FOOD AND DRUGS AUTHORITY

GUIDELINE FOR REGISTRATION OF MEDICAL DEVICE

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1.0. INTRODUCTION

In pursuance of Section 148 of the Public Health Act, 2012, Act 851, 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 Ghana. 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,
iii. a technical documentation,
iv. a declaration of conformity, and
v. the registration of manufacturers and their medical devices by the FDA.

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: GHTF/SG1/N77:2012
c. The European Standards (Medical Devices)
d. Essential Principles of Safety and Performance of Medical Devices: GHTF/SG1/N68:2012
e. Principles of Conformity Assessment of Medical Devices: GHTF/SG1/N78:2012

f. The Medical Devices Regulations – Global overview and guiding principles of WHO were also used
g. Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED): GHTF/SG1/N011:2008

These guidelines must be read and used in conjunction with the enabling legislation, the Public Health Act, 2012, Act 851, Part 7, as well as any other relevant Guidelines and Regulations issued by the Food and Drugs Authority.

2.0. GLOSSARY

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

***Active implantable medical device*:** Any active medical device, together with any accessories for its proper functioning, which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure.

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

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.

Authority: The Food and Drugs Authority, Ghana.

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.

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.

Clinical Investigation: Any designed and planned systematic study in human subjects undertaken to verify the safety and/or performance of a specific device.

Custom-made device**:** Any device made specifically in accordance with a duly qualified practitioner's written prescription which gives specific design characteristics and is intended for the sole use of a particular patient.

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, 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.

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.

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.

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

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.

Label: Written, printed or graphic information provided upon the medical device itself.
Where physical constraints prevent this happening, this term includes information provided on the packaging of each unit or on the packaging of multiple devices.

Labelling/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, processing, compounding, formulating, filling, refining, transformation, packing, packaging, re-packaging and labelling of medical devices.

Manufacturer: Means any natural or legal person1 with responsibility for design and/or manufacture of a medical device with the intention of making the medical device available for use, under 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).

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:

(a) recognized in the Official National Formulary, or Pharmacopoeia or any supplement to them;
(b) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease, in man or other animals or;
(c) 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 metabolised for the achievement of any of its principle intended purposes.

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 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 Ghana Standards Authority (GSA).

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.

Quality System: System which consists of the organizational structure, responsibilities, procedures, processes and resources for implementing quality management and achieving the objectives.

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.

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.

Recognised 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

Devices other than those referred to above and which produce penetration other than through an established body orifice, shall be treated as surgically invasive devices

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.

Validation: Confirmation by examination and provision of objective evidence that the specified requirements have been fulfilled.

ACRONYMS

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

EMEA: European Medicines Agency

EPSP: Essential Principles of Safety and Performance

FDA: Food and Drugs Authority

FSCA: Field Safety Corrective Action

FSN: Field Safety Notice

GHTF: Global Harmonisation Task Force

GMDN: Global Medical Device Nomenclature

GMP: Good Manufacturing Practices

IFU: Instructions for Use

IMDRF: International Medical Device Regulators Forum

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

STD: Summary Technical Documentation

TSE: Transmissible Spongiform Encephalopathy

UDI: Unique Device Identification

3.0. REQUIREMENTS

3.1. General Requirements

3.1.1 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
Food and Drugs Authority
P. O. Box CT 2783
Cantonment-Accra

3.1.2 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.

3.1.3 Local Agent

A local agent is a natural person resident in Ghana or a corporate body registered in Ghana, with the relevant mandate from the applicant, to act on the

applicant's behalf as regards matters relating to the registration of a medical device(s) in Ghana. The Local Agent would, among other things:

3.1.3.1 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.

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

3.1.3.3 Handle device recalls.

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

3.1.4 Classification of applications

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

3.1.4.1 New Applications for Registration

A new application for a medical device is one intended to be placed on the Ghanaian 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:

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

3.1.4.1.2 Samples of the product as per FDA sample schedule.

3.1.4.1.3 Non-refundable application fee for registration of medical devices as per FDA fee schedule.

3.1.4.2 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:

3.1.4.2.1 Dully filled application form for renewal of registration.

3.1.4.2.2 Samples of the product as per the FDA sample schedule

3.1.4.2.3 Non-refundable application fee for registration of medicines per FDA fee schedule.

3.1.4.3 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 or effectiveness of a registered product. Significant change(s) may include, but not limited to, any of the following:

3.1.4.3.1 the manufacturing process, facility or equipment;

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

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

3.1.4.3.4 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.

3.1.4.4 The requisite variation fee per the FDA Fees Schedule shall be paid.

3.1.5 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 Ghana Embassy or by the National Drug Regulatory Authority of the country from where the document originates.

3.1.6 DATA PRESENTATION

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/m^2 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.

3.1.7 AN OUTLINE OF THE EVALUATION PROCESS

3.1.7.1 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 FDA upon payment of the application fees.

3.1.7.2 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:

3.1.7.2.1 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 FDA from time to time.

3.1.7.2.2 Paediatric formulation.

3.1.7.2.3 Ministry of Health tender purposes only.

3.1.7.2.4 Post approval variation.

3.1.7.2.5 Renewal of registration.

The evaluation report produced by the evaluator is peer-reviewed by a second evaluator. The FDA reserves the right to request for any additional information to establish the safety, quality, and efficacy 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 FDA 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.

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) months 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.

3.1.7.3 Verification of compliance to current Good Manufacturing Practices (cGMP)

If the new application is from a new manufacturing site, FDA 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.

3.1.7.4 Review of application by Drug 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.

In the event that there are safety, quality or efficacy 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.

3.2. Specific Requirements

3.2.1 MANUFACTURER'S OBLIGATIONS

3.2.1.1 A manufacturer shall ensure that the medical device meets the safety and effectiveness requirements. (Appendix --)

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

3.3 Classification of Medical Devices

3.3.1 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.

3.3.2 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 TIMELINES

5.0. SANCTIONS

A person who contravenes these Guidelines or sections thereof is liable to regulatory sanctions per Sections 119 and 132, Part 7, Act 851, the Public Health Act, 2012 which shall be imposed by the Authority. These sanctions may include, but not limited to, any of the following:

5.1 Suspension of the processing of a pending product registration application.

5.2 Suspension of the processing of a pending manufacturing license application.

5.3 Suspension of the processing of a pending import/export license application.

5.4 Cancelation of the following:

5.4.1 a product registration

5.4.2 an import/export license

5.4.3 a manufacturing license

5.5 Payment of administrative charges as per Act……..

6.0. PENALTIES

In line with the provisions of Section 129, Part 7, Act 851, the Public Health Act, 2012, a person who contravenes these Guidelines commits an offence and is liable on summary conviction to a fine of

6.1 not less than seven thousand five hundred (7,500) penalty units and not more than fifteen thousand penalty units (15,000), or

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.

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 should include the following:

(a) the name of the device

(b) the name and address of the manufacturer

(c) the identifier of the device, including the identifier of a device that is part of a system, test kit, medical device group, medical device family or medical device group family

(d) in the case of a Class III or IV device, the control number, otherwise the batch or lot number

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

(f) the words “Sterile” if the manufacturer intends to sell the device in a sterile condition

(g) the words “for single use only” if the device is intended for that purpose

(h) the expiry date of the device expressed in month and year

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

(j) the directions for use, unless directions are not required for the safe and effective use of the device.

(k) any special storage conditions applicable to the device

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

(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.

APPENDIX II - DEVICE DETAILS

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.

2.5. 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.

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.

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

3.2 Evidence of Conformity to Essential Principles

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

3.2.1.1 Compliance with a recognized standard(s)

3.2.1.2 Internal industry methods

3.2.1.3 Comparison to other similar marketed device

3.2.2 When the manufacturer uses national, international or other standards to demonstrate conformity with the Essential Principles, full title of the standard,

identifying numbers, date of the standard and the organization that created the standard should be provided.

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 and sensitivity specificity of measuring devices, as well as other specifications including chemical, physical, mechanical, electrical and biological.

3.5 Device Verification and Validation

3.5.1 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:

3.5.1.1 Engineering tests.

3.5.1.2 Laboratory tests.

3.5.1.3 Simulated use testing.

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

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

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

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

3.5.2 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.

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

3.5.4 Devices Containing Biological Material (if applicable)

Provide results of studies substantiating the adequacy of the measures taken with regards 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.

3.5.5 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.

3.5.6 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 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.

APPENDIX IV - 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.

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.

(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

(*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:

(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.

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

	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 propagation in the Ghanaian 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 Ghanaian 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:

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.

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

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

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