rule	Illustrative Examples
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 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 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 steriliser) 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**: condoms; contraceptive diaphragms.
unless they are implantable or long-term invasive devices, in which case they are in Class D.	**Example**: intrauterine contraceptive device.

References:

1. WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices
2. GHTF/SG1/N12:2000 *Role of Standards in the Assessment of Medical Devices*
3. GHTF/SG1/N15:2006 *Principles of Medical Devices Classification*
4. GHTF/SG1/N40:2006 *Principles of Conformity Assessment for Medical Devices*
5. GHTF/SG1/N41:2005 *Essential Principles of Safety and Performance of Medical Devices*
6. GHTF/SG1/N43:2005 *Labelling for Medical Devices*
7. IMDRF/RPS WG/N9(Edition 3) FINAL:2019 *Non-In Vitro Diagnostic Device Market Authorization Table of Contents (nlVDMAToC)*
8. African Medical Devices Forum *Guidelines on regulatory requirements for issuance of market authorization of medical devices including in-vitro diagnostic medical devices*

APPENDICES

Appendix 1: Cover Letter

QMS Nº: DFAR/HMDAR/FMT/001
Revision No: 2
Effective Date: 16/06/2022

Cover Letter

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

Rwanda FDA,
1948 Kigali-Rwanda

Dear Sir/Madam,

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

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

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

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

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

You will find enclosed the submission dossier as specified hereafter:

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

Type of Submission: □Full registration Application □Abridged Application □Notification

□ sample(s) submitted

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

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

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

Yours sincerely,

<Signature>

<Name>

<Title>

<Phone number(s)>

<Email address>

Appendix 2:
Application Form for Medical Devices and In Vitro Diagnostics Devices (IVDDs) notification

Format: QMS/FMT/002 Revision No: 1 Effective Date: 20 June 2022	Department/Division/Office/Unit	DFAR Department/HMDAR Division
Document Type: **Form**		Doc. No :DFAR/HMDAR/FOM/023
RWANDA FDA Rwanda Food and Drugs Authority	Title: **Application Form for Medical Devices and In Vitro Diagnostics Devices (IVDDs) notification**	Revision Number : 1 Revision Date: : 19/12/2023 Effective Date : …….. Review Due Date : 18/12/2025 Ref Doc. :
Date of dossier submission		

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
1.5	Intended user: ☐ Professional ☐ Lay user
1.6	Name and address (physical and postal) of Applicant Address: Country: Telephone:

	Telefax: E-Mail:
1.7	Name and address (physical and postal) of manufacturing site Address: Country: Telephone: Telefax: E-Mail
1.8	Visual description of the Medical Device or IVDD
1.9	List all accessories that are manufactured/ sold with the devices
1.10	Pack size (number of unit products in a commercial pack) and packaging material
1.11	Proposed shelf life (in months) (where applicable):
1.12	Proposed storage conditions (where applicable):
1.13	Other regulatory authority(ies) approval(s) (Marketing Authorization issued by other authorities)
1.14	Country of origin (where the device was manufactured)
1.15	Name(s) and physical address(es) of all manufacturing site(s) of the Medical Device or IVDD and their functions. Alternative sites should be also declared here. Address: Country: Telephone: Telefax: E-Mail:
1.16	Name and address (physical and postal) of the Agent/Local Technical Representative (LTR) (Attach a valid appointment letter notarized from the country of origin): Address: Country: Telephone: Telefax: E-Mail:

1.17	Was a Declaration of Conformity specifying all standards used in the manufacturing of the Medical Device or IVDD attached? □ Yes □ No If Yes, indicate the attachment naming/number If No, provide a brief explanation
1.18	Was an ISO 13485 certificate, CE certificate, or equivalent certificate submitted? □ Yes □ No If Yes, indicate the attachment naming/number If No, provide a brief explanation
1.19	Medical device codes (GMDN, UDI, UNMDN, EMDN, etc) and code description (if available)
1.20	Version of the product insert (state the verion number and attach a copy of relevant labeling including the Instruction for Use (IFU))

2.0 DECLARATION BY THE APPLICANT

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

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

I further agree, that I am obliged to follow the requirements of Rwanda's Legislations and Regulations, which are applicable to Medical Devices and IVDDs. I also consent to the processing of information provided to Rwanda FDA. It is hereby confirmed that fees will be paid/have been paid according to the authority's rules.

Signature:

Date:

Appendix 4: Application Form for Medical Devices and In Vitro Diagnostics Devices (IVDDs) registration

Format: QMS/FMT/002 Revision No: 1 Effective Date: 20 June 2022	Department/Division/Office/ Unit	DFAR Department/HMDAR Division
Document Type: **Form**		Doc. No :DFAR/HMDAR/FOM/022
RWANDA FDA Rwanda Food and Drugs Authority	Title: **Application Form for Medical Devices and In Vitro Diagnostics Devices (IVDDs) registration**	Revision Number : 3 Revision Date: : 19/12/2023 Effective Date : 31/10/2022 Review Due Date : 18/12/2028 Ref Doc. :
Date of dossier submission	**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
1.5	Intended user: • Professional • Lay user
1.6	Name and address (physical and postal) of Applicant Address: Country: Telephone:

	Telefax: E-Mail:
1.7	Name and address (physical and postal) of the manufacturing site Address: Country: Telephone: Telefax: E-Mail
1.8	Visual description of the Medical Device or IVDD
1.9	Pack size (number of unit products in a commercial pack) and packaging material
1.10	Proposed shelf life (in months) (where applicable):
1.11	Proposed storage conditions (where applicable):
1.12	Other sister/variants of the medical device (s) or IVD (s) registered or applied for registration
1.13	List all accessories that are manufactured/ sold with the devices
1.14	Do you hold Marketing Authorization(s) for another/ other medical device(s) or In Vitro Diagnostics Devices (IVDDs) in any of the East African Community (EAC) or other National regulatory Authorities? • Yes • No If yes state Medical Device(s) or IVDD(s) name: Regulatory Authority(ies) where the product is authorized: Marketing authorization number(s):
1.15	Country of origin (where the device was manufactured)
1.16	Medical device codes (GMDN, UDI, UNMDN, EMDN, etc) and code description

1.17	Name(s) and physical address(es) of all manufacturing site(s) of the Medical Device or IVDD and their functions. Alternative sites should be also declared here. Address: Country: Telephone: Telefax: E-Mail:
1.18	Name and address (physical and postal) of the Local Technical Representative (LTR) (Attach a valid appointment letter notarized from the country of origin): Address: Country: Telephone: Telefax: E-Mail:
1.19	Name and address (physical and postal) of the person or company responsible for Pharmacovigilance and Post Marketing Surveillance: Address: Country: Telephone: Telefax: E-Mail:
1.20	Declaration of Conformity specifying all standards used in the manufacturing of the Medical Device or IVDD
1.21	Qualitative and Quantitative composition of the Medical Device or IVDD (If applicable)
1.22	Version of the product insert (state the verion number and attach a copy of relevant labeling including the Instruction For Use (IFU))
1.23	Name and address (physical and postal) of the Contract Research Organisation(s) where the clinical studies of the Medical Device or IVDD were conducted. (If applicable) Address: Country: Telephone: Telefax: E-Mail:

2.0 DECLARATION BY THE APPLICANT
I, , the undersigned certify that all the information in this form and accompanying documentation is correct, complete and true to the best of my knowledge. I further confirm that the information referred to in my application dossier is available for verification during the Quality audit inspection. I also agree that I shall carry out pharmacovigilance and Post-marketing Surveillance to monitor the safety, quality and performance of the device on the market and provide safety, quality and performance update reports to Rwanda FDA. I further agree that I am obliged to follow the requirements of Rwanda's Legislation and Regulations, which are applicable to Medical Devices and IVDDs. I also consent to the processing of information provided to Rwanda FDA. It is hereby confirmed that fees will be paid/have been paid according to the authority's rules* Signature: Date:

Appendix 5: 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 conformity to the essential principles

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

Applicable to device?

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

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

Method of conformity

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

Identity of specific documents

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

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 he 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.			

Essential Principle	**Applicable to the device?**	**Method of Conformity**	**Identity of Specific Documents**
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			

Essential Principle	**Applicable to the device?**	**Method of Conformity**	**Identity of Specific Documents**
• 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.			

Essential Principle	Applicable to the device?	Method of Conformity	Identity of Specific Documents
• The devices should be designed and manufactured in such a way that they can be used safely with the materials, substances and gases with which they enter into contact during their normal use or during routine procedures; if the devices are intended to administer medicinal products they should be designed and manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and restrictions governing these products and that their performance is maintained in accordance with the intended use.			
• 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.			

Essential Principle	**Applicable to the device?**	**Method of Conformity**	**Identity of Specific Documents**
• Devices should be designed and manufactured in such a way as to reduce as far as reasonably practicable and appropriate risks posed by the unintentional ingress or egress of substances into or from the device taking into account the device and the nature of the environment in which it is intended to be used.			
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 and substances should originate from animals that have been subjected to veterinary controls and surveillance adapted to the intended use of the tissues. National regulations may require that the manufacturer and/or the Regulatory Authority retain information on the geographical origin of the animals. Processing, preservation, testing and handling of tissues, cells and substances of animal origin should be carried out so as to provide optimal safety. 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.			

Essential Principle	**Applicable to the device?**	**Method of Conformity**	**Identity of Specific Documents**
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.			

Essential Principle	**Applicable to the device?**	**Method of Conformity**	**Identity of Specific Documents**
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.			

Essential Principle	**Applicable to the device?**	**Method of Conformity**	**Identity of Specific Documents**
• 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.			

Essential Principle	**Applicable to the device?**	**Method of Conformity**	**Identity of Specific Documents**
• 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.			

Essential Principle	**Applicable to the device?**	**Method of Conformity**	**Identity of Specific Documents**
• 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 the device. **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			

Essential Principle	**Applicable to the device?**	**Method of Conformity**	**Identity of Specific Documents**
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 and appropriate, compatible with the intended purpose, whilst not restricting the application of appropriate 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 the benefit of which is considered to outweigh the risks inherent in the emission, it should be possible for the user to control the emissions. Such devices should be designed and manufactured to ensure reproducibility of relevant variable parameters within an acceptable tolerance.			
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			

Essential Principle	**Applicable to the device?**	**Method of Conformity**	**Identity of Specific Documents**
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.			

Essential Principle	**Applicable to the device?**	**Method of Conformity**	**Identity of Specific Documents**
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.			

Essential Principle	**Applicable to the device?**	**Method of Conformity**	**Identity of Specific Documents**
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.			

Essential Principle	**Applicable to the device?**	**Method of Conformity**	**Identity of Specific Documents**
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			

Essential Principle	**Applicable to the device?**	**Method of Conformity**	**Identity of Specific Documents**
Devices for supplying the patient with energy or substances should be designed and constructed in such a way that the delivered amount can be set and maintained accurately enough to guarantee the safety of the patient and of the user.			
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			

Essential Principle	**Applicable to the device?**	**Method of Conformity**	**Identity of Specific Documents**
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 be anticipated 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 the relevant 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.			

ENDORSEMENT OF THE GUIDELINES

	Prepared by	**Checked by**		**Approved by**
Title	**Division manager**	**Head of Department**	**Quality Assurance Analyst**	**Director General**
Names	Clarisse IRASABWA	Dr. Vedaste HABYALIMANA	Theogene NDAYAMBAJE	Dr. Emile BIENVENU
Signature				
Date				