MINISTRY OF MEDICAL SERVICES



PHARMACY AND POISONS BOARD KENYA

GUIDELINESONSUBMISSIONOF DOCUMENTATIONFOR REGISTRATIONOF MEDICALDEVICES

FIRSTEDITIO

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Article 1: Acknowledgement

Article 2: Preface

1) Medical Device Regulation in Kenya will be supervised and directed by Kenya Pharmacy and Poisons Board (PPB). Classification, requirements and evaluation of Medical Devices will be mainly simulation of rules and regulations recognized by the international regulatory benchmarks, which are mainly:

a) Global Harmonization Task Force (GHTF) for Medical Device
b) European Union Directives (on Medical Device Directives 93/42/EEC,In VitroDiagnostic Device Directive (IVDD) 98/79/EC and Active Implantable Medical Device Directive (AIMDD) 90/385/EEC);
c) The Pharmacy and Poisons Act Chapter 244 of 2002;
d)
e) US FDA (United States Food & Drug Administration)

Australia TGA (Therapeutics Goods Act).

2) The objective of the regulations is to:

a. Protect public health and safety;
b. To allow patient for earlier access to new technology and for early detection, diagnosis, and treatment;
c. To facilitate trade and stimulate the medical devices industry

Article 3: Scope

1) These guidelines shall apply to medical devices and their accessories. For the purposes of these guidelines, accessories shall be treated as medical devices in their own right.

2) 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 use set by the PPB.

3) If, however, such a device is placed on the market in such a way that the device and the medicinal product form a single integral product which is intended exclusively for use in the given combination and which is not reusable, that single product shall be governed by corresponding regulations for registration of medicinal products for human use set by the PPB.

4) The relevant essential principles set in Annex 1 of this guideline shall apply as far as safety and performance related device features are concerned.

5) 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.

6) These guidelines do not apply to:
   a) Medicinal products;
   b) Cosmetic products;
   c) human blood, human blood products, human plasma or blood cells of Human origin or to devices which incorporate at the time of placing on the market such blood products, plasma or cells;
   d) Transplants or tissues or cells of neither human origin nor products incorporating or derived from tissues or cells of human origin;
   e) Transplants or tissues or cells of animal origin, unless a device is manufactured utilizing animal tissue which is rendered non-viable or non-viable products derived from animal tissue.

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Article 4: List of Abbreviations

1)	DoC	Declaration of Conformity
2)	EP	Essential Principles
3)	GHTF	Global Harmonization Task Force
4)	GMDN	Global Medical Devices Nomenclature
5)	ISO	International Organization for Standardization
6)	LAR -	Local Authorized Representative
7)	MoMS	Ministry of Medical Services
8)	PPB	Pharmacy and Poisons Board
9)	QMS	Quality Management System
10)	STED	Summary Technical Documentation
11)	MDD	Medical Device Directives
12)	IVDD	In-Vitro Diagnostic Device Directive
13)	AIMD	Active Implantable Medical Device Directive
14)	FDA	Food & Drug Administration
15)	TGA	Therapeutics Goods Act
16)	RA	Regulatory Authority

Article 5: Definitions

1) **Medical Device**

Medical device means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent, software, material or other similar or related article:

a) intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease; ,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
- investigation, replacement, modification, or support of the anatomy or of a physiological process;
- supporting or sustaining life;
- control of conception;
- disinfection of medical devices;
- providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body;

and

b) which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.

2) **Active Implantable Medical Device (AIMD)**

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.

3) **In-Vitro Diagnostic Device: (IVD)**

IVD medical device means a medical 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. IVD medical devices include reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles.

4) **Device Family Name**

4.1) The device family name is the name assigned by the manufacturer to a group of one or more devices manufactured by, or for, the same manufacturer. In order to belong to a device family, the device must have the same basic design and performance characteristics related to device safety and effectiveness; intended use and function; device classification and product code.

4.2) Devices that function in exactly the same way, have the same electrical and mechanical design and performance characteristics, have the same intended uses, and differ only cosmetically or in minor ways not related to device safety or effectiveness may be grouped as a family.

4.3) Brand name, common name and whether the devices were introduced into commercial distribution under the same approval may be used as factors when grouping devices into families

5) **Accessory**

Means anarticle whichwhilstnotbeing a device is intended specifically by its manufacturertobeusedtogetherwithadevicetoenableittobe used in accordancewiththeuseofthedeviceintendedbythemanufacturerofthe device

6) **Manufacturer**

6.1) Means the natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person her/himself or on her/his behalf by a third party.

6.2) The obligations of this guideline to be met by manufacturers also apply to the natural or legal person who assembles, packages, processes, fully refurbishes and/or labels one or more ready-made products and/or assigns to them their intended purpose as a device with a view to their being placed on the market under his own name.

7) **Local Authorized Representative**

7.1) Any manufacturer based outside the Kenya must designate a local authorized representative (LAR). The appointed LAR must provide written evidence that they are acting with the consent of a manufacturer located outside the Kenya.

7.2) The responsibility of the LAR is, to assure regulatory compliance and serve as the central communication pathway with the PPB

7.3) Local Authorized Representative roles include

a) Acting as primary contact point with the competent authority ;

b) Keeping technical file documentation ready and available for the Competent Authority;

c) Protecting documentation confidentiality because they are authorized to show them to the Competent Authorities only;
d) Notification of Adverse Event and Incident Reporting to the Competent Authorities;
e) Assurance of supply chain regulatory compliance and accountability of medical devices;
f) Product Safety Vigilance reporting;
g) Field Safety Corrective Action implementation, management, coordination and reporting;
h) Assistance with technical file documentation;
i) Annual review of your technical file;
j) Notification of changes and amendments to the Medical Device regulations that affect the device(s).

8) **User**
The healthcare institution, professional (including procurement officer), care or patient using or maintaining a medical device

9) Intended Use
Means the use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions and/or in promotional materials.

10) **Adverse Event**
Any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labeling or the instructions for use which, directly or indirectly, might lead to or might have led to the death of a patient, or user or of other persons or to a serious deterioration in their state of health.

11) **Device Label**
The device labelling refers to any written, printed or graphic representation affixed to a medical device or any part of its packaging, or accompanying a medical device, when the medical device is being supplied.

12) **Placement on the Market**
Means the first making available in return for payment or free of charge of a device with a view to distribution and/or use on the market, regardless of whether it is new or fully refurbished.

13) **Objective Evidence**
Information that can be proved true based on facts obtained through observation, measurement, testing or other means.

14) **Process Validation**

It is a confirmation by objective evidence that a process consistently produces a result or product meeting its pre-determined requirements.

15) **Quality System**
It is system which consists of the organizational structure, responsibilities, procedures, processes and resources for implementing quality management and achieving the objectives.

16) **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.

17) Field Safety Corrective Action

17) Any action taken by the manufacturer, importer or distributor in respect of a medical device that has been sold to field safety corrective action 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, National or international standards** deemed to offer the presumption of conformity to specific essential

18) principles performance

19) Harm: Physical injury or damage to the health of people or damage to property or the environment. (Source – ISO/IEC Guide 51:1999)

20) Hazard: Potential source of harm. (Source – ISO/IEC Guide 51:1999)

21) Immediate danger: A situation where the patient is at risk of either losing life or an important physiological function if no immediate preventative measure is taken.

22) **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.

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. (Source - European Directive 93/42/EEC)

23) **Life supporting or life sustaining**: A device that is essential to, or that yields information that is essential to, the restoration or continuation of a bodily function important to the continuation of human life.

24) **Reusable surgical instrument:** Instrument intended for surgical use by cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or other surgical procedures, without connection to any active medical device and which are intended by the manufacturer to be reused after appropriate procedures for cleaning and/or sterilisation have been carried out. (Source - European Directive 93/42/EEC – modified)

25) **Risk:** Combination of the probability of occurrence of harm and the severity of that harm. (Source – ISO/IEC Guide 51:1999)

26) **Specimen:** The discrete portion of a body fluid or tissue or other sample associated with thebody taken for examination, study, or analysis of one or more quantity or characteristic to determine the character of the whole.

Article 6: General Information

1) **Essential Principles of Safety and Performance** The Medical devices must meet essential principles of safety and performance set out in Annex 1 which apply to them, taking account of the intended purpose of the devices concerned.

Classification

2) DevicesshallbedividedintoClasses A, B, C and D. Classificationshall becarriedoutinaccordancewithAnnex2**.**

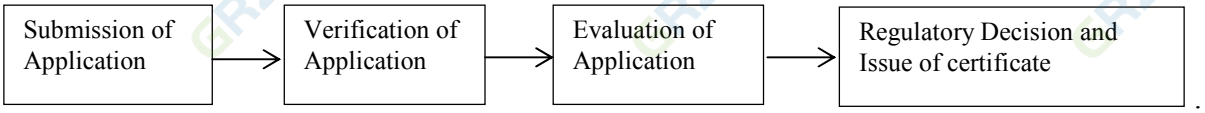
Payment of Fees

3.1) PPB charges a statutory fee each time for registration, notification, update or change of the registration details held with the PPB. The payment schedule is indicated in Annex 3

3.2) Initial registration fees and re-registration fee shall be based on a family of related devices, intended for the same purposes(s) and offered by the same manufacturer or importer.

Outline of Evaluation Process

3) Medical devices are classified based on a rule based risk classification system into four risks-class A to D with class A being the lowest risk class and this is in line with the recommendations from the GHTF. The actual risk classification of each medical device depends on the claims made by the product manufacturer and on its intended use/purpose.
4) The manufacturer or its local authorized representative is required to apply for the Medical device registration at the Pharmacy and Poisons Board.
5) The submission requirements are detailed in Annex 4.
6) Upon submission, an application fee will be charged immediately.
7) The application dossier will be verified for completeness before the application is accepted for evaluation



8) Upon acceptance for evaluation, the evaluation fees will be triggered.
9) Evaluation of the dossier is based on data set submitted by the applicant.
10) Request for additional will be made if clarification or additional information is required.
11) A regulatory decision is made based on the outcome of evaluation of the submitted data.

12) Only application which satisfy the registration will be issued with a certificate.

Technical Review Committee

13) The technical evaluation involves several layers of systematic examination focusing on the safety and effectiveness of the medical device.
14) The evaluation is carried out by a combination of internal reviewers and external expertise.
15) Technical reviewers selected one or a number of the following:
    - Scientific experts
    - Medical profession
    - Medical device industry
    - Medical device experts and researchers
    - Medical practitioners
    - Biomedical and biomaterials engineers and scientist
    - Medical device scientists or engineers
    - Kenya bureau of standards or other notified bodies such SGS
16) The selection of the technical review panel shall be made in such a manner as to ensure the highest standards of competence and broad range of relevant expertise to the device being evaluated
17) The Technical panels excepting those may be constituted for a specified period of time or for a specific task.
18) The PPB may, from time to time, re-constitute the Technical panels by adding new members or by omitting the existing members or by changing the name of the panel as the case may be.
19) At the end of the technical evaluation, the review team will issue an evaluation report passing its judgment on the device.
20) The evaluation report is submitted to the PPB for final approval.
21) According to related regulations, PPB may send an inspection/auditing group to Class III manufacturers abroad to check their quality assurance system based on Kenyan national standards and other relevant medical device standards and registered product standards.

Evaluation process time

22) Once an application has been accepted and evaluation fees paid the processing of application will take 90 calendar days.
23) The stop-clock starts whenever PPB issues request for additional data/information and ends when PPB receives a complete and satisfactory response from the applicant.
24) If the applicant does not supply answers to questions asked by the PPB within 90 calendars an extra charge of one-third of application fee will apply.
25) Note that some reviews may be completed in less than 90 calendars days

Termination of Registration

26) The PPB may by giving reasons in writing suspend or revoke the registration of a device, or amend the conditions of its registration within a reasonable time.
27) The registrant may by giving 60 days written notice and reasons to the PPB

Validity of Registration

28) When the Medical Device proves compliance to applicable essential principles and gets approval of the committee on medical Devices it will be granted a Registration certificate which in turn entitles the applicant to import and freely sell the registered medical device given that the said applicant will comply with all the post marketing requirements in article 7.
29) A registration certificate will be valid for 5 years unless significant changes are made to the approved application data.
30) PPB can cancel the registration certificate if any of the following takes place:
    a) Based on the request of the applicant
    b) Based on non-compliance with the manufacturer's obligations set in article 7
    c) The product proved to be not safe or harmful to health
    d) The quality became substandard to that in the time of the application
    e) They differ from the approved label
    f) The product proved to be a counterfeit

31) The registrar of PPB will notify the registration holder in writing of the cancellation.

Application against Cancellation of Registration

32) Any person aggrieved by a decision of the Board in relation to any application for registration or cancellation of a medical device may make representations in writing to PPB within 60 calendar days from date of the decision.
33) If after consideration of the representations, the Board is satisfied it may approve registration of a medical device and if not satisfied it shall reject the application.

Change Notification

34) PPB should be made aware, where a change that may affect the safety or effectiveness of a registered medical device.
35) PPB has categorised changes according to whether they are technical or administrative changes.
36) A summary of all these changes is provided in a tabular format in Annex 3.

37) All change notification to a registered device shall be made in writing and shall be accompanied by supporting information and appropriate fee. Please refer to the fee schedule in Annex 3 for fees that apply to change notification applications.

38) Multiple changes (both administrative and technical changes) will be considered in one change notification application if they are submitted together.

Reregistration of Registered Medical

39) Applications for renewal of registration shall be made at least 90 calendar days before the expiry date.
40) The application shall include submission of filled in application form and information pertaining to changes that were made to a registered device.

Article 7: Post-Market Requirements and Vigilance System

1) The purpose of a Medical Device Vigilance System is to minimize risk to the health and safety of patients, users and others by reducing the likelihood of a serious adverse event involving a medical device from occurring.
2) Close co-operation among the PPB, manufactures and practicing medical professionals is necessary to achieve an effective vigilance system.
3) Manufacturers and local authorized representatives must also meet post-market requirements that consist of:
    3.1) Maintain Distribution - The manufacturers, local authorized representatives, importers and distributors are required to keep distribution records to facilitate the accountability and traceability of a medical device. This ensures that the device distribution channels in Kenya, including medical device exports from Kenya, are identifiable. Maintain Complaint Handling Procedures and records
    3.2) The manufacturers and local authorized representative are required to maintain records of problem report relating to the safety of the device, including any consumer complaints and perform corrective action if necessary.
    3.3) Maintain Adverse event reporting procedures and records. The manufacturers and local authorized representative are required to notify the PPB of any adverse events related to a failure of the device or a deterioration of its effectiveness, or any inadequacy in its labelling or in its directions for use, which has resulted in the death or a serious deterioration in the state of health of a patient, users or other person, or could potentially lead to such consequences due to its recurrence
    3.4) Have Field safety corrective action procedures in place
    3.5) The manufacturers and local authorized representatives are to establish and implement documents, procedures that will enable them to carry out effective and timely investigations of reported problems and field safety corrective actions; and maintaining records of adverse event reports and of actions taken in response to these reports. Given that defective or potentially defective medical devices should either be removed from the market or measures are taken to correct the problem in an effective and timely fashion.
4) The device manufacturer or its local authorized representative must submit post-market procedures in applying to place the medical device on the Kenyan market.
5) If a particular establishment has already submitted its post-market procedures in one product application, it need not repeat this submission in subsequent applications provided:

5.1) Proper reference are made to the documents submitted in the earlier application and

5.2) There are no additional requirements and no changes made to the procedures

Adverse Event Reporting

6) Users have the primary responsibility to report to PPB and manufacturer any malfunction or deterioration in the characteristics and/or performance of a device as well as any inadequacy in the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his state or health
7) Guidance on how initial case reports should be made and what information should be included in them is given in Annex 6.
8) If the user cannot identify the manufacturer of the medical device then a report should be made direct to the PPB.
9) Where a reportable adverse adverse event occurs which involves medical devices placed on the market by more than one manufacturer, then a report should be made by each manufacturer involved (either separately or as a combined report) unless it is clear that the adverse event has been caused by one component only in which case the manufacturer of that component should report

Timing for Reporting

10) Upon becoming aware that an event has occurred and is associated with one of its devices, the medical device manufacturer must determine whether it is an adverse event.
11) Adverse events that result in unanticipated death or unanticipated serious injury or represent a serious public health threat must be reported immediately or in no more than 14 calendar days by the manufacturer.
12) All other reportable events must be reported as soon as possible by the manufacturer, but not later than 30-elapsed calendar days following the date of awareness of the event.
13) If after becoming aware of a potentially reportable adverse event, there is still uncertainty about whether the event is reportable, the manufacturer must submit a report within the timeframe required for that type of event.
14) After the initial case report has been made, the manufacturer or authorized representative carries out or continues an investigation, while the PPB monitors progress. The PPB may intervene, or initiate an independent investigation, if appropriate.
15) The manufacturer or its authorized representative has up to 90 calendar days to supply a report to PPB detailing investigation carried out, the root cause of the problem and actions taken or planned to be taken to implement corrective action.
16) The act of reporting an event to PPB is not to be construed as an admission of liability for the event and its consequences. Written reports may carry a disclaimer to this effect.
17) The reports shall be send to Chairman, Vigilance Committee, PPB P O Box XXX Nairobi. Upon receiving the report PPB will acknowledge in writing the receipt of the report to the sender.
18) Failure by the manufacturer or its authorized representative to report within stipulated period will lead to disciplinary action being taken. These include:

a) Financial penalties
b) Temporary stop the distribution of the affected product batch
c) Product Field safety corrective action
d) Temporary withdrawal of operating licence
e) Loss of operating licence.

19) Penalties for failure to submit vigilance report apply only to cases where the manufacturer, import, distributor or local authorized represeantative would have been aware of the alleged event. A party cannot be held responsible for failing to report an event of which it has no knowledge

Artcile 8: Implementation

1) These regulations fully come into force on 1st July 2013 and provide provide a transition period of three years.
2) All devices in or placed in the Kenyan market MUST be registered by 31st June 2016.

Annex 1: Essential Principles of Safety and Performance of Medical Devices

General Requirements

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

2) The solutions adopted by the manufacturer for the design and manufacture of the devices should conform to safety principles, taking account of the generally acknowledged state of the art. When risk reduction is required, the manufacturer should control the risk(s) so that the residual risk(s) associated with each hazard is judged acceptable. The manufacturer should apply the following principles in the priority order listed:
    - identify known or foreseeable hazards and estimate the associated risks arising from the intended use and foreseeable misuse,
    - eliminate risks as far as reasonably practicable through inherently safe design and manufacture,
    - reduce as far as is reasonably practicable the remaining risks by taking adequate protection measures, including alarms,
    - inform users of any residual risks.

3) Devices should achieve the performance intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions within the scope of the definition of a medical device applicable in each jurisdiction.

4) The characteristics and performances referred to in Clauses 1, 2 and 3 should not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by the manufacturer, when the device is subjected to thestresses which can occur during normal conditions of use and has been properlymaintained in accordance with the manufacturer's instructions.

5) The devices should be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected under transport and storage conditions (for example, fluctuations of temperature and humidity) taking account of the instructions and information provided by the manufacturer.

6) The benefits must be determined to outweigh any undesirable side effects for the performances intended.

Design and Manufacturing Requirements

7) **Chemical, physical and biological properties**

7.1) The devices should be designed and manufactured in such a way as to ensure the characteristics and performance referred to in Clauses 1 to 6 of the 'General Requirements'. Particular attention should be paid to:

- the choice of materials used, particularly as regards toxicity and, where appropriate, flammability;
- the compatibility between the materials used and biological tissues, cells, body fluids, and specimens, taking account of the intended purpose of the device;
- the choice of materials used should reflect, where appropriate, matters such as hardness, wear and fatigue strength.

7.2) The devices should be designed, manufactured and packed in such a way as to minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to patients, taking account of the intended purpose of the product. Particular attention should be paid to tissues exposed and to the duration and frequency of exposure.

7.3) devices should be designed and manufactured in such a way that they can be used safely with the materials, substances and gases with which they enter into contact during their normal use or during routine procedures; if the devices are intended to administer medicinal products they should be designed and manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and restrictions governing these products and that their performance is maintained in accordance with the intended use.

7.4) Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product/drug as defined in the relevant legislation that applies within that jurisdiction and which is liable to act upon the body with action ancillary to that of the device, the safety, quality and usefulness of the substance should be verified, taking account of the intended purpose of the device.

7.5) The devices should be designed and manufactured in such a way as to reduce as far as reasonably practicable and appropriate the risks posed by substances that may leach or leak from the device.

7.6) 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) **Infection and microbial contamination**

8.1) The devices and manufacturing processes should be designed in such a way as to eliminate or to reduce as far as reasonably practicable and appropriate the risk of

infection to patients, users and, where applicable, other persons. The design should:

- allow easy handling and, where necessary:
- reduce as far as reasonably practicable and appropriate any microbial leakage from the device and/or microbial exposure during use,
- prevent microbial contamination of the device, or specimen where applicable, by the patient, user or other person.

8.2) Where a device incorporates substances of biological origin, the risk of infection must be reduced as far as reasonably practicable and appropriate by selecting appropriate sources, donors and substances and by using, as appropriate, validated inactivation, conservation, and test and control procedures.

8.3) In some jurisdictions products incorporating tissues, cells and substances of nonhuman origin may be considered medical devices. In this case, such tissues, cells and substances should originate from animals that have been subjected to veterinary controls and surveillance adapted to the intended use of the tissues. National regulations may require that the manufacturer and/or the Regulatory Authority retain information on the geographical origin of the animals. Processing, preservation, testing and handling of tissues, cells and substances of animal origin should be carried out so as to provide optimal safety. In particular, safety with regard to viruses and other transmissible agents should be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.

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

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

8.6) Devices delivered in a sterile state should be designed, manufactured and packed in a non-reusable pack, and/or according to appropriate procedures, to ensure that they are sterile when placed on the market and remain sterile, under the transport and storage conditions indicated by the manufacturer, until the protective packaging is damaged or opened.

8.7) 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.

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

8.9) Packaging systems for non-sterile devices should keep the product without deterioration at the level of cleanliness stipulated and, if the devices are to be

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

8.10) The packaging and/or label of the device should distinguish between identical or similar products placed on the market in both sterile and non-sterile condition.

9. **Manufacturing and environmental properties**

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

9.2) Devices should be designed and manufactured in such a way as to remove or reduce as far as reasonably practicable and appropriate:

- the risk of injury, in connection with their physical features, including
- the volume/pressure ratio, dimensional and where appropriate ergonomic features;
- risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, pressure, humidity, temperature or variations in pressure and acceleration;
- the risks connected to their use in conjunction with materials, substances and gases with which they may come into contact during normal conditions of use;
- the risks of accidental penetration of substances into the device;
- the risk of incorrect identification of specimens;
- the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given;
- risks arising where maintenance or calibration are not possible (as with implants), from ageing of materials used or loss of accuracy of any measuring or control mechanism**.**

9.3) Devices should be designed and manufactured in such a way as to minimize the risks of fire or explosion during normal use and in single fault condition. Particular attention should be paid to devices whose intended use includes exposure to or use in association with flammable substances or substances which could cause combustion

9.4) Devices must be designed and manufactured in suc away as to facilitate the safe disposal of any waste substance.

10. **Device with a diagnostic or measuring function**

10.1) Devices with a measuring function, where inaccuracy could have a significant adverse effect on the patient, should be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability for their intended purpose of the device. The limits of accuracy should be indicated by the manufacturer

10.2) Diagnostic devices should be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability for their intended use, based on appropriate scientific and technical methods. In particular the design should address sensitivity, specificity, trueness, repeatability, reproducibility, control of known relevant interference and limits of detection, as appropriate.

10.3) Where the performance of devices depends on the use of calibrators and/or control materials, the traceability of values assigned to such calibrators and/or control materials should be assured through a quality management system.

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

10.5) Wherever possible values expressed numerically should be in commonly accepted, standardised units, and understood by the users of the device.

10.6) **Note:** While SG1 generally supports convergence on the global use of internationally standardised measurement units, considerations of safety, user familiarity, and established clinical practice may justify the use of other recognised measurement

11. **Protection against radiation**

11.1) General

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

11.2) Intended radiation

11.2.1) Where devices are designed to emit hazardous, or potentially hazardous, levels of visible and/or invisible radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent in the emission, it should be possible for the user to control the emissions. Such devices should be designed and manufactured to ensure reproducibility of relevant variable parameters within an acceptable tolerance.

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

11.3) Unintended radiation

11.3.1) Where devices are designed to emit hazardous, or potentially hazardous, levels of visible and/or invisible radiation

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

11.4) Instructions for use

11.4.1) The operating instructions for devices emitting radiation should give detailed information as to the nature of the emitted radiation,

means of protecting the patient and the user and on ways of avoiding misuse and of eliminating the risks inherent in installation.

11.5) Ionizing radiation

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

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

11.5.3) Devices emitting ionizing radiation, intended for therapeutic radiology should be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam type and energy and where appropriate the energy distribution of the radiation beam

12. **Requirements for medical devices connected to or equipped with an energy source**

12.1) Devices incorporating electronic programmable systems, including software, should be designed to ensure the repeatability, reliability and performance of these systems according to the intended use. In the event of a single fault condition in the system, appropriate means should be adopted to eliminate or reduce as far as practicable and appropriate consequent risks.

12.2) 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.

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

12.4) 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

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

12.6) 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.

12.7) Protection against electrical risks

12.7.1) Devices should be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks during normal use and in single fault condition, provided the

devices are installed and maintained as indicated by the manufacturer.

13. **Protection against mechanical risks**

13.1) Devices should be designed and manufactured in such a way as to protect the patient and user against mechanical risks connected with, for example, resistance to movement, instability and moving parts.

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

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

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

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

14.1) Devices for supplying the patient with energy or substances should be designed and constructed in such a way that the delivered amount can be set and maintained accurately enough to guarantee the safety of the patient and of the user.

14.2) 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 from an energy and/or substance source.

14.3) 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.

15. **Protection against the risks posed to the patient for devices for self-testing or self-administration**

15.1) Such devices should be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to users and the influence resulting from variation that can reasonably be anticipated in user's technique and environment. The information

and instructions provided by the manufacturer should be easy for the user to understand and apply

15.2) Such devices should be designed and manufactured in such a way as to reduce as far as practicable the risk of use error in the handling of the device and, if applicable, the specimen, and also in the interpretation of results.

15.3) Such devices should, where reasonably possible, include a procedure by which the user can verify that, at the time of use that the product will perform as intended by the manufacturer.

16. **Information supplied by the manufacturer**

16.1) Users should be provided with the information needed to identify the manufacturer, to use the device safely and to ensure the intended performance, taking account of their training and knowledge. This information should be easily understood.

17. **Performance evaluation including, where appropriate, clinical evaluation**

17.1) All data generated in support of performance evaluation should be obtained in accordance with the relevant requirements applicable in each jurisdiction.

17.2) 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.

ANNEX 2: Classification of Medical Devices

1) Basic definition

1.1) The classification rules are based on terms related to duration of contact with the patient degree of invasiveness and the part of the body affected by use of the device.

1.2) Duration of use

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

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

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

d) NOTE: For the purpose of this document, continuous use mean

- The entire duration of use of the device without regard to temporary interruption of use during a procedure or, temporary removal for purposes such as cleaning or disinfection of the device.
- The accumulated use of a device that is intended by the manufacturer to be replaced immediately with another of the same type. (Source - European Directive 93/42/EEC - modified)

1.3) **Invasive devices**

a) ***Invasive device:*** A device, which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body.

b) ***Body orifice:*** 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.

c) ***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.

d) *NOTE: Devices other than those referred to in the previous subparagraph and which produce penetration other than through an established body orifice, should be treated as surgically invasive devices*.

2. **General Classification System for Medical Devices**

1) Table 1 indicates the four risk classes of devices. The examples given are for illustration only and the manufacturer must apply the classification rules to each medical device according to its intended purpose.

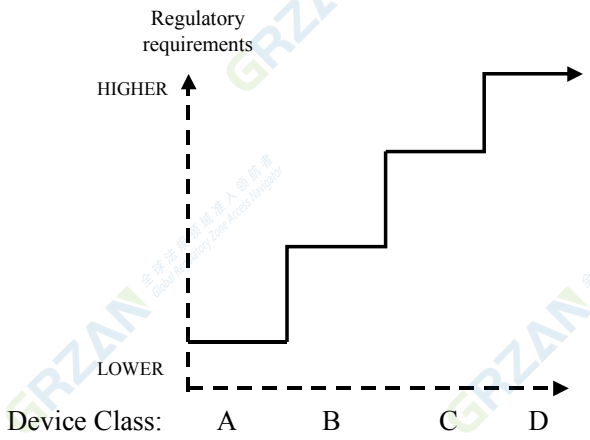
Table 1: General classification system for medical devices

CLASS	RISK LEVEL	DEVICE EXAMPLES
A	Low Risk	Surgical retractors / tongue depressors
B	Low-moderate Risk	Hypodermic Needles / suction equipment
C	Moderate-high Risk	Lung ventilator / bone fixation plate
D	High Risk	Heart valves / implantable defibrillator

3. Figure 1 shows a conceptual illustration of increasing levels of regulatory requirements as the device risk class increases. These regulatory controls may include, for example: -

1) operation of a quality system (recommended for all devices);
2) technical data;
3) product testing using in-house or independent resources;
4) documentation of clinical evidence to support the manufacturer's claims;
5) the need for and frequency of independent external audit of the manufacturer's quality system; and
6) independent external review of the manufacturer's technical data.

Figure 1: Conceptual illustration of regulatory controls increasing with device risk class



4. Determination of Device Classification using this Rules-based System

4.1) The manufacturer should:

a) Decide if the product concerned is a medical device, using the appropriate definition.

b) Document the intended use of the medical device.

c) Take into consideration all the rules that follow in order to establish the proper classification for the device, noting that where a medical device has features that place it into more than one class, classification and conformity assessment should be based on the highest class indicated.

d) Determine if the device is subject to special national rules that apply within a particular jurisdiction**.**

4.2) NOTES:

- Once a rules-based system has been adopted, modifications may occasionally be required. For example, where through post-market experience, a level of risk for a type of medical device, classified using the criteria found in this guidance document is no longer appropriate, consideration should be given to re-classification of the device type by a change to the rules.
- Similarly, the historical knowledge of a device may necessitate a different class than the one assigned by the initial classification. Unlike the principle of reclassification after post-market experience with a

device, this principle of historical knowledge should be applied immediately when the initial classification yields an inappropriate result.

- Where special national rules are applied, resulting in a device class other than that suggested by the present rules, then a different conformity assessment procedure may be indicated. This may have an effect on the acceptability of such devices for free movement in countries where these present rules have been adopted unless other, or additional, conformity assessment procedures are carried out.

5. **Initial Classification Rules**

5.1) The actual classification of each device depends on the claims made by the manufacturer and on its intended use.

5.2) While the provision of illustrative examples in the table that follows is helpful when interpreting the purpose of each rule, it must be emphasised that the actual classification of a particular device must be considered individually, taking account of its design and intended use.

Rules	**Illustrative Examples of Devices that May Confirm with a Rule**
Non-Invasive Devices	
Rule 1. All non-invasive devices which come into contact with injured skin:	Devices covered by this rule are extremely claim sensitive.
- are in Class A if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates only, i.e. they heal by primary intent;	Examples: simple wound dressings; cotton wool.
- are in Class B if they are intended to be used principally with wounds which have breached the dermis, including devices principally intended to manage the microenvironment of a wound.	Examples: non-medicated impregnated gauze dressings.
unless they are intended to be used principally with wounds which have breached the	Devices used to treat wounds where the subcutaneous tissue is as least partially exposed and the edges of the wound are not sufficiently close to

Rules	Illustrative Examples of Devices that May Confirm with a Rule
dermis and can only heal by secondary intent, in which case they are in Class C.	be pulled together. To close the wound, new tissue must be formed within the wound prior to external closure. The device manufacturer claims that they promote healing through physical methods other than 'primary intent'. Examples: dressings for chronic ulcerated wounds; dressings for severe burns.
Rule 2. All non-invasive devices intended for channelling or storing • body liquids or tissues, • liquids or • gases for the purpose of eventual infusion, administration or introduction into the body are in Class A,	Such devices are 'indirectly invasive' in that they channel or store liquids that will eventually be delivered into the body (see comment for Rule 4). Examples: administration sets for gravity infusion; syringes without needles.
unless they may be connected to an active medical device in Class B or a higher class, in which case they are Class B;	Examples: syringes and administration sets for infusion pumps; anaesthesia breathing circuits. **NOTE**: "Connection" to an active device covers those circumstances where the safety and performance of the active device is influenced by the non-active device and vice versa.
unless they are intended for use of channeling blood, or storing or channeling other body liquids, or for storing organs, parts of organs or body tissues, in which case they are Class B.	Examples: tubes used for blood transfusion, organ storage containers.
unless they are blood bags, in which case they are Class C.	Example: Blood bags that do not incorporate an anti-coagulant. NOTE: in some jurisdictions, blood bags have a special rule that places them within a different risk class.
Rule 3. All non-invasive devices intended for modifying the biological or chemical composition of • blood, • other body liquids, or • other liquids intended for infusion into the body are in Class C,	Such devices are indirectly invasive in that they treat or modify substances that will eventually be delivered into the body (see note to comment for Rule 4). They are normally used in conjunction with an active device within the scope of either Rule 9 or 11. Examples: haemodializers; devices to remove white blood cells from whole blood. **NOTE:** for the purpose of this part of the rule, 'modification' does not include simple, mechanical

Rules	Illustrative Examples of Devices that May Confirm with a Rule
	filtration or centrifuging which are covered below.
unless the treatment consists of filtration, centrifuging or exchanges of gas or of heat, in which case they are in Class B.	Examples: devices to remove carbon dioxide; particulate filters in an extracorporial circulation system.
Rule 4. All other non-invasive devices are in Class A.	These devices either do not touch the patient or contact intact skin only. Examples: urine collection bottles; compression hosiery; non-invasive electrodes, hospital beds.
Invasive Devices	
Rule 5. All invasive devices with respect to body orifices (other than those which are surgically invasive) and which: • are not intended for connection to an active medical device, or • are intended for connection to a Class A medical device only.	Such devices are invasive in body orifices and are not surgically invasive (refer to definition in Section 4). Devices tend to be diagnostic and therapeutic instruments used in ENT, ophthalmology, dentistry, proctology, urology and gynaecology. Classification depends on the duration of use and the sensitivity (or vulnerability) of the orifice to such invasion.
• are in Class A if they are intended for transient use;	Examples: examination gloves; enema devices.
• are in Class B if they are intended for short-term use;	Examples: urinary catheters, tracheal tubes.
unless they are intended for short-term use in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in a nasal cavity, in which case they are in Class A,	Examples: dentures intended to be removed by the patient; dressings for nose bleeds.
• are in Class C if they are intended for long-term use;	Example: urethral stent; contact lenses for long-term continuous use (for this device, removal of the lens for cleaning or maintenance is considered as part of the continuous use).
unless they are intended for long-term use in the oral cavity as far as the pharynx, in an ear canal up to the ear-drum or in a nasal cavity and are not liable to be absorbed by the mucous membrane, in which case they are in Class B.	Examples: orthodontic wire, fixed dental prosthesis.
All invasive devices with respect to body orifices (other than those which are surgically invasive) that are intended to be connected to an active	Examples: tracheal tubes connected to a ventilator; suction catheters for stomach drainage; dental aspirator tips. NOTE: independent of the time for which they are

Rules	Illustrative Examples of Devices that May Confirm with a Rule
medical device in Class B or a higher class, are in Class B.	invasive.
Rule 6. All surgically invasive devices intended for transient use are in Class B,	A majority of such devices fall into several major groups: those that create a conduit through the skin (e.g. syringe needles; lancets), surgical instruments (e.g. single-use scalpels; surgical staplers; single-use aortic punch); surgical gloves; and various types of catheter/sucker etc. **NOTE:** a surgical instrument (other than those in Class D) is in Class A if reusable and in Class B if supplied sterile and intended for single use. Also, a surgical instrument connected to an active device is in a higher class than A. **NOTE:** if the device incorporates a medicinal substance in a secondary role refer to Rule 13.
unless they are reusable surgical instruments, in which case they are in Class A; or	Examples: Manually operated surgical drill bits and saws.
unless intended to supply energy in the form of ionizing radiation, in which case they are in Class C; or	Example: catheter incorporating/containing sealed radioisotopes.
unless intended to have a biological effect or be wholly or mainly absorbed, in which case they are in Class C; or	**NOTES**: (a) the 'biological effect' referred to is an intended one rather than unintentional. The term 'absorption' refers to the degradation of a material within the body and the metabolic elimination of the resulting degradation products from the body. (b) This part of the rule does not apply to those substances that are excreted without modification from the body. Example: Insufflation gases for the abdominal cavity.
unless intended to administer medicinal products by means of a delivery system, if this is done in a manner that is potentially hazardous taking account of the mode of appli-cation, in which they are in Class C; or	Example: insulin pen for self-administration. **NOTE:** the term 'administration of medicines' implies storage and/or influencing the rate/volume of medicine delivered not just channelling. The term 'potentially hazardous manner' refers to the characteristics of the device and not the competence of the user.
unless they are intended specifically for use in direct contact with the central nervous system, in which case they are in Class D; or	
unless intended specifically to	Examples: angioplasty balloon catheters and related

Rules	Illustrative Examples of Devices that May Confirm with a Rule
diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class D.	guide wires; dedicated disposable cardiovascular surgical instruments.
Rule 7. All surgically invasive devices intended for short-term use are in Class B,	Such devices are mostly used in the context of surgery or post-operative care, or are infusion devices, or are catheters of various types. Examples: infusion cannulae; temporary filling materials; non-absorbable skin closure devices; tissue stabilisers used in cardiac surgery. **NOTE:** includes devices that are used during cardiac surgery but do not monitor or correct a defect. **NOTE:** if the device incorporates a medicinal substance in a secondary role refer to Rule 13.
unless they are intended to administer medicinal products, in which case they are in Class C; or	NOTE: the term 'administration of medicines' implies storage and/or influencing the rate/volume of medicine delivered not just channelling.
unless they are intended to undergo chemical change in the body (except if the devices are placed in the teeth), in which case they are in Class C; or	Example: surgical adhesive.
unless they are intended to supply energy in the form or ionizing radiation, in which case they are in Class C; or	Example: brachytherapy device.
unless they are intended to have a biological effect or to be wholly or mainly absorbed, in which case they are in Class D; or	Example: absorbable suture; biological adhesive. **NOTE**: the 'biological effect' referred to is an intended one rather than unintentional. The term 'absorption' refers to the degradation of a material within the body and the metabolic elimination of the resulting degradation products from the body.
unless they are intended specifically for use in direct contact with the central nervous system, in which case they are in Class D;	Example: neurological catheter.
unless they are intended specifically to diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class D.	Examples: cardiovascular catheters; temporary pacemaker leads; carotid artery shunts.

Rules	Illustrative Examples of Devices that May Confirm with a Rule
Rule 8. All implantable devices, and long-term surgically invasive devices, are in Class C,	Most of the devices covered by this rule are implants used in the orthopaedic, dental, ophthalmic and cardiovascular fields. Example: maxilla-facial implants; prosthetic joint replacements; bone cement; non-absorbable internal sutures; posts to secure teeth to the mandibula bone (without a bioactive coating). NOTE: if the device incorporates a medicinal substance in a secondary role refer to Rule 13.
unless they are intended to be placed into the teeth, in which case they are in Class B; or	Examples: bridges; crowns; dental filling materials.
unless they are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in Class D; or	Examples: prosthetic heart valves; spinal and vascular stents.
unless they are intended to be life supporting or life sustaining, in which case they are in Class D; or	
unless they are intended to be active implantable medical devices, in which case they are Class D; or	Example: pacemakers, their electrodes and their leads; implantable defibrillators.
unless they are intended to have a biological effect or to be wholly or mainly absorbed, in which case they are in Class D; or	Example: implants claimed to be bioactive. **NOTE**: hydroxy-apatite is considered as having biological effect only if so claimed and demonstrated by the manufacturer.
unless they are intended to administer medicinal products, in which case they are in Class D; or	Example: rechargeable non-active drug delivery system.
unless they are intended to undergo chemical change in the body (except if the devices are placed in the teeth), in which case they are in Class D; or	**NOTE**: bone cement is not within the scope of the term 'chemical change in the body' since any change takes place in the short rather than long term.
unless they are breast implants, in which case they are in Class D.	
ACTIVE DEVICES	
Rule 9(i). All active therapeutic devices intended to administer or exchange energy are in Class B,	Such devices are mostly electrically powered equipment used in surgery; devices for specialised treatment and some stimulators. Examples: muscle stimulators; TENS devices; powered dental hand pieces; hearing aids; neonatal phototherapy equipment; ultrasound equipment for

Rules	Illustrative Examples of Devices that May Confirm with a Rule
	physiotherapy.
unless their characteristics are such that they may administer or exchange energy to or from the human body in a potentially hazardous way, including ionizing radiation, taking account of the nature, the density and site of application of the energy, in which case they are in Class C.	Examples: lung ventilators; baby incubators; electrosurgical generators; external pacemakers and defibrillators; surgical lasers; lithotriptors; therapeutic X-ray and other sources of ionizing radiation. **NOTE:** the term 'potentially hazardous' refers to the type of technology involved and the intended application.
Rule 9(ii). All active devices intended to control or monitor the performance of active therapeutic devices in Class C, or intended directly to influence the performance of such devices, are in Class C.	Examples: external feedback systems for active therapeutic devices.
Rule 10(i). Active devices intended for diagnosis are in Class B:	Such devices include equipment for ultrasonic diagnosis/imaging, capture of physiological signals, interventional radiology and diagnostic radiology.
- if they are intended to supply energy which will be absorbed by the human body (except for devices used solely to illuminate the patient's body, with light in the visible or near infra-red spectrum, in which case they are Class A), or	Examples: magnetic resonance equipment; diagnostic ultrasound in non-critical applications; evoked response stimulators.
- if they are intended to image in vivo distribution of radiopharmaceuticals, or	Example: gamma/nuclear cameras.
- if they are intended to allow direct diagnosis or monitoring of vital physiological processes,	Example: electronic thermometers, stethoscopes and blood pressure monitors; electrocardiographs.
unless they are specifically intended for: a) monitoring of vital physiological parameters, where the nature of variations is such that it could result in immediate danger to the patient, for instance variations in cardiac performance, respiration, activity of central nervous system, or b) diagnosing in clinical situations where the patient is in immediate danger,	Example: monitors/alarms for intensive care; biological sensors; oxygen saturation monitors; apnoea monitors. Example: ultrasound equipment for use in interventional cardiac procedures.

Rules	Illustrative Examples of Devices that May Confirm with a Rule
in which case they are in Class C.	
Rule 10(ii). Active devices intended to emit ionizing radiation and intended for diagnostic and/or interventional radiology, including devices which control or monitor such devices, or those which directly influence their performance, are in Class C.	Example: these include devices for the control, monitoring or influencing of the emission of ionizing radiation.
Rule 11. All active devices intended to administer and/or remove medicinal products, body liquids or other substances to or from the body are in Class B,	Such devices are mostly drug delivery systems or anaesthesia equipment. Examples of Class B devices: suction equipment; feeding pumps; jet injectors for vaccination; nebuliser to be used on conscious and spontaneously breathing patients where failure to deliver the appropriate dosage characteristics is not potentially hazardous.
unless this is done in a manner that is potentially hazardous, taking account of the nature of the substances involved, of the part of the body concerned and of the mode and route of administration, in which case they are in Class C.	Examples: infusion pumps; anaesthesia equipment; dialysis equipment; hyperbaric chambers; nebuliser where the failure to deliver the appropriate dosage characteristics could be hazardous.
Rule 12. All other active devices are in Class A.	Examples: examination lamps; surgical microscopes; powered hospital beds & wheelchairs; powered equipment for the recording, processing, viewing of diagnostic images; dental curing lights.
Additional Rules	
Rule 13. All devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, and which is liable to act on the human body with action ancillary to that of the devices, are in Class D.	These medical devices incorporate medicinal substances in an ancillary role. Examples: antibiotic bone cements; heparin-coated catheters; wound dressings incorporating antimicrobial agents to provide ancillary action on the wound; blood bags incorporating an anti-coagulant. NOTE: Such medical devices may be subject to additional conformity assessment procedures according to the regional or national requirements of medicinal product Regulatory Authorities.
Rule 14. All devices manufactured	NOTE: In some jurisdictions such products:

Rules	Illustrative Examples of Devices that May Confirm with a Rule
from or incorporating animal or human cells/tissues/derivatives thereof, whether viable or non-viable, are Class D,	are considered to be outside the scope of the medical device definition; may be subject to different controls. It is likely the regulations controlling these devices will be the subject of future harmonization efforts. Examples: porcine heart valves; catgut sutures.
unless such devices are manufactured from or incorporate non-viable animal tissues or their derivatives that come in contact with intact skin only, where they are in Class A.	Examples: leather components of orthopaedic appliances.
Rule 15. All devices intended specifically to be used for sterilising medical devices, or disinfecting as the end point of processing, are in Class C.	Examples: devices for disinfecting or sterilising endoscopes; disinfectants intended to be used with medical devices. NOTE: This rule does not apply to products that are intended to clean medical devices by means of physical action e.g. washing machines.
unless they are intended for disinfecting medical devices prior to end point sterilisation or higher level disinfection, in which case they are in Class B; or	Example: washer disinfectors.
unless they are intended specifically to be used for disinfecting, cleaning, rinsing or, when appropriate, hydrating contact lenses, in which case they are in Class C.	In some jurisdictions solutions for use with contact lenses: are considered to be outside the scope of the medical devices definition; may be subject to different controls.
Rule 16. All devices used for contraception or the prevention of the transmission of sexually transmitted diseases are in Class C,	Examples: condoms; contraceptive diaphragms.
unless they are implantable or long-term invasive devices, in which case they are in Class D.	Example: intrauterine contraceptive device.

6. **Rationale for the inclusion of the Additional Rules**

6.1) There are a small number of products that fall within the scope of the definition of a medical device and which may need to be classified to take account of factors other than those covered by the general rules (Rules 1 to 12).

6.2) For the understanding of those countries that are not Founding Members of GHTF, it is felt important to offer guidance on the classification of such devices (see Clause 6.2, above).

6.3) Therefore, four Additional Rules are provided (Rules 13 to 16).

6.4) Matters that may need to be considered are: -

Rule 13: Devices incorporating a medicinal product

- The regulations applying to medicinal products require different acceptance procedures to those for medical devices.
- The behavior of a medicinal product used in conjunction with a medical device may differ from that covered by its approved use as a medicinal product alone.

Rule 14: Devices incorporating animal or human tissues

- There is an absence of global regulatory controls for such devices.
- Classification needs to acknowledge the diversity of opinions on such devices, globally.
- The possible risks associated with the transmission of infectious agents through materials used in such devices, e.g. Bovine Spongiform Encephalopathies (BSE) and Creutzfeldt-Jacob disease (CJD), demand classification at a higher risk level.

Rule 15 Disinfectants

- The particular concerns relating to those disinfectants that are used with contact lenses, due to sensitivity and vulnerability of the eye.

Rule 16 Contraceptive devices

- The risks associated with unwanted pregnancy if caused by mechanical failure of the device.
- The need to safeguard public health through the use of condoms to reduce the prevalence of sexually transmitted diseases.
- User expectation that contraceptive devices are perfectly reliable and safe despite published data to the contrary.

Annex 3: Medical Devices Registration Fees

1) The PPB requires that statutory fee is payable for new or subsequent changes to the registration details held with the PPB.

2) Initial registration fees shall be assessed per device family or a family of related devices

3) The fee is payable at the time of lodging an application and evaluation fee is payable once an application has been accepted for evaluation

4) The fee schedule applicable for each risk class of medical device is as detailed below

Risk Class	Initial Registration Fee	Evaluation Fee	Renewal Fee	Change Notification Fee
Class A	US$ 25		US$ 20	US$ 10
Class B	US$ 150	US$ 200	US$ 100	US$ 20
Class C	US$ 200	US$ 250	US$ 150	US$ 50
Class D	US$ 250	US$ 350	US$ 200	US$ 70

5) PPB is unable to process registration forms until payment of the fee has been received.

6) The applicant must receive confirmation that your payment has been processed before submitting registration dossier or the application will not be considered complete.

7) Fes will only be applicable for technical changes. Please refer to the fee schedule for fees that apply to changes notification applications

8) Evaluation fees shall not be payable for change notification applications that only involve administrative changes

9) A standard administrative fee (currently $30) may be payable when applications are rejected or withdrawn or in other applicable circumstances.

Payment Method

10) Payment shall be by crossed or bankers cheque payable to PHARMACY AND POISONS BOARD.

Annex 4: Registration Dossier

1) The manufacturer or its local authorized representative is required to apply for the Medical device registration at the Pharmacy and Poisons Board.
2) Registration contains three parts
   2.1) Administrative Information
   2.2) Supporting Documents
   2.3) Declaration

Part 1: Administrative Information

3) The following information is required

Description	Details of the manufacturer, if is also the applicant	Local Authorised Representative (if applicable)
Contact Person submitting the Application		
Company Name		
City		
P O Box		
Tel		
Fax		
Email		

Part 2: Registration Dossier Information

4) Executive Summary
   An executive summary shall include the following information:
   4.1) an overview, e.g., introductory descriptive information on the medical device and any novel features;
   4.2) commercial marketing history;
   4.3) intended uses and indications in labelling;
   4.4) list of regulatory approval or marketing clearance obtained;
   4.5) status of any pending request for market clearance and;
   4.6) Important safety/performance related information.

5) Relevant Essential Principles and Method Used to Demonstrate Conformity
   5.1) The applicant should identify the Essential Principles of Safety and Performance of Medical Devices that is applicable to the device. The applicant should identify the general method used to demonstrate conformity to each applicable Essential Principle. The methods that may be used include compliance with recognized or other standards, state of the art or internal industry methods, comparisons to other

similar marketed devices, etc. The applicant should identify the specific documents related to the method used to demonstrate conformity to the Essential Principles.

5.2) The evidence of conformity can be provided in tabular form with supporting documentation available for review as required. For example, a completed Essential Principles conformity checklist can be used to demonstrate that a recognized test standard was used as part of the method to demonstrate conformity to one Essential Principle. As such, applicant would then include a declaration of conformity to the standard or other certification permitted by the Regulatory Authority, and a summary of the test data, if the standard does not include performance requirements. When the manufacturer uses international or other standards to demonstrate conformity with the Essential Principles, the applicant should identify the full title of the standard, identifying numbers, date of the standard, and the organization that created the standard. When the manufacturer uses other means, such as internal standards, the applicant should describe the means.

5.3) Not all the essential principles will apply to all devices and it is for the manufacturer of the device to assess which are appropriate for his particular device product. In determining this, account must be taken of the intended purpose of the device.

6) Device Description

6.1) Besides a general description of the device, a more detailed description of the device attributes is necessary to explain how the device functions, the basic scientific concepts that form the fundamentals for the device, the component materials and accessories used in its principles of operation as well as packaging. A complete description of each functional component, material or ingredient of the device should be provided, with labelled pictorial representation of the device in the form of diagrams, photographs or drawings, as appropriate.

6.2) Intended use: - This means the use for which the medical device is intended, for which it is suited according to the data supplied by the manufacturer in the instructions as well as the functional capability of the device.

6.3) Instructions of use: - These are all necessary information from the manufacturer including the procedures, methods, frequency, duration, quantity and preparation to be followed for safe use of the medical device. Instructions needed to use the device in a safe manner should, to the extent possible, be included on the device itself and/or on its packaging by other formats /forms.

6.4) Limitations - This is a general description of the disease or condition and the patient population for which the device should not be used for the purpose of diagnosing, treating, curing or mitigating.

6.5) Warnings: - This is the specific hazard alert information that a user needs to know before using the device.

6.6) Precautions: - This alerts the user to exercise special care necessary for the safe and effective use of the device. They may include actions to be taken to avoid effects on patients/users that may not be potentially life-threatening or result in

serious injury, but about which the user should be aware. Precautions may also alert the user to adverse effects on the device of use or misuse and the care necessary to avoid such effects.

6.7) Materials: - This section must include complete chemical, biological and physical characterization of materials that have direct or indirect contact with the human body.

6.7.1) If applicable, process validation results to be provided to substantiate that manufacturing procedures are in place to minimise biological risks;

6.7.2) If applicable, information to be provided on irradiating components, non-ionising or ionising.

6.8) The functional characteristics and technical performance specifications for the device including, as relevant, accuracy, sensitivity, specificity of measuring and diagnostic medical devices, reliability and other factors; and other specifications including chemical, physical, electrical, mechanical, biological, software, sterility, stability, storage and transport, and packaging to the extent necessary to demonstrate conformity with the relevant Essential Principles

7. Product Verification and Validation Documents

7.1) This section includes data from pre-clinical and clinical studies. The data required is to the extent appropriate to the complexity and risk class of the device.

Pre-clinical Studies

7.2) Information on preclinical studies to establish the safety and performance of the medical device for its intended use must be provided. The pre-clinical studies provided should include information on study design, complete test or study protocols, and methods of data analysis, data summaries and study conclusions.

Clinical Evidence

7.3) This section should indicate how any applicable requirements of the EPs for clinical evaluation of the device have been met. Where applicable, this evaluation may take the form of a systematic review of existing bibliography, clinical experience with the same or similar medical devices, or by clinical investigation. Clinical investigation is most likely to be needed for higher risk class medical devices or for medical devices where there is little or no clinical experience.

7.3.1) Use of Existing Bibliography: - Copies are required of all literature studies, or existing bibliography, that the manufacturer is using to support safety and effectiveness. These will be a subset of the bibliography of references. General bibliographic references should be medical device-specific as supplied in chronological order. Care should be taken to ensure that the references are timely and relevant to the current application.

7.3.2) Clinical evidence of effectiveness may comprise device-related investigations conducted domestically or other countries. It may be derived from relevant publications in a peerreviewed scientific literature. The documented evidence submitted should include the objectives,

methodology and results presented in context, clearly and meaningfully. The conclusions on the outcome of the clinical studies should be preceded by a discussion in context with the published literature.

8. Device Labelling

- This section should summarize or reference or contain the following labelling data to the extent appropriate to the complexity and risk class of the device, which is generally considered as "labeling":
  - Labels on the device and its packaging
  - Instructions for use;
  - Physician's manual

- Any information and instructions given to the patient, including instructions for any procedure the patient is expected to perform (if applicable).

- **Samples of Labels on the Medical device and its Packaging**

8.3.1) This is the printed, written or graphic product information provided on or attached to one or more levels of packaging, including the outer packaging or the outside container wrapper. Any pack labelling, which is not provided on the outer packaging must be easily legible through this outer packaging.

8.3.2) If it is physically impossible to include samples of labels (e.g. large warning labels affixed onto an X-ray machine), alternative submission methods (e.g. photographs or technical drawings), to the extent appropriate, will suffice to meet the requirements of this section.

8.4. **Operative Technique**

The operative technique for use is commonly referred to as the physician's manual, user manual, operator's manual, prescriber's manual or reference manual. It contains directions under which the physician or end-user can use a device safely and for its intended purpose. This should include information on indications, contra-indications, warnings, precautions, potential adverse effects, alternative therapy and the conditions that should be managed during normal use to maintain the safety and effectiveness of the medical device.

8.5. **Risk Analysis**

This section should summarize or reference or contain the results of the risk analysis. This risk analysis should be based upon international or other recognized standards, and be appropriate to the complexity and risk class of the device.

8.6. **Results of Risk Analysis**

A list of possible hazards for these devices must be prepared. Indirect risks from medical devices may result from device-associated hazards, such as moving parts, which lead to sustained injury, or from user-related hazards, such as ionizing radiation from an X-ray machine. The evaluation of these risks against

the claimed benefits of the device and the method(s) used to reduce risk to acceptable levels must be described. The individual or organization that carries out the risk analysis must be clearly identified. The technique used to analyze risk must be specified, to ensure that it is appropriate for the medical device and the risk involved.

9. Manufacturer Information

9.3. This section should summarize or reference or contain documentation related to the manufacturing processes, including quality assurance measures, which is appropriate to the complexity and risk class of the medical device.

9.4. Manufacturing process for the medical device should be provided in the form of a list of resources and activities that transform inputs into the desired output.

9.5. Example: The manufacturing process should include the appropriate manufacturing methods and procedures, manufacturing environment or condition, and the facilities and controls used for the manufacturing, processing, packaging, labelling, storage of the medical device. Sufficient detail 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.

9.6. If multiple facilities are involved in the manufacture of medical device, the applicable information (e.g. quality assurance certificates issued by an accredited third party inspection body) for each facility must be submitted. Firms that manufacture or process the medical device under contract to the manufacturer may elect to submit all or a portion of the manufacturing information applicable to their facility directly to the Regulatory Authority in the form of a master file. The manufacturer should inform these contractors of the need to supply detailed information on the medical device. However, it is not the intent of this section to capture information relating to the supply of sub-components (i.e. unfinished medical device) that contributes towards the manufacture of the finished medical device itself

PART 3: Declaration

10. The Declaration by the applicant should be submitted and declare that:

10.1) All submitted documents are true;

10.2) They will be fully responsible for the product and post market plan submitted for complain handling or field safety corrective action;

10.3) They will fully comply with the requirements of the PPB after placing the product in the market.

10.4) All documents shall made available in English

10.5) The applicant may submit required documents in the form of the GHTF Summary Technical Documents (“STeD) including the Essential Principles Checklist.

ANNEX 5: Change Notification Checklist

1) All the required documents must be submitted. If any required document is not available, please provide the reason.
2) Changes have been categorised according to whether they are technical (T) or administrative (A) changes.
3) **Note:**
   - **A** denotes Administrative change
   - **T** denotes Technical change

Type of Change	Evaluation		PPB Requirements
	A	T	
Management System, Manufacturing Facility, Process and Quality			
Manufacturing facility (including sterilisation facility) Quality management Certificate	A		• Quality Management System certificate(s)Device labelling, if applicable • Validation studies from new site • Summary of new manufacturing process (Please provide a • Declaration if there is no change in manufacturing process)
Sterilisation method and process		T	• Sterilisation technique • Sterility assurance level achieved • Sterilisation protocol • Sterilisation validation results • Evidence of on-going revalidation of sterilisation process • Post-Sterilisation functional tests • Device labelling, if applicable
Design or Performance Specifications			
Control mechanism		T	• Pre-clinical studies • Device labelling • Software validation report (For software only)
Operating principles		T	• Pre-clinical studies • Clinical studies • Device labelling • Software validation report (For software only)
Design Characteristics		T	• Pre-clinical studies • Clinical studies • Device labelling • Software validation report (For software only)

Type of Change	Evaluation		PPB Requirements
	A	T	
Performance Specifications		T	• Pre-clinical studies • Clinical studies • Device labelling • Software validation report (For software only)
Materials (General Medical Device)			
Biological materials		T	• Biological safety data • Process validation results • Traceability from sources to the finished medical device
Direct and/or indirect contact with body tissues and fluids		T	• Complete chemical, biological and physical characterisation of the • material • Biocompatibility studies • Pre-clinical animal studies
Medical devices emitting ionising radiation		T	• Information on radiation source • Information on materials for shielding of radiation
Materials (In Vitro Diagnostic Device)			
Materials affecting performance specification		T	• Pre-clinical performance evaluation data • Clinical performance evaluation data
Biological materials (including supplier of materials)			• Source of material • Process validation result for inactivation of infectious agents
IVD devices emitting ionising radiation			• Information on radiation source • Information on materials for shielding of radiation
Labelling			
Indications for use ▪ Revision ▪ Addition.		T	• Regulatory approval documents from the reference agencies • Device Information • Device labelling for new product(s) • Declaration of conformity document • Pre-clinical studies • Clinical studies • Risk analysis • Software validation report (For software only) • Manufacturing information
Reduction in approved indications for use	A		• Reasons for the reduction of approved indications • Device labelling
Addition and removal of Contraindications,		T	• Reasons for addition or removal of contraindications, warnings and

Type of Change	Evaluation		PPB Requirements
	A	T	
Warnings and Precautions (include any editing)			• precautions • Device labelling • Pre-clinical studies • Clinical studies
Expiry duration, shelf life and storage condition		T	• Shelf life / stability data • Device labelling
Other labelling changes: ▪ Layout ▪ Colours ▪ Font sizes and design; ▪ Addition and removal of language(s) not required by Authority. ▪ Changes to software version number that are not due to changes affecting safety, quality or efficacy of the medical device.	A		• Device labelling • Reasons for change of software version number (For software only) • Software validation report (For software only)
Other Changes			
Addition of a new product to a device listing		T	• Justification for addition of product(s) to be grouped within the registered product • List of Configurations of Medical • Devices to be Registered • Regulatory approval documents from the reference agencies • Device Information • Device labelling for new product(s) • Declaration of conformity document • Letter of Authorisation • Pre-clinical studies • Clinical studies • Risk analysis • Software validation report (For software only) • Manufacturing information
Addition of a new product to a device listing (Package size)	A		• Justification for addition of product(s) to be grouped within the registered product • List of Configurations of Medical • Devices to be Registered • Regulatory approval documents from the reference agencies • Device Information • Device labelling for new product(s)

Type of Change	Evaluation		PPB Requirements
	A	T	
			• Declaration of conformity document • Letter of Authorisation
Deletion of products from a device listing	A		• Reason for deletion of products
Product Name only	A		• Device labelling • Declaration of Conformity document • Letter of Authorisation
Product Owner	A		• Device labelling • Declaration of Conformity document • Letter of Authorisation • Quality Management System certificate(s) • Regulatory approval certificate(s)
Regulatory status on rejection or withdrawal (in any reference agencies)	A		• Documents from relevant regulatory authorities citing the reason for • the change in regulatory status
Update of regulatory approval certificates (from reference agencies)	A		• Regulatory approval documents from the reference agencies

ANNEX 6: Initial Case Reporting Form

Submitter's Information	
Patient/Healthcare professional/Procurement Officer/Social Care worker/others	
Name of the contact Person	
Organisation Name	
Address	
City	Country
Phone	Fax
Email	
Device Information	
Manufacturer Name	

Contact Name		
Address		
Phone	Fax	
Email		
Generic Device Information		
Generic Device Information		
Nomenclature System		
Nomenclature Code		
Brand Name		
Model		
Catalogue		
Device Approval Information		
Regulatory/National Competent Authority who approved device		
Notified Body (NB) who approved device		
Other 3rd party name who approved device		
NB ID number		
Document approval number		
Adverse event Information		
User facility report reference number, ifapplicable		
Date the adverse event occurred		
Adverse event description narrative		
No of patients involved (if known)	No of medical devices involved (if known)	
Medical device current location/disposition (if known)		
Operator of the Medical Device at the Time of Adverse Event(If applicable)		
Health care professional	Patient	Other

Usage of the medical device (select from list below)	
Initial use	Re-use of a single use medical device
Re-use of a reusable medical device	Re-serviced/refurbished
other (please specify)	problem noted prior use
Patient Information (If applicable)	
Patient outcome	
Remedial action taken by the healthcare facility relevant to the care of the patient	
Age of the patient at the time of adverse event, if applicable	
Gender, if applicable	Female/ Male
Healthcare Facility Information(If applicable)	
Name of the health care facility	
Contact person within the facility	
Address	
City	Country
Phone	Fax
Email	
Send one copy to PPB and the other to Manufacturer or authorized representative	