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|  | Title: GUIDELINES FOR REGISTRATION OF MEDICAL DEVICE |  |
| Rev No: 02 | Doc No: PBSL/GL/027 | Version no. 03 |
| Issue date: 15 May 2024 | Effective date: 17 May 2024 | Approved by: Registrar |

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| Adopted By PBSL | |
| Start of public Consultation | |
| End of public Consultation | |
| Agreed by QMS committee | |
| Approved by Board | |

Pharmacy Board of Sierra Leone,
PMB 322
Central Medical Stores Compound
New England Ville
Freetown





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ACKNOWLEDGEMENTS

EXECUTIVE SUMMARY



1.0. INTRODUCTION

In pursuance of Section 44 of the Pharmacy and Drugs Act, 2001, these Guidelines are hereby promulgated for information, guidance and strict compliance by all concerned on the procedure and requirements for the registration of medical devices in Sierra Leone. These guidelines are applicable to all medical devices for use in humans as well as medical devices for veterinary use, where applicable.

Medical devices constitute an essential ingredient in the provision of quality and effective health care delivery. Medical devices must be safe, effective, and manufactured from premises that meet the codes of current good manufacturing practices (cGMPs). An appropriate regulatory framework is, therefore, required to ensure that these are adequately assured.

Such a regulatory framework must, therefore, provide appropriate guidelines that would assist the manufacturer and/or its local agent to substantially demonstrate compliance to the applicable legislation. The manufacturer would hence be required to demonstrate:

- i. a functional quality management system (QMS),
- ii. a system for post-market surveillance,

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- iii. a technical documentation,
- iv. a declaration of conformity, and
- v. the registration of the manufacturing facility and the medical devices.

It is acknowledged that in the development of these guidelines, reference was made to the Medical Devices Regulations of the USA, Canada and Australia. Reference was also made to the following:

- a. The Common Submission Dossier Template (CSDT) of the Asian Harmonization



Working Party (AHWP).

- b. Principles of Medical Device Classification
- c. The European Standards (Medical Devices)
- d. Essential Principles of Safety and Performance of Medical Devices
- e. Principles of Conformity Assessment of Medical Devices
- f. The Medical Devices Regulations – Global overview and guiding principles of WHO
- g. Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED):

These guidelines must be read and used in conjunction with the enabling legislation, the Pharmacy and Drug Act, 2001, section 44 Part VI, as well as any other relevant Guidelines and Regulations issued by the Pharmacy Board of Sierra Leone.

2.0 OBJECTIVES

This guideline has been designed to assist in the following;



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- Provide guidance on the technical and other general data requirements for the registration of medical devices and IVDs by the Pharmacy Board of Sierra Leone.
- To help facilitate the processes and procedures involved in the registration of medical devices and IVDs.
- Promote effective and efficient processes for the evaluation of these applications and the subsequent issuance of Marketing Authorization.

3.0 SCOPE

This guidance document describes the processes and general requirements for the submission of an application for the registration of a new medical devices and In-Vitro diagnostics.

- a. These guidelines shall apply to medical devices and their accessories.
- b. Where a device is intended to administer a medicinal product, that device shall be governed by this guideline, without prejudice to the corresponding regulations for registration of medicinal products for human and veterinary use set by the Pharmacy Board of Sierra Leone
- c. Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product and which is liable to act upon the body with action ancillary to that of the device, that device must be assessed and authorized in accordance with this guideline.

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4.0. SPECIFIC REQUIREMENTS

4.1. General Requirements

4.1.1 Cover Letter

All applications for registration of a medical device shall be made by submitting a cover letter and a completed application form (annex 1) addressed to:

The Chief Executive Officer

Pharmacy Board of Sierra Leone

Central Medical Stores



New England Ville

4.1.2 Applicant

An application for registration of medical device(s) can be made by a manufacturer or by an importer of the medical device. Such an applicant would be responsible for the product and all issues relating to the product, including any information accompanying the product. A non-resident applicant would be required to appoint a local agent with the requisite mandate to represent the said applicant. The agent would be required to produce the relevant documentation including, but not limited to, a power of attorney or any other documentation, affirming his/her appointment as an agent.

4.1.3 Local Agent

A local agent is a corporate body registered in Sierra Leone, with the relevant mandate from the applicant, to act on the applicant's behalf as regards matters

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relating to the registration of a medical device(s) in Sierra Leone. The Local Agent would, among other things:

4.1.3.1 Monitor the device on the market and appropriately inform the Authority of any relevant issue relating to a registered device, including any serious manufacturing defects with the potential to endanger the safety and/or health of the patient, operator or any other person, or public health.

4.1.3.2 Facilitate communication between the applicant and the Authority on matters relating to the product.

4.1.3.3 Handle device recalls.

4.1.3.4 Provide technical support and services to users of registered device(s).



4.1.4 Classification of applications

For purposes of submission to PBSL, applications are classified into three categories as follows:

4.1.4.1 New Applications for Registration

A new application for a medical device is one intended to be placed on the Sierra Leonean market for the first time. A separate application is required for each single medical device or a medical device group or a medical device family or medical device system

Such a new application for registration shall include:

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4.1.4.1.1 One original hard-copy and one electronic copy in a text selectable Portable Document Format (PDF) on a CD-Rom.

4.1.4.1.2 Samples of the product as per PBSL sample schedule.

4.1.4.1.3 Non-refundable application fee for registration of medical devices as per PBSL Fee Schedule.

4.1.4.2 Applications for Renewal of Registration

Applications for renewal of registration shall be made at least 3 months before the expiry of existing registration by submitting the following:

4.1.4.2.1 Dully filled application form for renewal of registration.

4.1.4.2.2 Samples of the product as per the PBSL sample schedule



4.1.4.2.3 Non-refundable application fee for registration of medical devices per PBSL Fee Schedule.

4.1.4.3 Application for Variation of a Registered Medical Device

Any application for variation to a registered product shall be made in accordance with all applicable requirements in this Guideline.

Such an application should indicate any significant change(s) that could reasonably be expected to affect the safety, quality or good performance of a registered product. Significant change(s) may include, but not limited to, any of the following:

4.1.4.3.1 The manufacturing process, facility or equipment;

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4.1.4.3.2 the manufacturing quality control procedures, including the methods, tests or procedures used to control the quality, purity, safety and sterility of the device or of the materials used in its manufacture;

4.1.4.3.3 the design of the device, including its performance characteristics, principles of operation and specifications of materials, energy source, software or accessories; and

4.1.4.3.4 the intended use of the device, including any new or extended use, any addition or deletion of a contraindication for the device, and any change to the period used to establish its expiry date.

4.1.4.4 The requisite variation fee per the PBSL Fees Schedule shall be paid.



4.1.5 LANGUAGE

All applications and supporting documents shall be in the English language and legible. Reports submitted only in a language other than English will not be accepted.

Where a material is not originally in English, a copy in the original language and a full translation into English should be submitted. The accuracy of the translation is the responsibility of the applicant.

Authentication of the translation has to be done at the nearest Sierra Leone Embassy or by the National Drug Regulatory Authority of the country from where the document originates

4.1.6 DATA PRESENTATION

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All printed materials submitted including any information, data, tables, diagrams, and attachments must be legible of font size 12 or more and shall be presented on A4 and 80g/m² paper. All pages shall be numbered sequentially with the format page numbered as page x of y, with a Table of Contents" indicating the sections and page numbers in the relevant sections of the application form.

Where applicable, acronyms and abbreviations should be defined the first time they are used in each part.



Dossiers should be securely bound and arranged sequentially and could be submitted in separately bound volumes for the different parts but shall be numbered serially (e.g. volume 1 of 2) for ease of reference. The dossier covers shall be made of a material which is thick and hard enough not to collapse in standing position.

Before submitting the completed form, check to ensure that all information requested for have been provided in full.

4.1.7 AN OUTLINE OF THE EVALUATION PROCESS

4.1.7.1 Receiving of New Applications

An application consists of documentation in hard copies and electronic copy (a summary of the dossier contents), samples and fees. An application may only be received by PBSL upon payment of the application fees.

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4.1.7.2 EVALUATION PROCESS



The evaluation of applications is done on a first-in-first-out (FIFO) basis unless the product meets the requirement for expedited review process as set out below.

An application may be expedited if the product is for:

- 4.1.7.2.1 Public health programmes. These include HIV/AIDS, Malaria, Tuberculosis, Reproductive Health, Neglected Tropical Diseases e.g. Buruli Ulcer, and any other disease condition that may be determined by the PBSL from time to time.
- 4.1.7.2.2 Pediatric programmes.
- 4.1.7.2.3 Ministry of Health tender purposes only.
- 4.1.7.2.4 Post approval variation.
- 4.1.7.2.5 Renewal of registration.

The evaluation report produced by the evaluator is peer- reviewed by a second evaluator. The PBSL reserves the right to request for any additional information to establish the safety, quality, and good performance of medical devices.

During evaluation, additional data and/or samples may be requested for, through a deferral letter. Once a query has been issued to the applicant the evaluation process stops until PBSL receives a written response to the query. Further processing of the application may only be made if responses to queries issued in the same deferral letter contain all outstanding information requested in one submission.

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Failure to comply with this condition, or if the queries have been reissued for a third time and the applicant provides unsatisfactory responses, the application will be rejected.

In the event the responses to the queries are not submitted within twelve (12) weeks from the date they were issued, it will be considered that the applicant has withdrawn the application.



Thereafter, registration of the product may only be considered upon submission of a new application.

4.1.7.3 Verification of compliance to current Good Manufacturing Practices (cGMP) and Quality Management System (QMS)

If the new application is from a new manufacturing site, PBSL will conduct inspection of the facility or use other means to verify whether the facility complies with cGMP Regulations and/or guideline before a product is registered. No product shall be registered unless the facility complies with cGMP. The report of the cGMP inspection will form part of the registration process.

4.1.7.4 Review of Application by Product Registration Committee.

All documentation dealing with the application including reports of label review, dossier evaluation, laboratory analysis and GMP status reports will be presented to the Drug Registration Committee for review and final determination of the status of the application. The decision might be either to grant, reject or defer the application.

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In the event that there are safety, quality or performance issues to be resolved as per the decision of the Committee, the application may be deferred pending resolution of the issues. Should the applicant fail to provide the required data within twelve months, it will be considered that the applicant has withdrawn the application. Thereafter, registration of the product may only be considered upon submission of a new application.

4.2. SPECIFIC REQUIREMENTS

4.2.1 MANUFACTURER'S OBLIGATIONS



4.2.1.1 A manufacturer shall ensure that the medical device meets the safety and effectiveness requirements. (Annex II)

4.2.1.2 A manufacturer shall keep objective evidence to establish that the medical device meets those requirements. (Appendix I).

4.2.2 Condoms

4.2.2.1 It is required that for the registration of condoms, 1600 pieces should be submitted as samples. This must be sampled from the batches whose COAs are presented in the dossier.

4.2.2.2 After registration, any consignment of condoms imported would be detained, sampled and analyzed. Sampling is done on batch-to-batch basis. The consignment would only be released if it passes the quality evaluation conducted at the Medical Devices Laboratory of the PBSL.

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4.2.2.3 For all imported condoms, a mandatory foreign inspection of the manufacturing facility will be conducted by the PBSL to ascertain compliance of the facility to cGMP and/or QMS Regulations. The fee for the foreign inspection is indicated in the sample schedule.

4.2.3 Diagnostic Test Kits

4.2.3.1 It is required that details of the manufacturing process of source materials, including the following information, are provided:



- (a) Control of starting materials
- (b) Source of materials – proteins, etc.
- (c) Method of manufacture and purification
- (d) Characterization
- (e) Specification and COAs
- (f) Quality Control

4.2.3.2 Manufacturing process of the Finished Product

- (a) Release specification
- (b) Shelf-life Specification

4.2.3.3 Finished Product

- (a) Specificity
- (b) Sensitivity
- (c) Accuracy
- (d) Stability - Justification of Shelf-life

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4.3 Classification of Medical Devices

4.3.1 Medical devices are classified into four groups, based on a risk assessment. Class I represents the group with the lowest risk and Class IV represents the group with the highest risk.



4.3.2 Where a medical device can be classified into more than one class, the class representing the higher risk applies.

| CLASS | RISK LEVEL |
|-------|-----------------|
| I | Low |
| II | Low - Moderate |
| III | Moderate - High |
| IV | High |

4.0. GLOSSARY



In these Guidelines, unless the context otherwise requires, the following terms have the assigned meanings:

- **Active device intended for diagnosis:** Any active medical device, whether used alone or in combination with other medical devices, to supply information for detecting, diagnosing, monitoring or treating physiological conditions, states of health, illnesses or congenital deformities.
- **Active implantable medical device:** Any active medical device, together with any accessories for its proper functioning, which is intended to be totally or partially introduced, surgically or medically, into the human body or by



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medical intervention into a natural orifice, and which is intended to remain after the procedure.

- **Active medical device:** Any medical device operation 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
- **Active therapeutic medical device:** Any active medical device, whether used alone or in combination with other medical devices, to support, modify, replace or restore biological functions or structures with a view to treatment or alleviation of an illness, injury or handicap
- **Authority:** The Pharmacy Board of Sierra Leone
- **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 by surgical intervention which is intended to remain in place after the procedure.
- **Certified Copy:** A true copy of the original document certified by a person registered to practice law in the Manufacturer's country of origin and endorsed with the legal practitioner's official stamp and signature.
- **Clinical Evaluation:** The review of relevant scientific literature and/or the review and assessment of data collected through clinical investigation.



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- **Clinical Investigation:** Any designed and planned systematic study in human subjects undertaken to verify the safety and/or performance of a specific device.
- **Conformity Assessment:** The systematic examination of evidence generated and procedures undertaken by the manufacturer, under requirements established by the Authority, to determine that a medical device is safe and performs as intended by the manufacturer and, therefore, conforms to the Essential Principles of Safety and Performance of Medical Devices.
- **Custom-made device:** Any device made specifically in accordance with a duly qualified
- **General Medical Device:** Refer to products falling within the definition of medical devices except in-vitro diagnostic medical device.
- **Implantable device:** Any device, including those that are partially or wholly absorbed, for the purpose for which it is intended. In addition, 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.
- **In Vitro Diagnostic Medical Device:** 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 intended for use in the



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diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease, in man or other animals or; intended to affect the structure or any function of the body of man or other animals and which does not achieve any of its principal intended purposes through chemical action within the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principle intended purposes.



- **Invasive devices:** A device, which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body.
- **Label:** Written, printed or graphic information provided upon the medical device itself.
- **Labeling/information supplied by the manufacturer:** Written, printed or graphic matter affixed to a medical device or any of its containers or wrappers, or, accompanying a medical device, related to identification, technical description, and use of the medical device, but excluding shipping documents.
- **Manufacture:** Includes all operations involved in the production, preparation, and processing, compounding, formulating, filling, refining, transformation, packing, packaging, re-packaging and labeling of medical devices.
- **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).

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- **Medical Device Family:** 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.
- **Medical Device Group:** Medical device comprising a collection of medical devices, such as a procedure pack or tray, which is sold under a single name.
- **Medical Device or Devices:** Refer to an instrument, apparatus, implement, medical equipment, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part or accessory, which is:
- **Medical Device System:** A medical device comprising a number of components or parts intended to be used together to fulfill some or the entire device's intended functions and that is sold under a single name.
- **National Standard:** A standard as prescribed by Sierra Leone Standards Bureau.
- **Objective Evidence:** Information that can be proved true based on facts obtained through observation, measurement, testing or other means.
- **Performance Evaluation:** Review of the performance of a medical device based upon data already available, scientific literature and, where appropriate, laboratory, animal or clinical investigations.
- **Process Validation:** Confirmation by objective evidence that a process consistently produces a result or product meeting its pre-determined requirements.

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- **Quality Management System:** Management system to direct and control an organization with regard to quality, from establishing quality policy, quality objectives and implementing and maintaining quality system.
- **Quality System:** System which consists of the organizational structure, responsibilities, procedures, processes and resources for implementing quality management and achieving the objectives.
- **Recall:** Any action taken by the manufacturer, importer or distributor in respect of a medical device that has been sold to recall or correct the device, or to notify its owners and users of its defectiveness or potential defectiveness, after being aware that the device may be hazardous to health, may fail to conform to any claim made by the manufacturer or importer relating to its effectiveness, benefits, performance characteristics or safety or may not meet the requirements of the Act or regulations recognized in the Official National Formulary, or Pharmacopoeia or any supplement to them.
- **Recognized Standards:** National or International standards deemed to offer the presumption of conformity to specific essential principles of safety and performance.
- **Surgically invasive device:** An invasive device which penetrates inside the body through the surface of the body, with the aid or in the context of a surgical operation.
- **Technical Documentation:** 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 to be



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totally introduced into the human body; or, to replace an epithelial surface or the surface of the eye,

- **Validation:** Confirmation by examination and provision of objective evidence that the specified requirements have been fulfilled. Where physical constraints prevent this happening, this term includes information provided on the packaging of each unit or on the packaging of multiple devices.

6.0 REFERENCES

1. Global Harmonization Task Force (GHTF)-/SG1/N12:2000 Role of Standards in the Assessment of Medical Devices.
2. GHTF/SG1/N29:2005 Information Document Concerning the Definition of the Term 'Medical Device'.
3. GHTF/SG1/N40:2006 Principles of Conformity Assessment for Medical Devices.
4. GHTF/SG1/N41:2005 Essential Principles of Safety and Performance of Medical Device.
4. The Global Harmonization Task Force (GHTF) which is now The International Medical Devices Regulatory Forum (IMDRF)
6. The Asian Harmonization Working Party (AHWP)
7. Global Medical Devices Agency
8. ISO Standards
9. World Health Organization (WHO)

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7.0 APPENDICES

8.0 APPENDIX I - LABELLING REQUIREMENTS

The label of the medical device shall have a labelling information which shall be in English and shall be expressed in a manner which is legible, permanent and in a prominent manner, and which can be easily understood by the intended user.

1. The labelling information shall include the following:

- (a) the name of the device, both „proprietary“ and „common“.
- (b) the name and address of the manufacturer
- (c) the manufacturing site address
- (d) the identifier of the device, including the identifier of a device that is part of a system, test kit, medical device group, medical device family or medical device group family
- (e) in the case of a Class III or IV device, the control number, otherwise the batch or lot number
- (f) an indication of what the package contains, expressed in terms appropriate to the device, such as size, net weight, length, volume or number of units
- (g) the word “Sterile” if the manufacturer intends to sell the device in a sterile condition
- (h) the words “for single use only” if the device is intended for that purpose

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- (i) the expiry date of the device expressed in day, month and year
- (j) the medical conditions, purposes and uses for which the device is manufactured, sold or represented, including the performance specifications of the device if those specifications are necessary for proper use unless self-evident to the intended user
- (f) the directions for use, unless directions are not required for the safe and effective use of the device.
- (k) warnings, precautions and limitations of product
- (l) any special storage conditions applicable to the device
- (j) The labeling design shall not bear close resemblance to other products already registered by the Authority

2 (a) In addition to the above requirements, where the device is for sale to the general public, the labeling information shall be set out on the outside of the package that contains the device, and must be visible under normal conditions of sale;

(b) where a package that contains a device is too small to display all the information as specified in (1) above, the directions for use shall accompany the device but need not be set out on the outside of the package or be visible under normal conditions of sale.

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

8.1 APPENDIX II - DEVICE DETAILS

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2.1. Name(s): State both the generic and brand names of the device.

2.2. Description: A general description on design, characteristics and performance of the device should be stated. This should include relevant information on device packaging.

2.3. Category: Where applicable, provide the GMDN category of the device. Otherwise, specify any other applicable codes.



2.4. Intended Use/Indication: State the intended use of the device and/or provide a general description of the disease or condition that the device will diagnose, treat, prevent, cure or mitigate. The description of the target patient population for which the device is intended should also be included.

2.4. Instruction for Use: A summary of information for safe use of the device including procedures, methods, frequency, duration, quantity and preparation to be followed should be provided.

2.6. Contraindications: These are conditions under which the device should not be used.

2.7. Warnings: Provide the specific hazard alert information that a user needs to know before using the device.

2.8. Precautions: Briefly state precautions to be taken and any special care necessary for the safe and effective use of the device.

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2.9. Adverse Effects: Specify all adverse and side effects associated with the device under normal conditions of use.

2.10. Alternative Use: Provide, if any, alternative practices or procedures for diagnosing, treating, curing or mitigating the disease or condition for which the device is intended.

2.11. Storage conditions: State the storage conditions for the device.

2.12. Recommended shelf-life (where applicable): State the recommended shelf-life of the device.

8.2 APPENDIX III – SUMMARY TECHNICAL DOCUMENTATION

3.1 Device description and features



Provide a detailed description of the device attributes that are necessary to explain how the device functions. This should include, but not limited to, the following: -

3.1.1 The principle of operation of the device

3.1.2 Description of the key functional elements of the device e.g. its parts/components, formulation, composition and functionality.

3.1.3 Labeled pictorial representation of the device in the form of diagrams, photographs or drawings with sufficient explanation.

3.2 Evidence of Conformity to Essential Principles

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

Note:

3.2.1 It is the responsibility of the manufacturer to identify the essential principles of safety and performance that are applicable to the device and the general methods used to demonstrate conformity to each applicable Essential Principle. The methods that may be used include:

3.3 Materials



Provide description of the materials of the device and their physical properties to the extent necessary to demonstrate conformity with the relevant Essential Principles. The information shall include complete chemical, biological and physical characterization of the materials of the device.

3.4 Device Specifications

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

3.5 Device Verification and Validation

3.4.1 A summary of the results of verification and validation studies undertaken to demonstrate compliance of the device with applicable Essential Principles should be provided. Where applicable, the information should include:

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3.4.1.1 Engineering tests.

3.4.1.2 Laboratory tests.

3.4.1.3 Simulated use testing.

3.4.1.4 Animal tests for demonstrating feasibility or proof of concept of the finished device.

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

3.4.1.6 Reports of tests and evaluations based on other standards, manufacturer methods and tests or alternative ways of demonstrating compliance.



3.4.1.7 Declarations/certificate of compliance to a recognized standard as applied by the manufacturer should be provided.

3.4.2 Biocompatibility (if applicable)

Provide details of all biocompatibility tests conducted on materials used in a device. At a minimum, tests must be conducted on samples from the finished and sterilized device. All materials that are significantly different must be characterized. Information describing the tests, the results and the analysis of data must be presented.

3.4.3 Software Verification and Validation (if applicable)

Provide information on the software design and development process and evidence of the validation of the software, as used in the finished device. This information should typically include the summary results of all verification, validation protocol and report and testing performed both in-house and in a simulated or actual user

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environment prior to final release. It should also address all of the different hardware configurations and, where applicable, operating systems identified in the labelling.

3.4.4 Devices Containing Biological Material (if applicable)

Provide results of studies substantiating the adequacy of the measures taken with regard to the risks associated with transmissible agents. This will include viral clearance results for known hazards. Donor screening concerns must be fully addressed and methods of harvesting must also be fully described.



Process validation results are required to substantiate that manufacturing procedures are in place to minimize biological risks.

3.4.5 Pre-clinical Studies (if applicable)

Provide detailed information on pre-clinical animal studies conducted to justify the probability of effectiveness in humans. These studies must follow Good Laboratory Practices. The objective, methodology, results, analysis and manufacturer's conclusions must be presented. The study conclusion should address the device's interactions with animal fluids and tissues and the functional effectiveness of the device in the experimental animal model(s). The rationale (and limitations) of selecting the particular animal model should be discussed.

3.4.6 Clinical Evidence (if applicable)

Provide detailed information on clinical evaluation studies undertaken to demonstrate compliance of the device with the Essential Principles of Safety and

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Performance. The clinical evaluation report should be summarized as per current IMDRF guidance documents.

3.6 Risk Analysis



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

3.7 Manufacturing Information

Provide details of manufacturing process for the device in the form of a list of resources and activities that transform inputs into the desired output. The manufacturing process should include the appropriate manufacturing methods and procedures, manufacturing environment or conditions and the facilities and controls used for the manufacturing, processing, packaging, labelling and storage of the device. A manufacturing process flow chart should be submitted.

Sufficient details must be provided to enable a person generally familiar with quality systems to judge the appropriateness of the controls in place. A brief summary of the sterilization method and processing should be included, if any. Reports of process validation studies must also be included.

If multiple facilities are involved in the manufacture of device, the physical address and overview of activities for each facility should be provided.

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8.3 APPENDIX IV - TIMELINES



All new applications and applications for renewal would be processed within a minimum period of six months, unless:

- 4.1 The application is for expedited review as specified above 3.1.7.2.1 to 3.1.7.2.4 where the process would be shorter; or
- 4.2 Where queries have been raised for the attention of the applicant, which queries have not been addressed or not been addressed adequately, for which reason the process would be longer.

8.4 APPENDIX V - SANCTIONS

A person who contravenes these Guidelines or sections thereof is liable to regulatory actions shall be imposed by the Authority. These sanctions may include, but not limited to, any of the following:

- 4.1 Suspension of the processing of a pending product registration application.
- 4.2 Suspension of the processing of a pending manufacturing license application.
- 4.3 Suspension of the processing of a pending import/export license application.
- 4.4 Cancellation of the following:
 - 4.4.1 a product registration
 - 4.4.2 an import/export license
 - 4.4.3 a manufacturing license
- 4.5 Payment of administrative charges . The amount would be as specified in the Fees schedule.

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8.5 APPENDIX VI - PENALTIES

A person who contravenes these Guidelines commits an offence and is liable on summary conviction to a fine of:

- 6.1 not less than fifty million Leones
- 6.2 to a term of imprisonment of not less than fifteen years and not more than twenty-five years, or
- 6.3 to both.

8.6 APPENDIX VII



7.0 FILING AN APPEAL FOR A REJECTED APPLICATION

The final decision for the issuance of MAC rests with the Pharmacy Board of Sierra Leone, in line with Section 44 of the Pharmacy and Drugs Act 2001. However, in the event that the PBSL during the registration process decides to reject an application, the applicant may submit a notice of appeal within four (4) weeks following the date of issuance of the letter of rejection.

The appeal representation shall be made in writing to the Authority addressed to:

The Registrar Pharmacy Board of Sierra Leone
Central Medical Stores Compound
New England Ville
Freetown
Sierra Leone

Upon submission of the notice of appeal, it will be subjected to internal scrutiny by the PBSL. Decisions on outcome of appeals shall be communicated to applicants within four (4) weeks after receipt of an appeal.

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If the PBSL is satisfied with the notice of appeal submitted, it may approve the registration of the medical product (s); otherwise the notice of appeal shall be rejected.

8.7 APPENDIX VIII -ACRONYMS/ABBREVIATIONS

AIMD: Active Implantable Medical Device

AIMDD: Active Implantable Medical Device Directive 90/385

AHWP: Asian Harmonization Working Party

BSE: Bovine Spongiform Encephalopathy

CA: Competent Authority

CAB: Conformity Assessment Body

CSDT: Common Submission Dossier Template

CTS: Common Technical Specifications

DA: Designating Authority

DoC: Declaration of Conformity

EMA: European Medicines Agency

EPSP: Essential Principles of Safety and Performance

PBSL: Pharmacy Board of Sierra Leone

FSCA: Field Safety Corrective Action

FSN: Field Safety Notice



GHTF: Global Harmonization Task Force

GMDN: Global Medical Device Nomenclature

GMP: Good Manufacturing Practices

IFU: Instructions for Use

IMDRF: International Medical Device Regulators Forum

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ISO: International Organization for Standardization

IVD: In vitro diagnostic medical device

IVDD: In Vitro Diagnostic Medical Device Directive 98/79/EC

MD: Medical Device

MRA: Mutual Recognition Agreements

QMS: Quality Management System

STED: Summary Technical Documentation

TSE: Transmissible Spongiform Encephalopathy

UDI: Unique Device Identification

8.8 APPENDIX IX - CLASSIFICATION RULES FOR MEDICAL DEVICES

PART 1

MEDICAL DEVICES OTHER THAN IN VITRO DIAGNOSTIC DEVICES



Invasive Devices

Rule 1:

(1) Subject to sub-rules (2) and (3), all surgically invasive devices are classified as Class II.

(2) A surgically invasive device that is intended to diagnose, monitor, control or correct a defect of the central cardiovascular system or the central nervous system or of a fetus in utero is classified as Class IV.

(3) A surgically invasive device that is intended to be absorbed by the body, or that is normally intended to remain in the body for at least 30 consecutive days, is classified as Class III.

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Rule 2:

(1) Subject to sub-rules (2) to (4), all invasive devices that penetrate the body through a body orifice or that come into contact with the surface of the eye are classified as Class II.

(2) A device described in sub-rule (1) that is intended to be placed in the oral or nasal cavities as far as the pharynx or in the ear canal up to the ear drum is classified as Class I.

(3) A device described in sub-rule (1) that is normally intended to remain in the body or in contact with the surface of the eye for at least 30 consecutive days is classified as Class III.

(4) A device described in sub-rule (1) that is intended to be represented as preventing the transmission of infectious agents during sexual activities or reducing the risk thereof is classified as Class III.

Rule 3:

Despite rules 1 and 2

(a) all denture materials and orthodontic appliances, and their accessories are classified as Class II;



(b) all surgical or dental instruments are classified as Class I; and

(c) all latex condoms are classified as Class II.

Non-invasive Devices

Rule 4:

(1) Subject to sub-rule (2), all non-invasive devices that are intended to come into contact with injured skin are classified as Class II.

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(2) A device described in sub-rule (1) that is intended to be used as a mechanical barrier, for compression or for absorption of exudations, is classified as Class I.

Rule 5:

A non-invasive device intended for channeling or storing gases, liquids, tissues or body fluids for the purpose of introduction into the body by means of infusion or other means of administration is classified as Class II.

Rule 6:

(1) Subject to sub-rules (2) and (3), a non-invasive device intended for modifying the biological or chemical composition of blood or other body fluids, or liquids, for the purpose of introduction into the body by means of infusion or other means of administration is classified as Class III.



(2) A device described in sub-rule (1) whose characteristics are such that the modification process may introduce a foreign substance into the body that is potentially hazardous, taking into account the nature and quantity of the substance, is classified as Class IV.

(3) A device described in sub-rule (1) that accomplishes the modification by centrifugation, gravity filtration or the exchange of gas or heat is classified as Class II.

Rule 7:

(1) Subject to sub-rule (2), all other non-invasive devices are classified as Class I.

(2) A device described in sub-rule (1) is classified as Class II if it is intended

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(a) to act as a calibrator, tester or quality control support to another medical device; or

(b) to be connected to an active device that is classified as Class II, III or IV.

Active Devices

Rule 8:

(1) Subject to sub-rules (2) and (3), an active device intended to emit ionizing radiation, including any device or software intended to control or monitor such a device or directly influence its performance, is classified as Class III.

(2) A device described in sub-rule (1) that is intended to be used in radiographic mode is classified as Class II.

(3) Despite sub-rule (2), an active device that is intended to be used for mammography is classified as Class III.



Rule 9:

(1) Subject to sub-rules (2) and (3), an active therapeutic device, including any dedicated software, intended to be used to administer or withdraw energy to or from the body is classified as Class II.

(2) If the administration or withdrawal by a device described in sub-rule (1) is potentially hazardous, taking into account the nature of the administration or withdrawal, the intensity of the energy and the part of the body concerned, the device is classified as Class III.

(3) A device described in sub-rule (2) that is intended to control the treatment of a patient's condition through a closed loop system is classified as Class IV.

Rule 10:

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(1) Subject to sub-rule (2), an active diagnostic device, including any dedicated software, that supplies energy for the purpose of imaging or monitoring physiological processes is classified as Class II.

(2) A device described in sub-rule (1) that is intended to be used to monitor, assess or diagnose a disease, a disorder, an abnormal physical state or a pregnancy, if erroneous readings could result in immediate danger, is classified as Class III.

Rule 11:

(1) Subject to sub-rules (2) and (3), an active device, including any dedicated software, intended to administer drugs, body fluids or other substances to the body or withdraw them from the body is classified as Class II.

(2) If the administration or withdrawal by a device described in sub-rule (1) is potentially hazardous, taking into account the nature of the administration or withdrawal, the nature of the substance involved and the part of the body concerned, the device is classified as Class III.

(3) A device described in sub-rule (2) that is intended to control the treatment of a patient's condition through a closed loop system is classified as Class IV.

Rule 12:

Any other active device is classified as Class I.



Special Rules

Rule 13:

A medical device that is intended to be used for

(a) disinfecting or sterilizing blood, tissues or organs that are intended for transfusion or transplantation is classified as Class IV; and

(b) disinfecting or sterilizing a medical device is classified as Class II.

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Rule 14:

- (1) Subject to sub-rule (2), the following medical devices are classified as Class IV:
- (a) a medical device that is manufactured from or that incorporates human or animal cells or tissues or their derivatives; and
 - (b) a medical device that is manufactured from or that incorporates a product produced through the use of recombinant DNA technology.
- (2) A device described in sub-rule (1) that is intended to come into contact with intact skin only is classified as Class I.



Rule 15:

Any medical device that is a material intended to be sold to a health care professional or dispenser for the specific purpose of configuration or arrangement into a mould or shape to meet the needs of an individual is classified in the class that applies to the finished medical device.

Rule 16:

Despite rules 1 to 15, a medical device set out in column 1 of an item of the table to this rule is classified as the class set out in column 2 of that item.

TABLE

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| Column 1 | Column 2 |
|--|----------|
| Item Medical device | Class |
| 1. Breast implants | IV |
| 2. Tissue expanders for breast reconstruction and augmentation | IV |

PART 2

IN VITRO DIAGNOSTIC DEVICES

Use with respect to Transmissible Agents

- Rule 1:
- An IVDD that is intended to be used to detect the presence of, or exposure to, a transmissible agent in blood, blood components, blood derivatives, tissues or organs to assess their suitability for transfusion or transplantation is classified as Class IV.
- Rule 2:
- An IVDD that is intended to be used to detect the presence of, or exposure to, a transmissible agent is classified as Class II, unless
- (a) it is intended to be used to detect the presence of, or exposure to, a transmissible agent that causes a life-threatening disease if there is a risk of

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propagation in the Sierra Leonean population, in which case it is classified as Class IV; or

(b) it falls into one of the following categories, in which case it is classified as Class III:

(i) it is intended to be used to detect the presence of, or exposure to, a transmissible agent that causes a serious disease where there is a risk of propagation in the Sierra Leonean population,

(ii) it is intended to be used to detect the presence of, or exposure to, a sexually transmitted agent,

(iii) it is intended to be used to detect the presence of an infectious agent in cerebrospinal fluid or blood, or

(iv) there is a risk that an erroneous result would cause death or severe disability to the individual being tested, or to the individual's offspring.

Rule 3:



An IVDD that is intended to be used for patient management is classified as Class II, unless it falls into one of the following categories, in which case it is classified as Class III:

(a) it is intended to be used for the management of patients suffering from a life-threatening disease; or

(b) there is a risk that an erroneous result will lead to a patient management decision resulting in an imminent life-threatening situation for the patient.

Other Uses

Rule 4:

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An IVDD that is not subject to rules 1 to 3 and that is intended to be used in diagnosis or patient management is classified as Class II, unless it falls into one of the following categories, in which case it is classified as Class III:

- (a) it is intended to be used in screening for or in the diagnosis of cancer;
- (b) it is intended to be used for genetic testing;
- (c) it is intended to be used in screening for congenital disorders in the fetus;
- (d) there is a risk that an erroneous diagnostic result would cause death or severe disability to the patient being tested or to that patient's offspring;
- (e) it is intended to be used for disease staging; or
- (f) it is intended to be used to monitor levels of drugs, substances or biological components, if there is a risk that an erroneous result will lead to a patient management decision resulting in an imminent life-threatening situation for the patient.

Rule 5:

An IVDD that is intended to be used for blood grouping or tissue typing to ensure the immunological compatibility of blood, blood components, tissue or organs that are intended for transfusion or transplantation is classified as Class III.



Special Rules

Rule 6:

A near patient IVDD is classified as Class III.

Rule 7:

In cases where an IVDD, including its analyzers, reagents and software, is intended to be used with another IVDD, the class of both IVDDs will be that of the IVDD in the class representing the higher risk.

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Rule 8:

If rules 1 to 7 do not apply, all other IVDDs are classified as Class I.

Rule 9:

Despite rules 1 to 8, an IVDD set out in column 1 of an item of the table to this rule is classified as the class set out in column 2 of that item.



| | |
|---|------|
| TABLE | |
| Column | 1 |
| Column 2 | |
| Item | IVDD |
| Class | |
| 1. Near patient in vitro diagnostic device for the detection of pregnancy | |
| II | |
| or for fertility testing | |
| 2. Near patient in vitro diagnostic device for determining cholesterol | |
| II | |
| level | |
| 3. Microbiological media used to identify or infer the identity of a | I |
| microorganism | |

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4. IVDD used to identify or infer the identity of a cultured I
microorganism

8.9 SCHEDULE I - IMPLANTS

1. Heart valve
2. Annuloplasty ring
3. Active implantable device systems
 - (a) all models of implantable pacemakers and leads;
 - (b) all models of implantable defibrillators and leads;
 - (c) artificial heart;
 - (d) implantable ventricular support system; and
 - (e) implantable drug infusion system
4. Devices of human origin
 - (a) human dura mater; and
 - (b) wound covering containing human cells

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9.0 ANNEX II



Essential Principles of Safety and Performance (EPSP)

No. Essential Principle Applicable Method of Identity of to the Conformity Specific device? Documents

General Requirements

1 Medical devices should be designed and manufactured such that, when used under the conditions and for the purposes intended and, where applicable, by virtue of the technical knowledge, experience, education or training, and the medical and physical conditions of intended users, they will perform as intended by the manufacturer and not compromise the clinical condition or the safety of patients, or the safety and health of users or other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety

2 Any solutions adopted for the design and manufacture of the devices should conform to the state of the art safety principles. When required, risk should be controlled such that the residual risk associated with each hazard is judged acceptable. This can be achieved by identifying known or foreseeable hazards and estimating the associated risks arising from the intended use and foreseeable misuse; eliminating risks, as far as reasonably practicable, through inherently safe design and manufacture; reducing ,as far as reasonably practicable, the remaining

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risks by taking adequate protection measures, including alarms; and informing users of any residual risks.

3 Medical devices should achieve the performance intended by the manufacturer and be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose.

4 The characteristics and performances referred to in Clauses 1 to 3 should not be adversely affected to such a degree that the health or safety of the patient or the user and/or other persons are compromised during the lifetime of the device, as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer's instructions.

5 Medical devices should be designed, manufactured and packaged such that their characteristics and performances during their intended use will not be adversely affected by transport and storage conditions (e.g. fluctuations of temperature and humidity) taking account of the instructions and information provided by the manufacturer.

6 All known and foreseeable risks, and any undesirable effects, should be minimized and be acceptable when weighed against the benefits of the intended performance of medical devices during normal conditions of use.

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Design and manufacturing Principles applicable to Medical Devices other than IVD Medical Devices which are additional to the general principles of safety and performance listed above.

7.0 Chemical, Physical and Biological Properties

7.1 The devices should be designed and manufactured so as to ensure the characteristics and performance referred to in the General Requirements above. Particular attention should be paid to the choice of materials used, particularly as regards toxicity and, where appropriate, flammability; the compatibility between the materials used and biological tissues, cells, and body fluids taking account of the intended purpose of the device; and the choice of materials used, reflecting, where appropriate, matters such as hardness, wear and fatigue strength.

7.2 The devices should be designed, manufactured and packaged in a manner that would minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to patients, taking account of the intended purpose of the device. Particular attention should be paid to tissues exposed and to the duration and frequency of exposure.

7.3 The devices should be designed and manufactured in such a way that they can be used safely with the materials, substances and gases with which they enter into contact during their normal use

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or during routine procedures; if the devices are intended to administer medicinal products they should be designed and manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and restrictions governing these products and that their performance is maintained in accordance with the intended use.

7.4 The devices should be so designed and reasonably practicable and appropriate, the risks posed by substances that may leach or leak from the device. Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction.

7.5 Devices should be designed and manufactured in such a way as to reduce, as far as reasonably practicable and appropriate, risks posed by the unintentional ingress or egress of substances into or from the device taking into account the device and the nature of the environment in which it is intended to be used.

8.0 Infection and microbial contamination

8.1 The devices and manufacturing processes should be so designed to eliminate or to reduce, as far as reasonably practicable and appropriate, the risk of infection to patients, users and/or 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

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microbial contamination of the device or specimen, where applicable, by the patient, user or other person.

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



8.3 Devices delivered in a sterile state should be designed, manufactured and packaged in

a non-reusable pack, and/or according to appropriate procedures, to ensure that they are sterile when placed on the market and remain sterile, under the transport and storage conditions indicated by the manufacturer, until the protective packaging is damaged or opened.

8.4 Devices labelled either as sterile or as having a special microbiological state should have been processed, manufactured and, if applicable, sterilized by appropriate, validated methods.

8.5 Devices intended to be sterilized should be manufactured in appropriately controlled (e.g. environmental) conditions.

8.6 Packaging systems for non-sterile devices should maintain the integrity and cleanliness of the product and, if the devices are to be sterilized prior to use,

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minimize the risk of microbial contamination; the packaging system should be suitable taking account of the method of sterilization indicated by the manufacturer.



8.7 The labelling of the device should distinguish between identical or similar products placed on the market in both sterile and non-sterile condition.

9.0 Medical Devices Incorporating a Substance Considered to be a Medicinal Product/Drug

9.1 Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product/drug as defined in the relevant legislation that applies within that jurisdiction and which is liable to act upon the body with action ancillary to that of the device, the safety, quality and performance of the device as a whole should be verified, as well as the safety, quality and efficacy of the substance in the specific application,

10.0 Medical Devices Incorporating Materials of Biological Origin

10.1 Where products incorporating tissues, cells and substances of animal origin may be considered as medical devices, 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. Information on the geographical origin of the animals should be provided.



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Processing, preservation, testing and handling of tissues, cells and substances of animal origin should be carried out so as to provide optimal safety for patients, users and other persons. In particular, safety with regard to viruses and other transmissible agents should be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.

10.2 Where products incorporating human tissues, cells and substances may be considered medical devices, the selection of sources, donors and/or substances of human origin, the processing, preservation, testing and handling of tissues, cells and substances of such origin should be carried out so as to provide optimal safety for patients, users and, other persons. In particular, safety with regard to viruses and other transmissible agents should be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.

10.3 Where products incorporating cells and substances of microbial origin may be considered medical devices, processing, preservation, testing and handling of cells and substances should be carried out so as to provide optimal safety for patients, users and, other persons. In particular, safety with regard to viruses and other transmissible agents should be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.

11 Devices with a diagnostic or measuring function

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11.1 i. Diagnostic devices and devices with a measuring function, should be so designed and manufactured to provide sufficient accuracy, precision and stability for their intended purpose of the device, based on appropriate scientific and technical methods. The limits of accuracy should be indicated by the manufacturer.



ii. Any measurement, monitoring or display scale should be designed in line with ergonomic principles, taking account of the intended purpose of the device.

iii. 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 standardized measurement units, considerations of safety, user familiarity, and established clinical practice may justify the use of other recognised measurement unit.

12 Protection against radiation

12.1 General

Devices should be designed and manufactured and packaged such that exposure of patients, users and other persons to any emitted radiation should be reduced as far as reasonably practicable and appropriate, compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.

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12.2 Intended radiation

i. 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.



ii. Where devices are intended to emit potentially hazardous, visible and/or invisible radiation, they should be fitted, where reasonably practicable, with visual displays and/or audible warnings of such emissions.

12.3 Unintended radiation

Devices should be designed and manufactured such that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as reasonably practicable and appropriate.

12.4 Ionizing radiation

i. Devices intended to emit ionizing radiation should be designed and manufactured such as to ensure that, where reasonably practicable, the quantity, geometry and energy distribution (or quality) of radiation emitted can be varied and controlled taking into account the intended use.

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ii. Devices emitting ionizing radiation intended for diagnostic radiology should be designed and manufactured such as to achieve appropriate image and/or output quality for the intended medical purpose whilst minimising radiation exposure of the patient and user.

iii. 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.

13 Medical devices that incorporate software and standalone medical device software

13.1 Devices incorporating electronic programmable systems, including software, or standalone software that are devices in themselves, should be designed to ensure repeatability, reliability and performance according to the intended use. In the event of a single fault condition, appropriate means should be adopted to eliminate or reduce as far as reasonably practicable and appropriate consequent risks.

13.2 For devices which incorporate software or for standalone software that are devices in themselves, the software must be validated according to the state of the art taking into account the principles of development lifecycle, risk management, verification and validation.

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14 Active medical devices and devices connected to them

14.1 For active medical devices, in the event of a single fault condition, appropriate means should be adopted to eliminate or reduce as far as reasonably practicable and appropriate consequent risks.



14.2 Devices where the safety of the patients depends on an internal power supply should be equipped with a means of determining the state of the power supply.

14.3 Devices where the safety of the patients depends on an external power supply should include an alarm system to signal any power failure.

14.4 Devices intended to monitor one or more clinical parameters of a patient should be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health.

14.5 Devices should be designed and manufactured in such a way as to reduce as far as reasonably practicable and appropriate the risks of creating electromagnetic interference which could impair the operation of this or other devices or equipment in the usual environment.

14.6 Devices should be designed and manufactured in such a way as to provide an adequate level of intrinsic immunity to electromagnetic disturbance to enable them to operate as intended.

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14.7 Devices should be designed and manufactured in such a way as to avoid, as far as reasonably practicable, the risk of accidental electric shocks to the patient, user or any other person, both during normal use of the device and in the event of a single fault condition in the device, provided the device is installed and maintained as indicated by the manufacturer.

15 Protection against mechanical risks

14.1 Devices should be so designed and manufactured to protect the patient and user against mechanical risks connected with, for example, resistance to movement, instability and moving parts.

14.2 Devices should be so designed and manufactured 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.

14.3 Devices should be so designed and manufactured 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.

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14.4 Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user has to handle should be so designed and constructed to minimize all possible risks.



14.5 Devices should be so designed and manufactured to reduce to the lowest practicable level, the risk of error when certain parts within the device are intended to be connected or reconnected before or during use.

14.6 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 conditions of use.

16.0 Protection against the risks posed to the patient or user by supplied energy or substances

16.1 Devices for supplying the patient with energy or substances should be so designed and constructed that the delivered amount can be set and maintained accurately enough to guarantee the safety of the patient and of the user.

16.2 Devices should be fitted with the means of preventing and/or indicating any inadequacies in the delivered amount which could pose a danger. Devices should incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy or substances from an energy and/or substance source.

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16.3 The function of the controls and indicators should be clearly specified on the devices. Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information should be understandable to the user and, as appropriate, the patient.



17.0 Protection against the risks posed to the patient or user by supplied energy or substances

17.1 Devices for use by lay persons should be so designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to lay persons and the influence resulting from variation that can reasonably be anticipated in the lay person's technique and environment. The information and instructions provided by the manufacturer should be easy for the lay person to understand and apply.

17.2 Devices for use by lay persons should be so designed and manufactured to reduce as far as reasonably practicable, the risk of error during use by the lay person in the handling of the device and also in the interpretation of results.

17.3 Devices for use by lay persons should, where reasonably possible, include a procedure by which the lay person can verify that, at the time of use, the product will perform as intended by the manufacturer.

18.0 Label and Instructions for Use

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18.1 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.



19.0 Clinical Evaluation

19.1 For all medical devices, the demonstration of conformity with essential principles includes a clinical evaluation in accordance with GHTF guidance. The clinical evaluation should review clinical data in the form of any:

- clinical investigation reports,
- literature reports/reviews, and
- clinical experience to establish that a favourable benefit-risk ratio exists for the device.

19.2 Clinical investigations on human subjects should be carried out in accordance with the spirit of the Helsinki Declaration. This includes every step in the clinical investigation from first consideration of the need and justification of the study to publication of the results. In addition, some countries may have specific regulatory requirements for pre-study protocol review or informed consent.

Essential Principles applicable to IVD Medical Devices

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20.0 Chemical, physical and biological properties

20.1 The IVD medical devices should be so designed and manufactured to ensure the characteristics and performance referred to above. Particular attention should be paid to the possibility of impairment of analytical performance due to incompatibility between the materials used and the specimens and/or analyte (measure and) to be detected (such as biological tissues, cells, body fluids and microorganisms), taking account of its intended purpose.

20.2 The IVD medical devices should be so designed, manufactured and packaged to minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to patients, taking account of the intended purpose of the device.

20.3 The IVD medical devices should be so designed and manufactured to reduce, as far as reasonably practicable and appropriate, the risks posed by substances that may leach or leak from the IVD medical device. Special attention should be given to substances which are carcinogenic, mutagenic or toxic to reproduction.

20.4 IVD medical devices should be so designed and manufactured to reduce, as far as reasonably practicable and appropriate, risks posed by the unintentional ingress or egress of substances into or from the IVD medical device taking into

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account the device and the nature of the environment in which it is intended to be used.

21.0 Infection and microbial contamination

21.1 Where IVD medical devices include tissues, cells and substances originating from animals, the processing, preservation, testing and handling of tissues, cells and substances of animal origin should be carried out so as to provide optimal safety for user, professional or lay, or other person. In particular, safety with regard to viruses and other transmissible agents should be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process. This may not apply to certain IVD medical devices if the activity of the virus and other transmissible agent are integral to the intended purpose of the IVD medical device or when such elimination or inactivation process would compromise the performance of the IVD medical device.

Relevant information on the geographical origin of the animals must be kept.

21.2 Where IVD medical devices include human tissues, cells and substances, the selection of sources, donors and/or substances of human origin, the processing, preservation, testing and handling of tissues, cells and substances of such origin should be carried out so as to provide optimal safety for user, professional or lay, or other person. In particular, safety with regard to viruses and other transmissible agents should be addressed by implementation of validated methods of elimination



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or inactivation in the course of the manufacturing process. This may not apply to certain IVD medical devices if the activity of the virus and other transmissible agent are integral to the intended purpose of the IVD medical device or when such elimination or inactivation process would compromise the performance of the IVD medical device.

21.3 Where IVD medical devices include cells and substances of microbial origin, the processing, preservation, testing and handling of cells and substances should be carried out so as to provide optimal safety for user, professional or lay, or other person. In particular, safety with regard to viruses and other transmissible agents should be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process. This may not apply to certain IVD medical devices if the activity of the virus and other transmissible agent are integral to the intended purpose of the IVD medical device or when such elimination or inactivation process would compromise the performance of the IVD medical device.

22.0 Environmental Properties

22.1 If the IVD medical device is intended for use in combination with other devices or equipment, the whole combination, including the connection system should not impair the specified performance of the devices. Any restrictions on use applying to such combinations should be indicated on the label and/or in the instructions for use.

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22.2 IVD medical devices should be designed and manufactured in such a way as to remove or reduce as far as reasonably practicable and appropriate:

i. the risk of injury to user, professional or lay, or other person in connection with their physical and ergonomic features;

ii. the risk of use error due to the ergonomic features, human factors and the environment in which the IVD medical device is intended to be used;



iii. risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, pressure, humidity, temperature or variations thereof;

iv. the risks associated with the use of the IVD medical device when it comes into contact with materials, liquids, and gases to which it is exposed during normal conditions of use;

v. the risk associated with the possible negative interaction between software and the environment within which it operates and interacts;

vi. the risks of accidental penetration of substances into the IVD medical device;

vii. the risk of incorrect identification of specimens/samples;

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viii. the risks of reasonably foreseeable interference

v .with other devices such as carry over between IVD medical devices.



22.3 IVD medical devices should be so designed and manufactured to minimize the risks of fire or explosion during normal use and in single fault condition. Particular attention should be paid to IVD medical devices whose intended use includes exposure to or use in association with flammable substances or substances which could cause combustion.

22.4 IVD medical devices should be designed and manufactured in such a way that adjustment, calibration, and maintenance, where such is necessary to achieve the performances intended, can be done safely.

22.5 IVD medical devices should be designed and manufactured in such a way as to facilitate the safe disposal of any waste substances.

23.0 Performance Characteristics

23.1 IVD medical devices should be so designed and manufactured in such a way that the performance characteristics support the intended use, based on appropriate scientific and technical methods. In particular, where appropriate, the design should address sensitivity, specificity, accuracy which is trueness and precision (repeatability and reproducibility), control of known relevant

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interference and limits of detection. These performance characteristics need to be maintained during the lifetime of the IVD medical device as indicated by the manufacturer.



23.2 Where the performance of devices depends on the use of calibrators and/or control materials, the traceability of values assigned to such calibrators and/or control materials should be assured through available reference measurement procedures and/or available reference materials of a higher order.

23.3 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 standardized measurement units, considerations of safety, user familiarity, and established clinical practice may justify the use of other recognised measurement units.

24.0 Protection Against Radiation

24.1 IVD medical devices should be so designed, manufactured and packaged that exposure of user, professional or lay, or other person to the emitted radiation (intended, unintended, stray or scattered) is reduced as far as reasonably practicable and appropriate.

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24.2 When IVD medical devices are intended to emit potentially hazardous, visible and/or invisible radiation, they should as far as reasonably practicable and appropriate be:

- designed and manufactured in such a way as to ensure that the characteristics and the quantity of radiation emitted can be controlled and/or adjusted; and
- fitted with visual displays and/or audible warnings of such emissions.



24.0 IVD medical devices that incorporate software and standalone IVD medical device software

24.1 For IVD medical devices which incorporate software or for standalone software that are IVD medical devices in themselves, the software must be validated according to the state of the art taking into account the principles of development lifecycle, risk management, verification and validation.

26.0 IVD medical devices connected to, or equipped with, an energy source

26.1 IVD medical devices, where the safety of the patient depends on an internal power supply in the IVD medical device, should be equipped with a means of determining the state of the power supply.

26.2 IVD medical devices should be so designed and manufactured to reduce as far as reasonably practicable and appropriate the risks of creating electromagnetic

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interference which could impair the operation of this or other devices or equipment in the usual environment.

26.3 IVD medical devices should be designed and manufactured in such a way as to provide an adequate level of intrinsic immunity to electromagnetic disturbance to enable them to operate as intended.

26.4 IVD medical devices should be designed and manufactured in such a way as to avoid, as far as reasonably practicable, the risk of accidental electric shocks to the user, professional or lay, or other person both during normal use of the device and in the event of a single fault condition in the device, provided the IVD medical device is installed and maintained as indicated by the manufacturer.

27.0 Protection against mechanical and thermal risks

27.1 IVD medical devices should be designed and manufactured in such a way as to protect the user, professional or lay, or other person against mechanical risks connected with, for example, resistance to movement, instability and moving parts. IVD medical devices should be designed and manufactured in such a way as to protect the user, professional or lay, or other person against mechanical risks connected with, for example, resistance to movement, instability and moving parts.

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27.2 Where there are risks due to the presence of moving parts, risks due to break-up or detachment, or leakage of substances, then appropriate protection means must be incorporated.

27.3 IVD medical devices should be designed and manufactured in such a way as to reduce to the lowest practicable level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.

27.4 IVD medical devices should be designed and manufactured in such a way as to reduce to the lowest practicable level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source.

27.5 Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user, professional or lay, or other person has to handle should be designed and constructed in such a way as to minimize all possible risks.

27.6 IVD medical devices should be designed and manufactured in such a way as to reduce to the lowest practicable level, the risk of error when certain parts within the device are intended to be connected or reconnected before or during use.

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27.7 Accessible parts of the IVD medical devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings should not attain potentially dangerous temperatures under normal use.



28.0 Protection against the risks posed by IVD medical devices for self-testing

28.1 IVD medical devices for self-testing should be so designed and manufactured that they perform appropriately for their intended purpose taking into account the skills and the means available to lay persons and the influence resulting from variation that can reasonably be anticipated in the layperson's technique and environment. The information and instructions provided by the manufacturer should be easy for the lay person to understand and apply.

28.2 IVD medical devices for self-testing should be designed and manufactured in such a way as to reduce as far as reasonably practicable the risk of error by the lay person in the handling of the device and, if applicable, the specimen, and also in the interpretation of results.

28.3 IVD medical devices for self-testing should, where reasonably possible, include a procedure by which the lay person can verify that, at the time of use, the product will perform as intended by the manufacturer.

29.0 Label and Instructions for Use

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29.1 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



30.0 Performance evaluation including analytical performance and, where appropriate, clinical performance

31.1 For an IVD medical device a performance evaluation should be conducted in accordance with GHTF guidance. The performance evaluation should review analytical performance data and, where appropriate, clinical performance data in the form of any:

- literature;
- performance study reports; and
- experience gained by routine diagnostic testing.

To establish that the IVD medical device achieves its intended performance during normal conditions of use and that the known, and foreseeable risks, and any undesirable effects, are minimized and acceptable when weighed against the benefits of the intended performance.

31.2 Clinical performance studies using specimens from human subjects should be carried out in accordance with the spirit of the Declaration of Helsinki. This includes every step in the clinical performance study from first consideration of the need and justification of the study to publication of the results. In addition, some countries may have specific regulatory requirements for informed consent.

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