Guideline for classification of medical device in Sri Lanka

Medical Device Regulatory Division
National Medicines Regulatory Authority
Sri Lanka

Version 1.0 of dated 25/08/2019

[This document has been produced by the Medical Device Division of National Medicines Regulatory Authority, Sri Lanka in consultation with the Medical Device Evaluation Committee of NMRA. This is a guidance document to medical device industry who is willing to register their products in Sri Lanka]

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1.0 Introduction

According to the National Medicines Regulatory Authority Act No. 05 of 2015 the National Medicines Regulatory Authority (NMRA) shall be responsible for the regulation and control of registration, licensing, manufacture, importation and all other aspects pertaining to medical devices in Sri Lanka.

The aim of this Guideline is to assist the regulators manufacturers, importers and distributors-of medical devices in the classification of medical devices required for the registration and licensing of medical devices and related matters.

This guideline presents the classification rules for Medical Devices and classified as per the different Classes based on a risk assessment and intended use.

These guidelines are constantly evolving as a result of scientific developments and harmonization of the requirements of regional and international regulatory authorities. The NMRA endeavors to regularly update the guidelines to reflect current thinking and keep its technical requirements and evaluation policies in line with "**Good Regulatory Practice"**

2.0 Scope

This document applies to all products that fall within the definition of a medical device that appears in this document including in vitro examination of specimens derived from the human body.

3.0 References

GHTF/SG1/N29: 2005 Information document concerning the definition of the term "Medical Device"

GHTF/SG1/N40:2006 Principles of Conformity Assessment for Medical Devices

GHTF/SG1/N15:2006 Principles of Medical Devices classification

GHTF/SG1/N41:2006 Essential principles of safety and performance of Medical Devices

GHTF/SG1/N43:2005 Labeling for Medical Devices

GHTF/SG1/N45: 2008 Principles of IVD medical devices classification

EU Regulations for Medical Devices 2017/745

4.0 Definitions

a) "Medical Device" means any instrument, apparatus, equipment , appliance, software, material, other article, or any specimen derived from the human body, IVD ?? whether used alone or in combination, including the software or accessory intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease,
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- Investigation, replacement or modification of the anatomy or of a physiological process,
- Control of conception,
- The care of a human being during pregnancy and at and after the birth of a child, including the care of the child.
- and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means but which may be assisted in its function by such means.

b) "Accessory" means an article which whilst not being a device is intended specifically by its manufacturer to be used together with a device to augment or extend the capabilities of that device in fulfilment of its intended use in accordance with the use of the device

c) "Spare parts" means a sub-assy or component used in the composition of a medical device or system and which is not in itself a medical device with an intrinsic function intended for the final user and which may also be supplied for replacement of existing components of a medical device.

d) "In vitro diagnostic medical device" means any medical device which is a reagent, reagent product, calibrator, control material, specimen receptacles, kit, instrument, apparatus, equipment or system including software, whether used alone or in combination, intended by the manufacturer to be used in the examination of specimens including blood and tissue donations, derived from the human body, solely or principally providing information for :

- diagnostic
- monitoring

- safety and compatibility purposes.

e) "Specimen receptacles" are those devices, whether vacuum-type or not, specifically intended by their manufacturers for the primary containment and preservation of specimens derived from the human body for the purpose of *in vitro* diagnostic examination. Specimen receptacles are considered to be *in vitro* diagnostic medical devices.

Products for general laboratory use are not "*in vitro*" diagnostic medical devices unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for *in vitro* diagnostic examination.

f) "Custom made device" means device specifically made in accordance with a duly qualified medical practitioner's written prescription which gives, under his responsibility, specific design characteristics and is intended for the sole use of a particular patient.

The above mentioned prescription may also be made out by any other person authorized by virtue of his professional qualifications to do so.

Mass produced devices which need to be adapted to meet the specific requirements of the medical practitioner or any other professional user shall not be considered to be custom made devices.

g) "Device intended for clinical trial" means any device intended for use by a duly qualified medical professional when conducting an investigation referred to as a clinical trial in an adequate clinical environment.

Following key terms are found within the risk classification rules. Terms that appear in bold in the text of this document indicates that they have been defined in this section.

h) **"Active Device"** Means a medical device that depends for its operation on a source of energy other than the energy generated by the human body or gravity. A medical device that transmits or withdraws energy or a substance to or from a patient without substantially altering the energy or the substance is not an active device.

i) **"Active Diagnostic Device"** Means an active device that, whether used alone or in combination with another medical device, is intended to supply information for the purpose of detecting, monitoring or treating a physiological condition, state of health, illness or congenital deformity.

j) **"Active Therapeutic Device"** Means an active device that, whether used alone or in combination with another medical device, is intended to support, modify, replace or restore a

biological function or structure for the purpose of treating or mitigating an illness or injury or a symptom of an illness or injury.

k) **"Body Orifice"** Means a natural opening or a permanent artificial opening in the body, such as a stoma.

l) **"Cardiovascular System"** Means the heart, pericardium, pulmonary veins, pulmonary arteries, cardiac veins, coronary arteries, common carotid arteries, cerebral arteries, brachiocephalic artery, aorta, inferior and superior vena cava, renal arteries, iliac arteries and femoral arteries

m) **"Nervous System"** Means the brain, meningitis, spinal cord and cerebrospinal fluid

n) **"Closed-loop System"** In respect of a medical device, means a system that enables the device to sense, interpret and treat a medical condition without human intervention.

o) **"Dental Material"** Means a medical device that is to be inserted into the pulp cavity of a tooth or attached only to the enamel or dentin of a tooth. It does not include a surgical or dental instrument.

p) **"Invasive Device"** Means a medical device that is intended to come into contact with the surface of the eye or penetrate the body, either through a body orifice or through the body surface.

q) **"Surgical or Dental Instrument"** Means a reusable medical device that is intended for surgical or dental use, including cutting, drilling, sawing, scraping, clamping, hammering, puncturing, dilating, retracting or clipping without connection to a medical device.

r) **"Surgically Invasive Device"** Means an invasive device that is intended to enter the body through an artificially created opening that provides access to body structure and fluids in the body.

s) " Implantable device" Means 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 surgically 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

t) Active implantable devices" Means any active medical device 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".

5.0 Medical Device classification system

The classification of medical devices is a risk-based system.

Medical devices other than IVD are grouped into 5 classes as follows:

1. Listed medical device – regarded as lowest risk
2. Class I - Generally regarded as low risk
3. Class IIa - Generally regarded as medium risk
4. Class IIb - Generally regarded as medium high risk (moderate risk)
5. Class III - Generally regarded as high risk

Medical Device Classification System			
Device Class	**Risk Level**	**Examples**	**Regulatory Status**
Listed Device	Lowest	Baby diapers, Toothbrush, Feeding bottle, Bio safety cabinets etc.	Listing certificate
Class I	Low	Reusable Surgical instrument, , cotton wool etc.	Certificate of registration
Class IIa	Medium	Contact lenses, endoscopes, ultrasound scanners etc.	
Class IIb	Moderate	Orthopedic implants, dental implants, hemodialysis machines etc.	
Class III	High	Cardiac pacemakers, angiography catheters, cranial shunts etc.	

6.0 Regulatory status

The National Medicines Regulatory Authority (NMRA) categorizes medical devices other than IVD into 5 categories as listed device and Class I, IIa, IIb, or III, based on risk associated at the point of usage to patients, users and other persons.

The risk presented in the device depends on its intended purpose, the degree of invasiveness, duration and extent of contact with the patient, technology & energy transmission hazard,

intended user, effectiveness of the risk management techniques applied during design manufacture and use and consequences of device malfunction or failure.

Any device defined as Medical device which present the lowest potential risk, but not belongs to any class described under the classification rules is considered as listed device. Each device needs to be regulated as a listed device and Certificate of Listing valid for a period of five years is issued on fulfilment of the requirements. Sample import license, annual renewal of import licence or manufacturing licence should be obtained.

Class I present low risk devices and require the manufacturer's declaration of conformity for safety and effectiveness. Each device needed to be registered and certificate of registration is issued on fulfilment of the requirements. Sample import license, annual renewal of import licence or manufacturing licence should be obtained.

Class IIa presents medium risk require the certificate of conformity for safety and effectiveness issued by accredited notified body. Each device needed to be registered and certificate of registration is issued on fulfilment of the requirements. Sample import license, Annual renewal of import licence or manufacturing licence should be obtained.

Class IIb and III devices present a greater potential for risk and are subject to in depth regulatory scrutiny with certificate of conformity for safety and effectiveness issued by accredited notified body before registration. Each device needed to be registered and certificate of registration is issued on fulfilment of the requirements. Sample import license, annual renewal of import licence or manufacturing licence should be obtained.

In addition to the above requirements sterile or professional use only medical device shall sell only by a holder of retail or whole sale licence or sales outlet owned by the wholesaler approved by the authority.

When a deviation from a guideline is decided on, a detailed motivation giving the reason(s) for the deviation and justification for the alternative approach should be included in the expert report submitted with the application for the consideration and authentication of the MDR Division.

6.1 Quality Requirements

The medical devices regulations require Class II medical devices to be manufactured under a quality standard (ISO standard 13488:2003) developed by the International Organization for Standardization. Class III and IV devices must meet ISO standard 13485:2003, which deals with both design and manufacturing standards.

6.2 Application Process

The medical devices regulations are supplemented by guidance documents, which outline the safety, quality and effectiveness data required for each class of medical device. All applications for medical devices should be submitted according to the guidance document published by NMRA.

6.3 Investigational testing in human clinical trials

Manufacturers or importers may submit a clinical trial application to use unapproved Class IIa, IIb, and III devices for clinical trials provided that:

- the life, health and safety of patients, users or other persons is not seriously endangered
- it is not contrary to the best interests of the patients recruited to the trial
- the objective of the testing will be achieved.

Formal authorization is not required to use a Class I device in a clinical trial, although full trial records must be retained. Devices must be labeled “for investigational use only” and any serious adverse events must be reported to the NMRA within 72 hours.

Trial sponsors must identify all investigators and clinical trial sites and must comply with Clinical trials Evaluation Committee (CTEC) of the NMRA requirements, including protocol approval and informed patient consent. In making their final decision on the application, reviewers of the NMRA evaluate the study protocol and design, the hypotheses, the validity of the endpoints and statistical methods, as well as the documentation and management of the trial.

7.0 Principles of classification system

The rules for medical devices other than *in vitro* diagnostic devices can be grouped into four sets characterized as:

- Rules for Invasive Devices
- Rules for Non-invasive Devices
- Rules for Active Devices
- Special Rules

The first step in determining the risk classification of a device is to check “Special Rules” from 14 to 22. If the device in question is not described by one of these “Special Rules” then it should be determined if the device is invasive, non-invasive or active. A device could be described as both non-invasive and active or invasive and active and it is not unusual for more than one Rule to apply to any given device. The final classification, however, will be determined by the Rule which assigns the index device to the highest risk classification.

It must be stressed that it is the "intended use" of the device that ultimately determines the device's classification. An example would be an ECG machine intended only to be used in a doctor's office for routine check-ups versus an ECG machine intended to be used in critical care settings. The former would be Class IIa by Rule 10(1) and the latter Class IIb by Rule 10(2)

7.1. Duration of Use
Device are classified into following groups according to the duration of use.

Transient: Normally intended for continuous use for less than 60 minutes
Short term : Normally intended for continuous use for between 60 minutes and 30 days
Long term : Normally intenede for continuous use for more than 30 days

Continuous use is understood to be uninterrupted use for the intended purpose

The Sri Lankan rule system only distinguishes between devices whose use is considered to be "long term" or not. Long term use, implies "continuous use" for a period of 30 days or greater. Continuous use is understood to be uninterrupted use for the intended purpose.

7.2 Invasiveness
Any device which, in whole or in part, penetrates the body, either through a body orifice or through the surface of the body is an invasive device. A body orifice may be either a natural body orifice or a permanent artificial opening. A surgically invasive device implies that it always enters through an artificially created opening. This can be a large opening, such as a surgical incision, or it can be a pinprick opening created by a needle. Therefore, surgical gloves, and needles used with syringes are surgically invasive.

There are two exceptions to this interpretation:

- A surgically created stoma used in colostomy and ileostomy is considered, for classification purposes, to be a natural “body orifice”. Therefore, devices introduced into such a stoma are not surgically invasive. In contrast, a surgically created opening, to allow access to the circulatory system, should not be considered to be such a "natural body orifice." Devices, introduced into such an opening, are surgically invasive.
- A device that administers energy to the body should not be considered as invasive if only energy penetrates the body and not the device itself. Energy, as such, is not a device and therefore, it cannot be classified. Only the device generating the energy can be classified. However, if a device administers a substance, whether this substance is a medicine or a medical device, such substances must be assessed in their own right
  (eg., substances administered by a jet injector).

7.3 Active Devices
The definition of "active device" contains the sentence, "devices intended to transmit energy, substances or other elements between an active device and the patient, without any significant change, are not considered to be active devices." For example, an electrode is not considered to be an active medical device. Rather, an electrode is attached to an active device, and is classified accordingly.

Medical Devices using pre-stored gases and/or vacuum as a power source are regarded as active devices. For example, gas mixers with anaesthesia machines and gas powered suction pumps are considered active medical devices. Any device whose function depends on gravity or a force provided by a human is not considered an active device. For example, intravenous administration sets rely on gravity for drainage and are not active devices. Likewise a syringe which relies on a human hand to depress the plunger is not an active medical device.

Radioactive sources that are intended to deliver ionizing radiation are also considered to be active medical devices.

7.4 Application of the Rules

a. If a device can be classified according to several rules, then the highest possible class applies.
b. Classification must be consistent with the claims that appear on the labeling or that are contained within other information provided with the device such as brochures, operating manuals and the directions for use.
c. If the intended use of the device is not clearly specified in the information accompanying the device, then the intended use will be deemed to be that accepted in general medical practice.
d. Multi-application equipment such as laser printers and identification cameras, which may be used in combination with medical devices, are not medical devices, unless their manufacturer places them on the market with the specific restriction that they are intended to be used only with medical devices.
e. The manufacturer of a "medical device" consisting of component parts has the option of classifying the device as a system, or classifying each of the parts separately. For example, a drainage device will have an invasive tube and a non-invasive collection device. It is up to the manufacturer to determine whether he will classify the drainage system as a whole, or classify the components.

7.5 How to use the Rule and the Decision Tree

The manufacturer must take into consideration **all the rules** in order to establish the proper classification for his device. It is quite conceivable, in the case of an active device that one of the general rules, (invasive/noninvasive), that is not specific to active devices, nevertheless applies to such a device. **All device characteristics must be taken into account**.

8.0 Classification Rules

This section begins with a reproduction of the Rules as they are presented in the medical devices regulations, followed by a graphical depiction of the Rules.

Each Rule is then individually addressed and examples given. It is the responsibility of the manufacturer to classify his "device" as it may have characteristics or intended purposes that would exclude it from the example given.

NON- INVASIVE DEVICES

8.1. Rule 1

All non-invasive devices are classified as class I, unless one of the rules set out hereinafter applies.

8.2. Rule 2

All non-invasive devices intended for channelling or storing blood, body liquids, cells or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the body are classified as class IIa:

— if they may be connected to a class IIa, class IIb or class III active device; or

— if they are intended for use for channelling or storing blood or other body liquids or for storing organs, parts of organs or body cells and tissues, except for blood bags; blood bags are classified as class IIb.

all other cases, such devices are classified as class I.

8.3. Rule 3

All non-invasive devices intended for modifying the biological or chemical composition of human tissues or cells, blood, other body liquids or other liquids intended for implantation or administration into the body are classified as class IIb, unless the treatment for which the device is used consists of filtration, centrifugation or exchanges of gas, heat, in which case they are classified as class IIa.

All non-invasive devices consisting of a substance or a mixture of substances intended to be used *in vitro* in direct contact with human cells, tissues or organs taken from the human body or used *in vitro* with human embryos before their implantation or administration into the body are classified as class III.

8.4. Rule 4

All non-invasive devices which come into contact with injured skin or mucous membrane are classified as:

— class I if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates;

— class IIb if they are intended to be used principally for injuries to skin which have breached the dermis or mucous membrane and can only heal by secondary intent;

— class IIa if they are principally intended to manage the micro-environment of injured skin or mucous membrane; and — class IIa in all other cases.

This rule applies also to the invasive devices that come into contact with injured mucous membrane.

INVASIVE DEVICES

8.5. Rule 5

All invasive devices with respect to body orifices, other than surgically invasive devices, which are not intended for connection to an active device or which are intended for connection to a class I active device are classified as:

— class I if they are intended for transient use;

— class IIa if they are intended for short-term use, except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in the nasal cavity, in which case they are classified as class I; and

— class IIb if they are intended for long-term use, except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in the nasal cavity and are not liable to be absorbed by the mucous membrane, in which case they are classified as class IIa.

All invasive devices with respect to body orifices, other than surgically invasive devices, intended for connection to a class IIa, class IIb or class III active device, are classified as class IIa.

8.6. Rule 6

All surgically invasive devices intended for transient use are classified as class IIa unless they:

— are intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with those parts of the body, in which case they are classified as class III;

— are reusable surgical instruments, in which case they are classified as class I;

— are intended specifically for use in direct contact with the heart or central circulatory system or the central nervous system, in which case they are classified as class III;

— are intended to supply energy in the form of ionising radiation in which case they are classified as class IIb;

— have a biological effect or are wholly or mainly absorbed in which case they are classified as class IIb; or

— are intended to administer medicinal products by means of a delivery system, if such administration of a medicinal product is done in a manner that is potentially hazardous taking account of the mode of application, in which case they are classified as class IIb.

8.7. Rule 7

All surgically invasive devices intended for short-term use are classified as class IIa unless they:

— are intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with those parts of the body, in which case they are classified as class III;

— are intended specifically for use in direct contact with the heart or central circulatory system or the central nervous system, in which case they are classified as class III;

— are intended to supply energy in the form of ionizing radiation in which case they are classified as class IIb;

— have a biological effect or are wholly or mainly absorbed in which case they are classified as class III;

— are intended to undergo chemical change in the body in which case they are classified as class IIb, except if the devices are placed in the teeth; or

— are intended to administer medicines, in which case they are classified as class IIb.

8.8. Rule 8

All implantable devices and long-term surgically invasive devices are classified as class IIb unless they:

— are intended to be placed in the teeth, in which case they are classified as class IIa;

— 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 classified as class III;

— have a biological effect or are wholly or mainly absorbed, in which case they are classified as class III;

— are intended to undergo chemical change in the body in which case they are classified as class III, except if the devices are placed in the teeth;

— are intended to administer medicinal products, in which case they are classified as class III;

— are active implantable devices or their accessories, in which cases they are classified as class III;

— are breast implants or surgical meshes, in which cases they are classified as class III;

— are total or partial joint replacements, in which case they are classified as class III, with the exception of ancillary components such as screws, wedges, plates and instruments; or

— are spinal disc replacement implants or are implantable devices that come into contact with the spinal column, in which case they are classified as class III with the exception of components such as screws, wedges, plates and instruments.

ACTIVE DEVICES

8.9. Rule 9

All active therapeutic devices intended to administer or exchange energy are classified as class IIa unless their characteristics are such that they may administer energy to or exchange energy with the human body in a potentially hazardous way, taking account of the nature, the density and site of application of the energy, in which case they are classified as class IIb.

All active devices intended to control or monitor the performance of active therapeutic class IIb devices, or intended directly to influence the performance of such devices are classified as class IIb.

All active devices intended to emit ionizing radiation for therapeutic purposes, including devices which control or monitor such devices, or which directly influence their performance, are classified as class IIb.

All active devices that are intended for controlling, monitoring or directly influencing the performance of active implantable devices are classified as class III.

8.10. Rule 10

Active devices intended for diagnosis and monitoring are classified as class IIa:

— if they are intended to supply energy which will be absorbed by the human body, except for devices intended to illuminate the patient's body, in the visible spectrum, in which case they are classified as class I;

— if they are intended to image *in vivo* distribution of radiopharmaceuticals; or

— if they are intended to allow direct diagnosis or monitoring of vital physiological processes, unless they are specifically intended for monitoring of vital physiological parameters and the nature of variations of those parameters is such that it could result in immediate danger to the patient, for instance variations in cardiac performance, respiration, activity of the central nervous system, or they are intended for diagnosis in clinical situations where the patient is in immediate danger, in which cases they are classified as class IIb.

Active devices intended to emit ionizing radiation and intended for diagnostic or therapeutic radiology, including interventional radiology devices and devices which control or monitor such devices, or which directly influence their performance, are classified as class IIb.

8.11. Rule 11

Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes is classified as class IIa, except if such decisions have an impact that may cause:

— death or an irreversible deterioration of a person's state of health, in which case it is in class III; or

— a serious deterioration of a person's state of health or a surgical intervention, in which case it is classified as class IIb.

Software intended to monitor physiological processes is classified as class IIa, except if it is intended for monitoring of vital physiological parameters, where the nature of variations of those parameters is such that it could result in immediate danger to the patient, in which case it is classified as class IIb.

All other software is classified as class I.

8.12. Rule 12

All active devices intended to administer and/or remove medicinal products, body liquids or other substances to or from the body are classified as class IIa, 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 of application in which case they are classified as class IIb.

8.13. Rule 13

All other active devices are classified as class I.

SPECIAL RULES

8.14. Rule 14

All devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, as defined in point 2 of Article 1 of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma, as defined in point 10 of Article 1 of that Directive, and that has an action ancillary to that of the devices, are classified as class III.

8.15. Rule 15

All devices used for contraception or prevention of the transmission of sexually transmitted diseases are classified as class IIb, unless they are implantable or long term invasive devices, in which case they are classified as class III.

8.16. Rule 16

All devices intended specifically to be used for disinfecting, cleaning, rinsing or, where appropriate, hydrating contact lenses are classified as class IIb.

All devices intended specifically to be used for disinfecting or sterilising medical devices are classified as class IIa, unless they are disinfecting solutions or washer-disinfectors intended specifically to be used for disinfecting invasive devices, as the end point of processing, in which case they are classified as class IIb.

This rule does not apply to devices that are intended to clean devices other than contact lenses by means of physical action only.

8.17. Rule 17

Devices specifically intended for recording of diagnostic images generated by X-ray radiation are classified as class IIa.

8.18. Rule 18

All devices manufactured utilising tissues or cells of human or animal origin, or their derivatives, which are non- viable or rendered non-viable, are classified as class III, unless such devices are manufactured utilising tissues or cells of animal origin, or their derivatives, which are non-viable or rendered non-viable and are devices intended to come into contact with intact skin only.

8.19. Rule 19

All devices incorporating or consisting of nanomaterial are classified as:

— class III if they present a high or medium potential for internal exposure;

— class IIb if they present a low potential for internal exposure; and

— class IIa if they present a negligible potential for internal exposure.

8.20. Rule 20

All invasive devices with respect to body orifices, other than surgically invasive devices, which are intended to administer medicinal products by inhalation are classified as class IIa, unless their mode of action has an essential impact on the efficacy and safety of the administered medicinal product or they are intended to treat life- threatening conditions, in which case they are classified as class IIb.

8.21. Rule 21

Devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body via a body orifice or applied to the skin and that are absorbed by or locally dispersed in the human body are classified as:

— class III if they, or their products of metabolism, are systemically absorbed by the human body in order to achieve the intended purpose;

— class III if they achieve their intended purpose in the stomach or lower gastrointestinal tract and they, or their products of metabolism, are systemically absorbed by the human body;

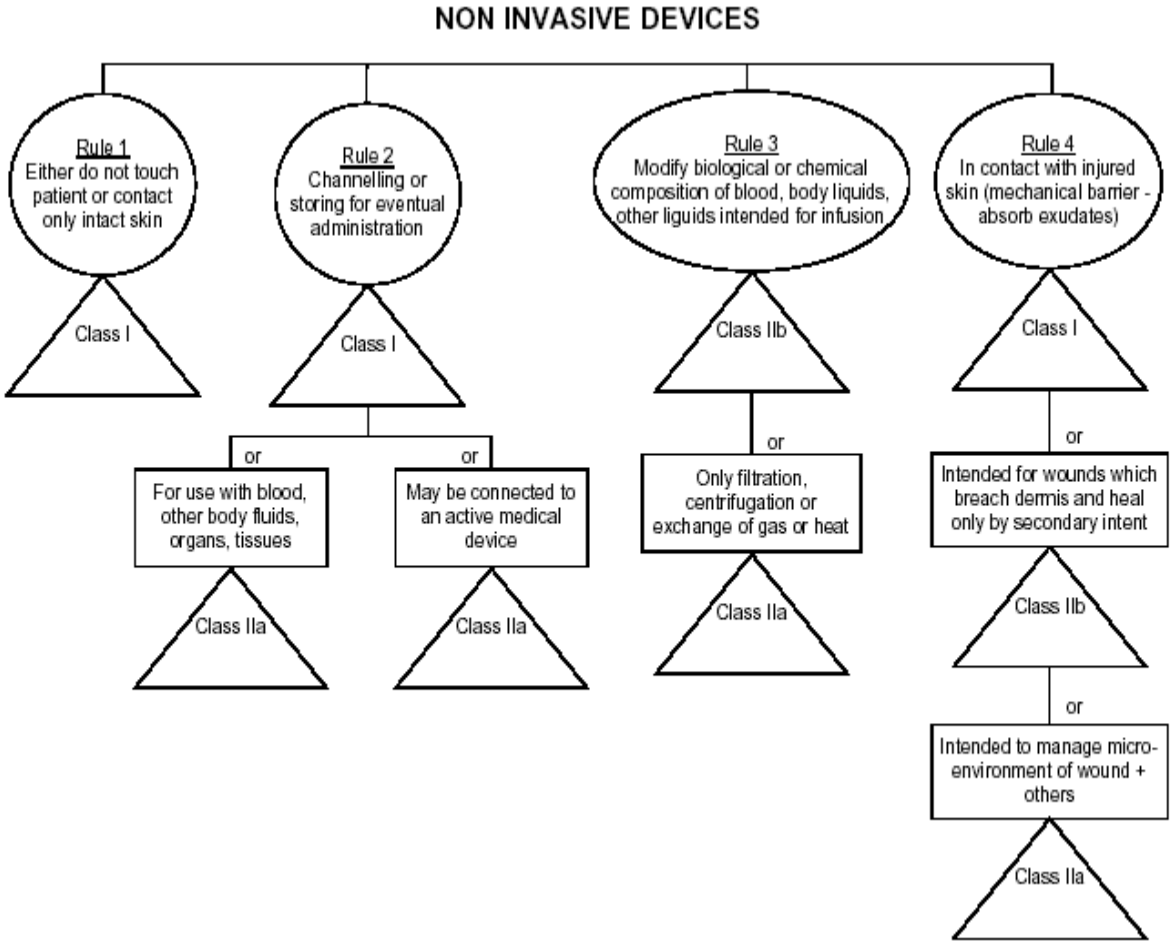
— class IIa if they are applied to the skin or if they are applied in the nasal or oral cavity as far as the pharynx, and achieve their intended purpose on those cavities; and

— class IIb in all other cases.

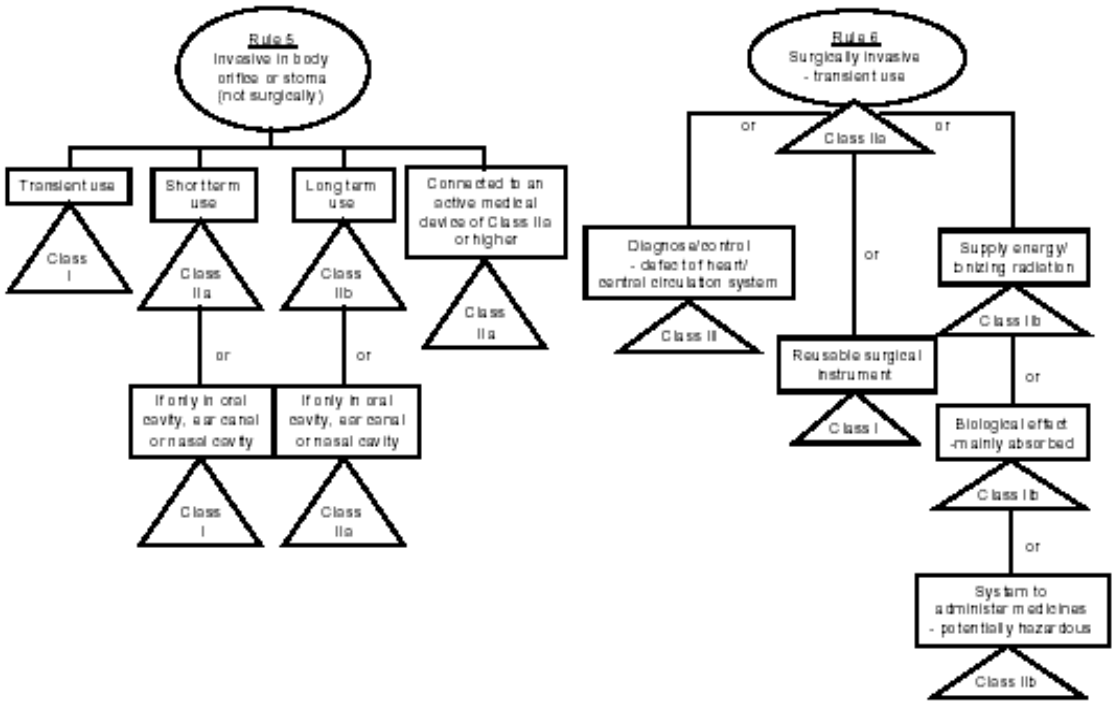
8.22. Rule 22

Active therapeutic devices with an integrated or incorporated diagnostic function which significantly determines the patient management by the device, such as closed loop systems or automated external defibrillators, are classified as class III.

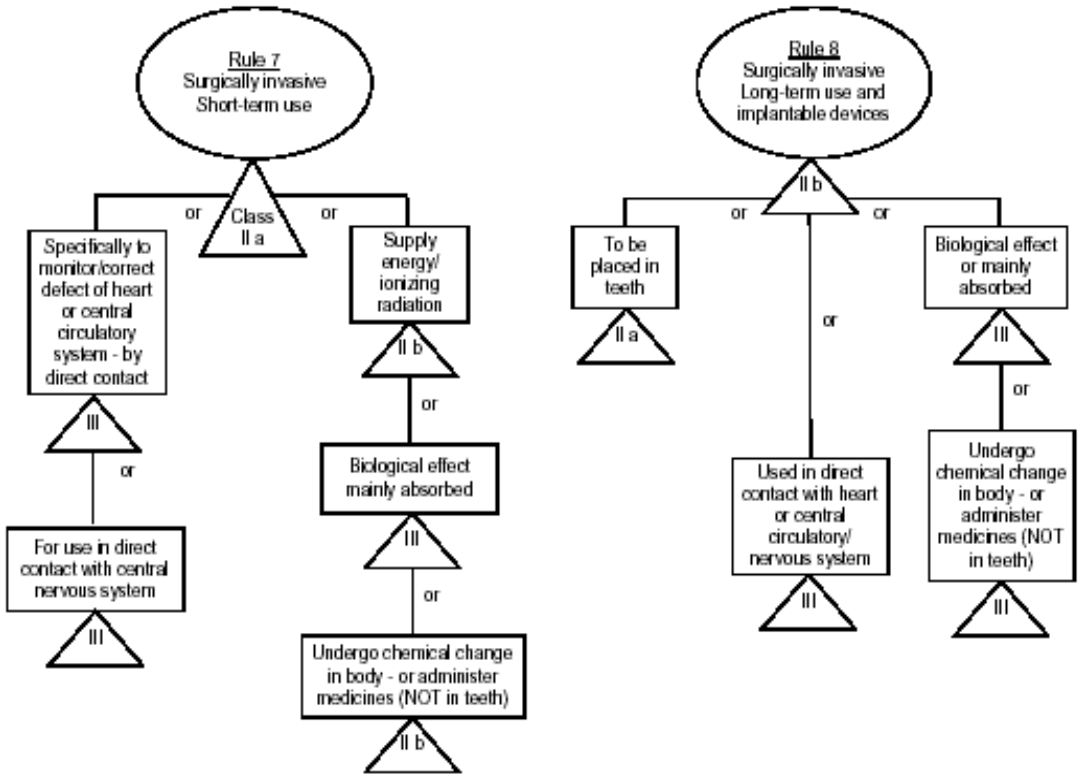
9.0 Flow Diagrams

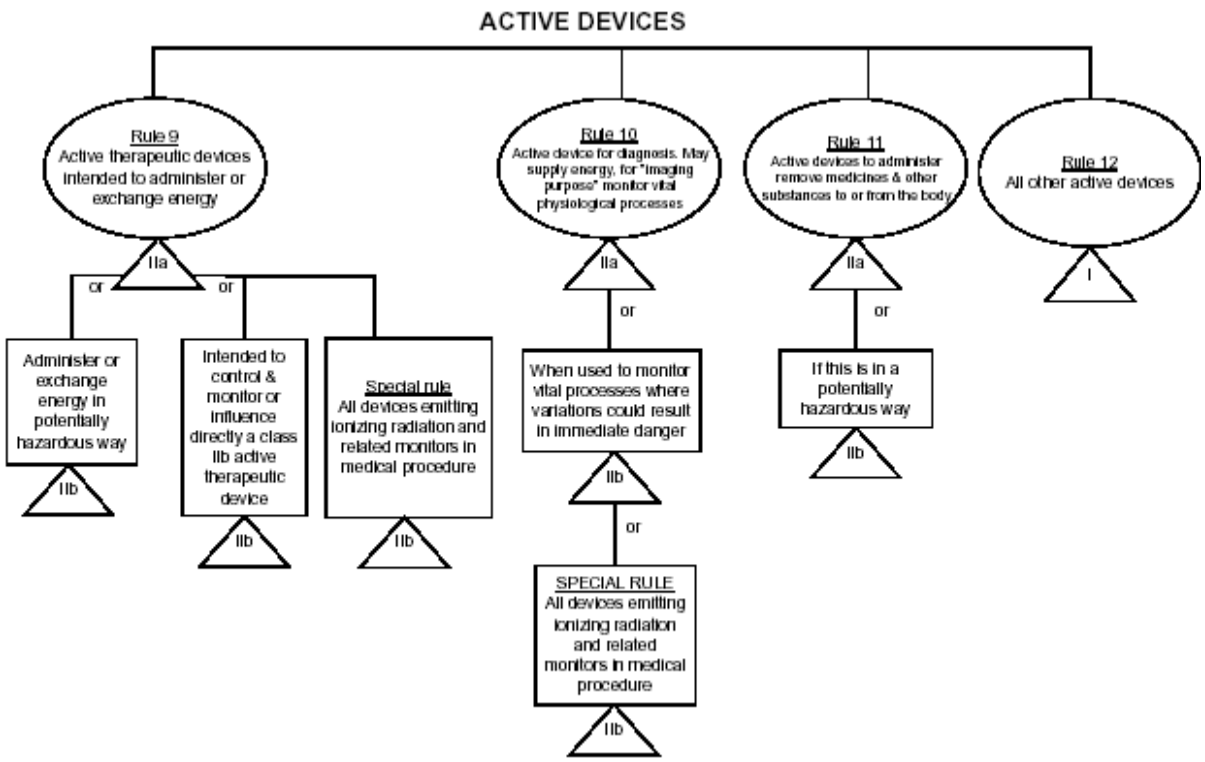


INVASIVE DEVICES



INVASIVE DEVICES




ACTIVE DEVICES
Rule 9
Active therapeutic devices intended to administer or exchange energy
IIa
or
or
Administer or exchange energy in potentially hazardous way
IIb
Intended to control & monitor or influence directly a class IIb active therapeutic device
IIb
Special rule
All devices emitting ionizing radiation and related monitors in medical procedure
IIb
Rule 10
Active device for diagnosis. May supply energy, for "imaging purpose" monitor vital physiological processes
IIa
or
When used to monitor vital processes where variations could result in immediate danger
IIb
or
SPECIAL RULE
All devices emitting ionizing radiation and related monitors in medical procedure
IIb
Rule 11
Active devices to administer remove medicines & other substances to or from the body
IIa
or
If this is in a potentially hazardous way
IIb
Rule 12
All other active devices
I

10.0 Classification of In vitro Diagnostic Devices (IVDD)

The Classification of an IVD Medical Device is based on the following criteria:

- the intended use and indications for use as specified by the manufacturer (specific disorder, condition or risk factor for which the test is intended)
- the technical/scientific/medical expertise of the intended user (lay person or professional)
- the importance of the information to the diagnosis (sole determinant or one of several), taking into consideration the natural history of the disease or disorder including presenting signs and symptoms which may guide a physician
- the impact of the result (true or false) to the individual and/or to public health

CLASS	RISK LEVEL	DEVICE EXAMPLES
A	Low Individual Risk and Low Public Health Risk	Clinical Chemistry Analyser , prepared selective culture media
B	Moderate Individual Risk and/or Low Public Health Risk	Vitamin B12, Pregnancy self testing, Anti-Nuclear Antibody, Urine test strips
C	High Individual Risk and/or Moderate Public Health Risk	Blood glucose self-testing, HLA typing, PSA screening, Rubella
D	High Individual Risk and High Public Health Risk	HIV Blood donor screening, HIV Blood diagnostic

The Determination of Device Class for IVD's

Where more than one of the classification rules applies to the IVD medical device, it should be allocated to the highest class indicated, e.g. a self-testing for HIV would be a class D under rule 1 and not a class C under rule 4.

Classification Rules

Rule 1: IVD medical devices intended for the following purposes are classified as Class D:

- Devices intended to be used to detect the presence of, or exposure to, a transmissible agent in blood, blood components, blood derivatives, cells, tissues or organs in order to assess their suitability for transfusion or transplantation, or
- Devices intended to be used to detect the presence of, or exposure to, a transmissible agent that causes a life-threatening, often incurable, disease with a high risk of propagation

Rationale: Devices in this Class are intended to be used to ensure the safety of blood and blood components for transfusion and/or cells, tissues and organs for transplantation. In most cases, the result of the test is the major determinant as to whether the donation/ product will be used. Serious diseases are those that result in death or long-term disability, that are often incurable or require major therapeutic interventions and where an accurate diagnosis is vital to mitigate the public health impact of the condition

Examples: Tests to detect infection by HIV, HCV, HBV, HTLV. This Rule applies to first-line assays, confirmatory assays and supplemental assays.

Rule 2: IVD medical devices intended to be used for blood grouping, or tissue typing to ensure the immunological compatibility of blood, blood components, cells, tissue or organs that are intended for transfusion or transplantation, are classified as Class C, except for ABO system [A (ABO1), B (ABO2), AB (ABO3)], rhesus system [RH1 (D), RH2 (C), RH3 (E), RH4 (c), RH5 (e)], Kell system [Kel1 (K)], Kidd system [JK1 (Jka), JK2 (Jkb)] and Duffy system [FY1 (Fya), FY2 (Fyb)] determinations which are classified as Class D.

Rationale: The application of this rule as defined above should be in accordance with the rationale for this rule which is as follows: A high individual risk, where an erroneous result would put the patient in an imminent life-threatening situation places the device into Class D. The rule divides blood grouping devices into two subsets, Class C or D, depending on the nature of the blood group antigen the IVD medical device is designed to detect, and its importance in a transfusion setting.

Examples: HLA, Duffy system (other Duffy systems except those listed in the rule as Class D are in Class C).

Rule 3: IVD medical devices are classified as Class C if they are intended for use:

- in detecting the presence of, or exposure to, a sexually transmitted agent. Examples: Sexually transmitted diseases, such as *Chlamydia trachomatis*, *Neisseria gonorrhoeae*.
- in detecting the presence in cerebrospinal fluid or blood of an infectious agent with a risk of limited propagation. Examples: *Neisseria meningitidis* or *Cryptococcus neoformans.*
- in detecting the presence of an infectious agent where there is a significant risk that an erroneous result would cause death or severe disability to the individual or fetus being tested. Examples: diagnostic assay for CMV, *Chlamydia pneumoniae*, Methycillin Resistant *Staphylococcus aureus*.
- in pre-natal screening of women in order to determine their immune status towards transmissible agents. Examples: Immune status tests for Rubella or Toxoplasmosis.
- in determining infective disease status or immune status, and where there is a risk that an erroneous result will lead to a patient management decision resulting in an imminent life-

threatening situation for the patient. Examples: Enteroviruses, CMV and HSV in transplant patients.

- in screening for selection of patients for selective therapy and management, or for or for disease staging, or in the diagnosis of cancer. Example: personalized medicine.
- in human genetic testing. Examples: Huntington's Disease, Cystic Fibrosis.
- to monitor levels of medicines, substances or biological components, when there is a risk that an erroneous result will lead to a patient management decision resulting in an immediate life-threatening situation for the patient. Examples: Cardiac markers, Cyclosporin, Prothrombin time testing.
- In the management of patients suffering from a life-threatening infectious disease. Examples: HCV viral load, HIV Viral Load and HIV and HCV geno- and subtyping.
- In screening for congenital disorders in the fetus. Examples: Spina Bifida or Down Syndrome.

Rationale: The application of this rule as defined above should be in accordance with the rationale for this rule which is as follows: Devices in this Class present a moderate public health risk, or a high individual risk, where an erroneous result would put the patient in an imminent life-threatening situation, or would have a major negative impact on outcome. The devices provide the critical, or sole, determinant for the correct diagnosis. They may also present a high individual risk because of the stress and anxiety resulting from the information and the nature of the possible follow-up measures.

Rule 4: IVD medical devices intended for self-testing are classified as Class C, except those devices from which the result is not determining a medically critical status, or is preliminary and requires follow-up with the appropriate laboratory test in which case they are Class B.

IVD medical devices intended for blood gases and blood glucose determinations for near-patient testing would be Class C. Other IVD medical devices that are intended for near-patient should be classified in their own right using the classification rules.

Rationale: The application of this rule as defined above should be in accordance with the rationale for this rule which is as follows: In general, these devices are used by individuals with no technical expertise and thus the labelling and instructions for use are critical to the proper outcome of the test.

Example for self-testing class C: Blood glucose monitoring,

Example for self-testing class B: Pregnancy self test, Fertility testing, Urine test-strips.

Rule 5: The following IVD medical devices are classified as Class A:

- Reagents or other articles which possess specific characteristics, intended by the manufacturer to make them suitable for in vitro diagnostic procedures related to a specific examination.
- Instruments intended by the manufacturer specifically to be used for in vitro diagnostic procedures

- Specimen receptacles

Rationale: The application of this rule as defined above should be in accordance with the rationale for this rule which is as follows: These devices present a low individual risk and no or minimal public health risk.

Examples: Selective/differential microbiological media (excluding the dehydrated powders which are considered not to be a finished IVD medical device), identification kits for cultured microorganisms, wash solutions, instruments and plain urine cup.

Rule 6: IVD medical devices not covered in Rules 1 through 5 are classified as Class B.

Rationale: The application of this rule as defined above should be in accordance with the rationale for this rule which is as follows: These devices present a moderate individual risk as they are not likely to lead to an erroneous result that would cause death or severe disability, have a major negative impact on patient outcome or put the individual in immediate danger. The devices give results that are usually one of several determinants. If the test result is the sole determinant however other information is available, such as presenting signs and symptoms or other clinical information which may guide a physician, such that classification into Class B may be justified. Other appropriate controls may also be in place to validate the results. This Class also includes those devices that present a low public health risk because they detect infectious agents that are not easily propagated in a population.

Examples: Blood gases, *H. pylori* and physiological markers such as hormones, vitamins, enzymes, metabolic markers, specific IgE assays and celiac disease markers.

Rule 7: IVD medical devices that are controls without a quantitative or qualitative assigned value will be classified as Class B.

Rationale: For such controls, the qualitative or quantitative value is assigned by the user and not the manufacturer.

When a deviation from a guideline is decided on, a detailed motivation giving the reason(s) for the deviation and justification for the alternative approach should be included in the expert report submitted with the application for the consideration and authentication of the MDR Division.