

MDS – G42

Guidance on Medical Devices Classification



Version Number: 1.0
Version Date: 27/11/2019

Table of Content

Purpose.....	3
Scope.....	3
Guidance.....	4
Revision history	61



Introduction

1 Purpose

The purpose of this guidance is to help medical device manufacturers to correctly classify their devices in KSA.

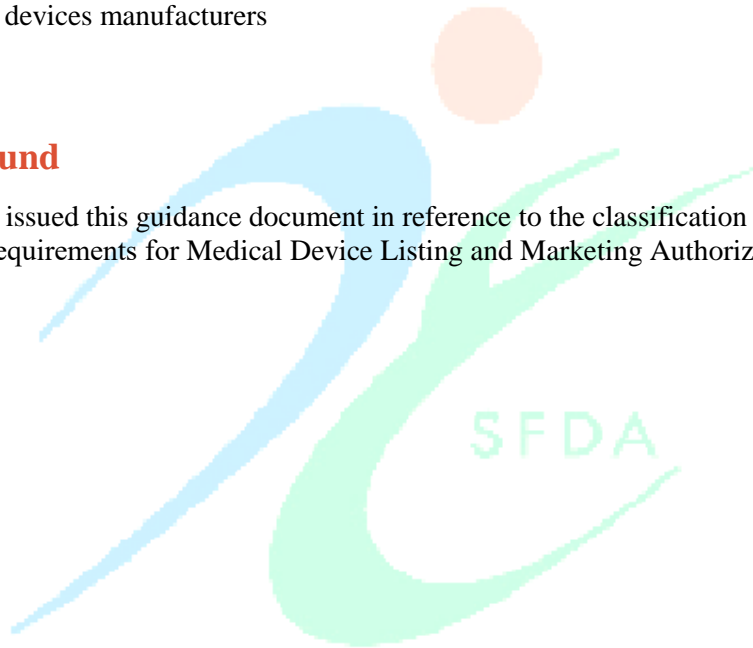
2 Scope

This guidance applies to the following products and parties:

- Medical devices and in-vitro medical devices (IVD)
- Medical devices manufacturers

3 Background

SFDA/MDS has issued this guidance document in reference to the classification rules specified in “Guidance on Requirements for Medical Device Listing and Marketing Authorization (MDS – G5)”.



4 Classification Guidance

4.1 General

The medical devices regulatory framework has a classification system for medical devices as per the classification rules specified in guidance document “Guidance on Requirements for Medical Device Listing and Marketing Authorization (MDS – G5)”

Table 1 - The classification levels for devices other than IVD Medical Devices

Classification level	Level of risk
Class A	Low
Class A – supplied sterile	Low-medium
Class A – incorporating a measuring function	Low-medium
Class A – reusable surgical instruments	Low-medium
Class B	Low-medium
Class C	Medium-high
Class D	High

The manufacturer is responsible for determining the classification of a device using a set of classification rules based on the:

- manufacturer’s intended use of the device
- level of risk to patients, users and other persons (the probability of occurrence of harm and the severity of that harm)
- degree of invasiveness in the human body
- duration of use

Identical devices may be classified differently if they are to be used in different parts of the body. Therefore, the manufacturer’s intended use of the device is critical to determining the appropriate classification. The intended use can be obtained from the:

- Instructions for Use (IFU)
- Label
- Manufacturer’s advertising materials
- Technical documentation

In addition to the devices meeting the definitions for medical devices and IVD medical devices per Medical Devices Interim Regulation, the devices covered in Table 2 below shall also be classified using the classification rules for medical devices.

Table 2 - Groups of products without an intended medical purpose

#	Product description
1	Contact lenses or other items intended to be introduced into or onto the eye.
2	Products intended to be totally or partially introduced into the human body through surgically invasive means for the purpose of modifying the anatomy or fixation of body parts with the exception of tattooing products and piercings.
3	Substances, combinations of substances, or items intended to be used for facial or other dermal or mucous membrane filling by subcutaneous, submucous or intradermal injection or other introduction, excluding those for tattooing.
4	Equipment intended to be used to reduce, remove or destroy adipose tissue, such as equipment for liposuction, lipolysis or lipoplasty.
5	High intensity electromagnetic radiation (e.g. infra-red, visible light and ultra-violet) emitting equipment intended for use on the human body, including coherent and non-coherent sources, monochromatic and broad spectrum, such as lasers and intense pulsed light equipment, for skin resurfacing, tattoo or hair removal or other skin treatment.
6	Equipment intended for brain stimulation that apply electrical currents or magnetic or electromagnetic fields that penetrate the cranium to modify neuronal activity in the brain.

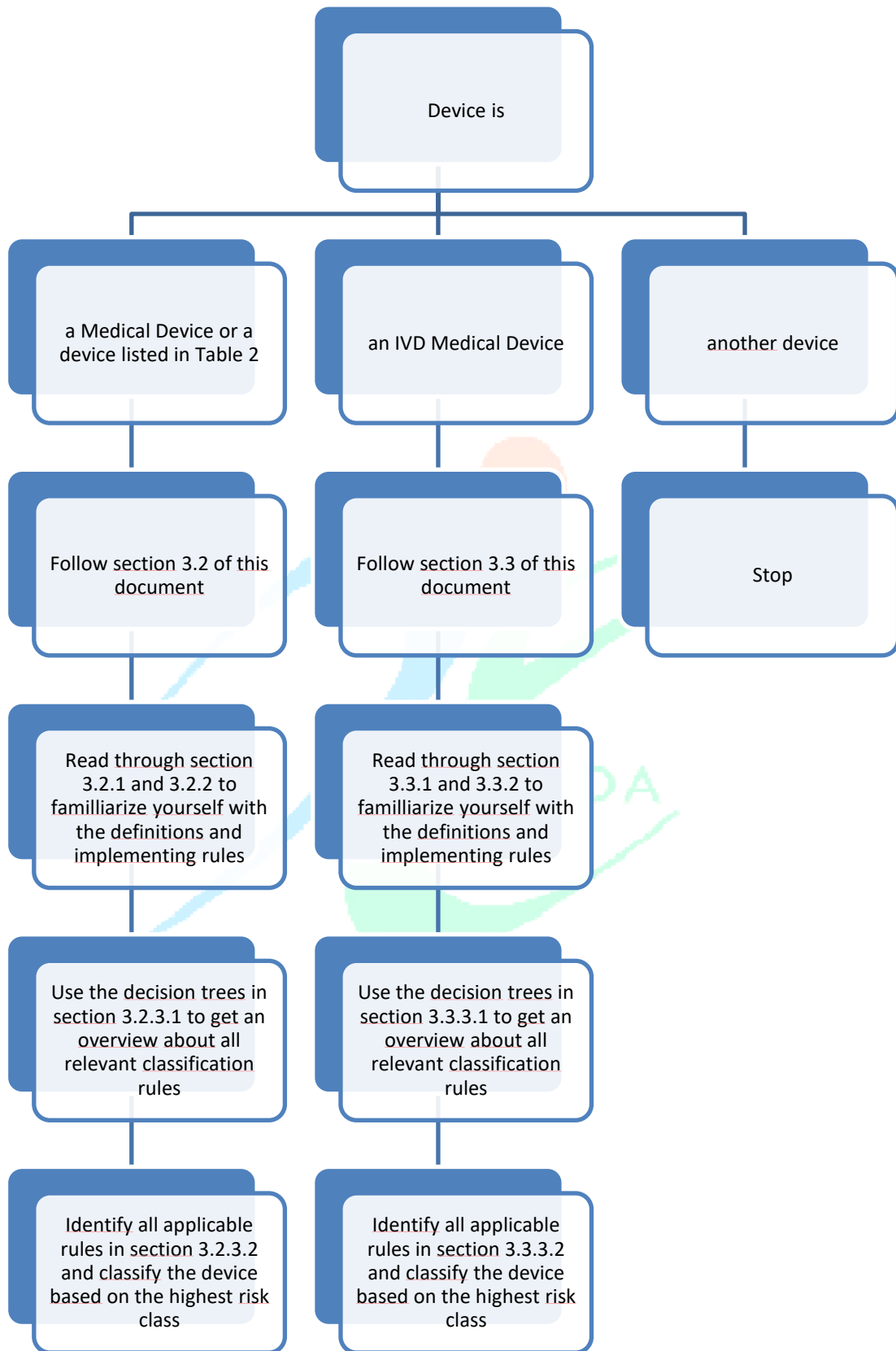
Table 3 - The classification levels IVD Medical Devices

Classification	Level of risk
Class A	Low Individual Risk and Low Public Health Risk
Class B	Moderate Individual Risk and/or Low Public Health Risk
Class C	High Individual Risk and/or Moderate Public Health Risk
Class D	High Individual Risk and High Public Health Risk

The manufacturer is responsible for determining the class of the IVD by:

- Using the classification rules for IVD medical devices, and
- Considering both the:
 - Intended use of the device,
 - Level of risk to the patient and public of an incorrect result.

Figure 1 - Classification process



4.2 Medical devices and devices without an intended medical purpose

The classification rules are based on different criteria such as the duration of contact with the patient, the degree of invasiveness and the part of the body affected by the use of the device. The implementing rules and related definitions are reproduced below, together with some additional guidance.

4.2.1 Definitions related to classification

4.2.1.1 Duration of use

‘Transient’ means normally intended for continuous use for less than 60 minutes.

‘Short term’ means normally intended for continuous use for between 60 minutes and 30 days.

‘Long term’ means normally intended for continuous use for more than 30 days.

In certain instances, the duration of effect for a product needs to be considered as the duration of use. For instance, application of a topical cream to the skin may only take seconds to apply but the cream may remain in situ for many hours. The duration of use should therefore not be considered as the time taken to apply the product but rather the duration for which the product achieves its intended purpose. Refer to section 5.2.2.6 for guidance on continued use.

4.2.1.2 Invasive and active devices

‘Body orifice’ means any natural opening in the body, as well as the external surface of the eyeball, or any permanent artificial opening, such as a stoma.

Natural openings in the body can be considered as: Nostrils (nasal cavity), mouth (oral cavity), ear canal, anus, urinary meatus and vagina.

‘Invasive device’ means any device which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body.

‘Surgically invasive device’ means:

- *an invasive device which penetrates inside the body through the surface of the body, including through mucous membranes of body orifices with the aid or in the context of a surgical operation; and*
- *a device which produces penetration other than through a body orifice.*

The term surgical operation used in this definition includes all clinical interventional procedures in which a device is placed into the body through the surface in the context of a surgical operation or other clinical procedure.

In this context it should be noted the following:

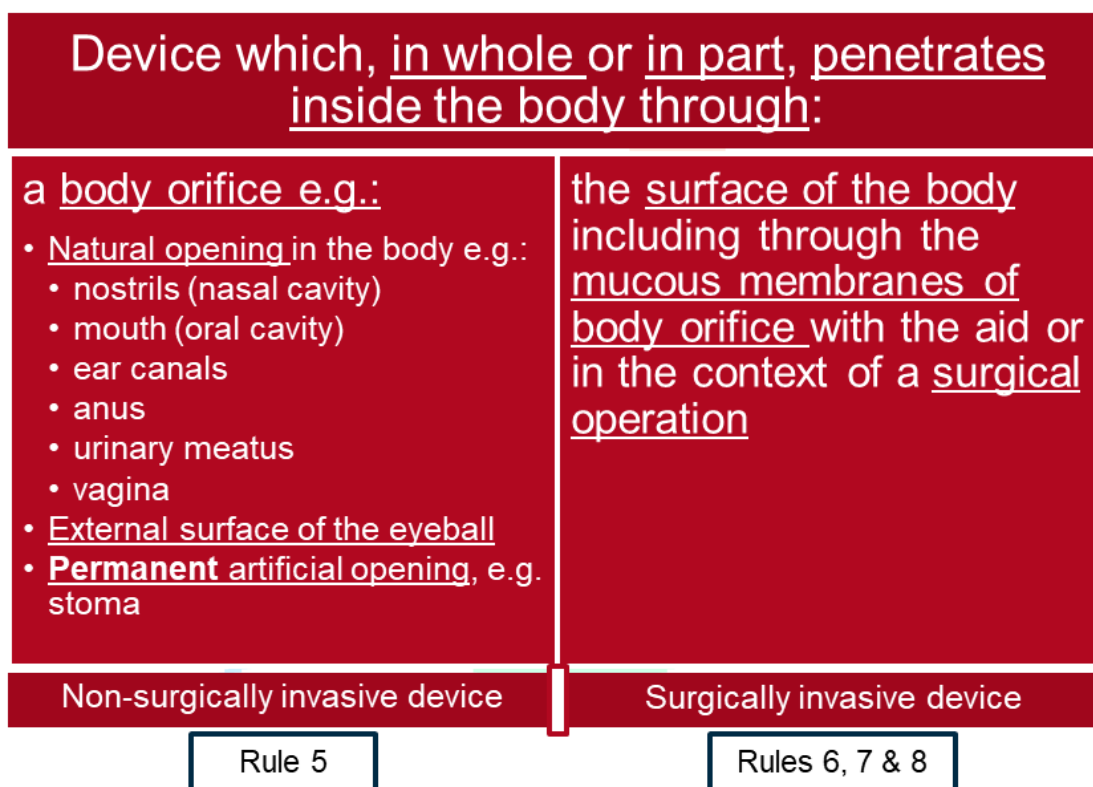
- A surgically created stoma used in urostomy, colostomy and ileostomy or permanent tracheostomy is considered to be a body orifice. Therefore, devices introduced into such a stoma are not surgically invasive. A surgically created opening to allow access to the circulatory system in contrast should not be considered to be such a "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 must be classified. However, if a

device administers a substance, whether this substance is a medicine or a medical device, such a substance must be assessed in its own right (e.g. substances administered by a jet injector).

Any device which, in whole or in part, penetrates inside the body, either through a natural body orifice or through the surface of the body is an invasive device. A surgically invasive device always implies that it 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.

The concept of surgically invasive should be understood as covering also liquids that are in invasive contact with organs, tissue or other parts of the body if the access for such liquids is through a surgically created opening.

Figure 2 - Difference between non-surgically and surgically invasive devices



‘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
- to replace the surface of the eye,

by clinical intervention and which is intended to remain in place after the procedure.

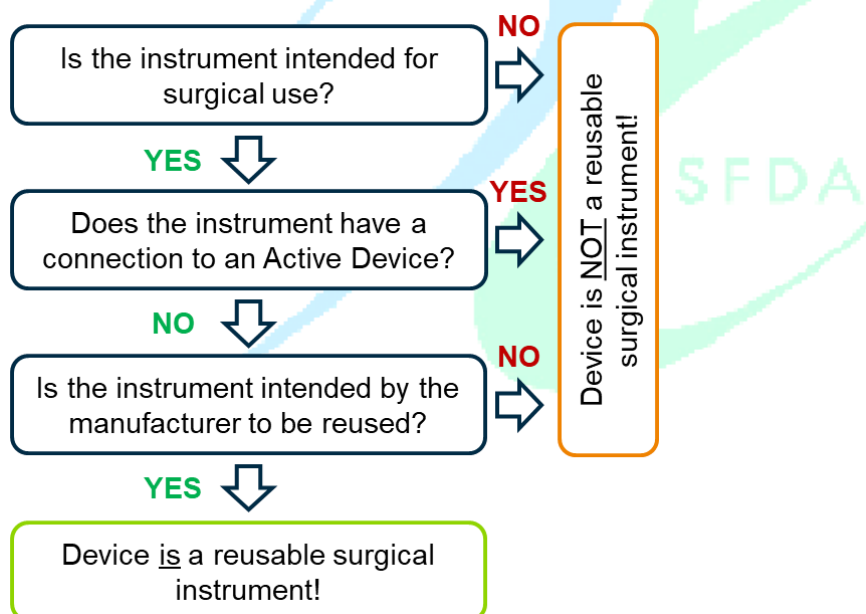
Any device intended to be partially introduced into the human body by clinical intervention and intended to remain in place after the procedure for at least 30 days shall also be deemed to be an implantable device;

One of the key elements in defining an implantable device is the concept of "procedure". Thus, an implantable device must remain in the patient after the procedure. A "procedure" must be understood in this context to include the surgical procedure during which the implant is placed into the body and the immediate post-operative care that is associated with the procedure. The "procedure" does not extend to the conclusion of the therapeutic treatment, e.g. the removal of an implant must be considered to be another "procedure". Thus, a plate used to reduce a fracture of the bone is an implant even if it is taken out after the fracture has healed. In this case the placing of the plate and its explanations are two different surgical procedures.

Some partially implanted devices are deemed to be implants. For instance, if an operation is carried out specifically to place an infusion port into the body, then such an infusion port would remain for at least 30 days after the procedure and consequently be an implant. However, a non-tunnelled central venous catheter which is intended for use for temporary vascular access and intended to be removed after 7 – 10 days is not a long-term implantable device. Nor would a suture used for skin wound closure that is taken out prior to 30 days be considered an implant.

***‘Reusable surgical instrument’** means an instrument intended for surgical use in cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar procedures, without a connection to an active device and which is intended by the manufacturer to be reused after appropriate procedures such as cleaning, disinfection and sterilization have been carried out.*

Figure 3 - Decision tree for reusable surgical instruments



***‘Active device’** means any device, the operation of which depends on a source of energy other than that generated by the human body for that purpose, or by gravity, and which acts by changing the density of or converting that energy.*

Devices intended to transmit energy, substances or other elements between an active device and the patient, without any significant change, shall not be deemed to be active devices.

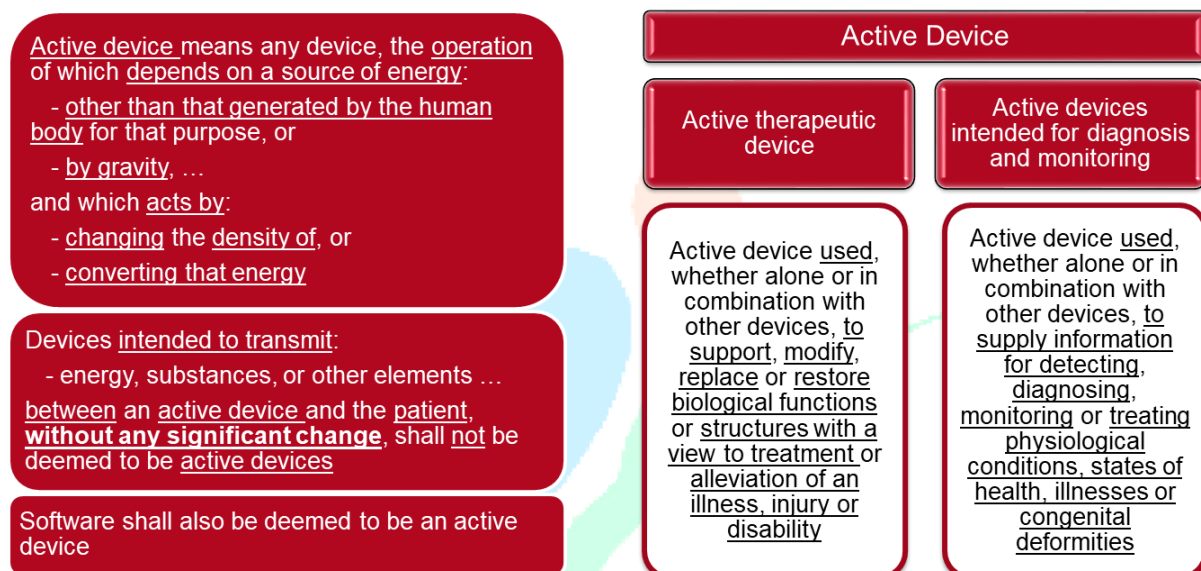
Software shall also be deemed to be an active device.

The following forms of energy can be considered: thermal, mechanical, electrical, radiant, nuclear, chemical, elastic, magnetic, light, sound, etc.

‘Active therapeutic device’ means any active device used, whether alone or in combination with other devices, to support, modify, replace or restore biological functions or structures with a view to treatment or alleviation of an illness, injury or disability.

‘Active device intended for diagnosis and monitoring’ means any active device used, whether alone or in combination with other devices, to supply information for detecting, diagnosing, monitoring or treating physiological conditions, states of health, illnesses or congenital deformities.

Figure 4 - Overview active devices, active therapeutic devices and active devices intended for diagnosis & monitoring



‘Central circulatory system’ means the following blood vessels: arteriae pulmonales, aorta ascendens, arcus aortae, aorta descendens to the bifurcatio aortae, arteriae coronariae, arteria carotis communis, arteria carotis externa, arteria carotis interna, arteriae cerebrales, truncus brachiocephalicus, venae cordis, venae pulmonales, vena cava superior and vena cava inferior.

‘Central nervous system’ means the brain, meninges and spinal cord.

‘Injured skin or mucous membrane’ means an area of skin or a mucous membrane presenting a pathological change or change following disease or a wound.

4.2.1.3 Others

‘Non-viable’ means having no potential for metabolism or multiplication.

‘Derivative’ means a ‘non-cellular substance’ extracted from human or animal tissue or cells through a manufacturing process. The final substance used for manufacturing of the device in this case does not contain any cells or tissues.

‘Nanomaterial’ means a natural, incidental or manufactured material containing particles in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1-100 nm. Fullerenes, graphene flakes and single-wall carbon nanotubes with one or more external dimensions below 1 nm shall also be deemed to be nanomaterials.

‘Particle’, for the purposes of the definition of nanomaterial, means a minute piece of matter with defined physical boundaries.

‘Agglomerate’, for the purposes of the definition of nanomaterial, means a collection of weakly bound particles or aggregates where the resulting external surface area is similar to the sum of the surface areas of the individual components.

‘Aggregate’, for the purposes of the definition of nanomaterial, means a particle comprising of strongly bound or fused particles.

‘Serious deterioration in state of health’ means any of the following:

- life-threatening illness or injury,
- permanent impairment of a body structure or a body function,
- hospitalisation or prolongation of patient hospitalisation,
- medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function,
- chronic disease

4.2.2 Implementing rules

4.2.2.1 Intended purpose

Application of the classification rules shall be governed by the intended purpose of the devices.

It is the intended purpose/use that determines the class of the device and not the particular technical characteristics of the device, unless these have a direct bearing on the intended purpose. e.g. incorporation of an ancillary substance, tissue of animal origin etc.

It is the intended and not the accidental use of the device that determines the class of the device. For instance, a suture organizer, that is intended to keep order of suture threads used in open heart surgery, should not be considered as an invasive device if in the normal use it can be kept outside the patient. Similarly, if a medical practitioner uses the device in a manner not intended by the manufacturer, this does not change the class of the device for the purpose of conformity assessment. However, if the normal clinical use of the device changes in time with evolving clinical practice such that the intended purpose and classification of the device changes this should be addressed by the manufacturer and the conformity of the device assessed for the new intended purpose.

It is the intended purpose assigned by the manufacturer to the device that determines the class of the device and not the class assigned to other similar products. For instance, two sutures that have the same composition may well have different intended purposes.

For a device to be "intended specifically" for the purpose referenced in a particular classification rule, the manufacturer must clearly indicate that the device is intended for such a specific purpose in the information accompanying the device. Otherwise it is deemed to have the intended use which is principally used and accepted in general medical practice. Only the following rules use the term "intended specifically": Rules 6, 7, 10, 16 and 17.

4.2.2.2 Combination with another device and accessories

If the device in question is intended to be used in combination with another device, the classification rules shall apply separately to each of the devices. Accessories for a medical device and for a product

listed in Table 2 shall be classified in their own right separately from the device with which they are used.

Systems may be classified as a whole based on their intended use. As an alternative to classifying the system as a whole, the determination of the class of a particular device may be made with respect to the simplest configuration that can still be considered, in view of its proper functional features, as a device in its own right. A device that is part of a system, e.g. a tube in an extra corporeal circulation set, may be classed as a device in its own right rather than classifying the system as a whole. The device, however, must be cleared in its own right as a separate device in such instances.

Similarly, combined devices with parts that have different functional purposes may be analysed separately with respect to each of these parts. For instance, a drainage device will have an invasive tube and a non-invasive collection device. These components may be classified separately, provided that they are also cleared separately.

Figure 5 - Options for classifying a simple wound drainage device

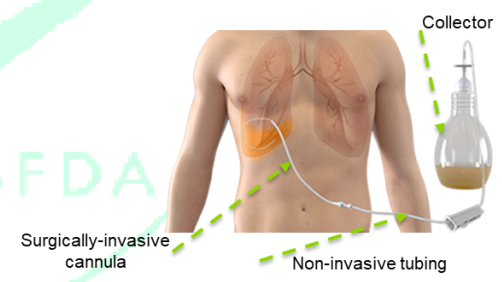
A simple wound drainage device has three components that must be taken into consideration: the cannula, the tubing and the collector unit.

If the device is sold without a cannula, then the classification of the cannula does not need to be taken into account.

Assumptions:

- short term use (60 min > t < 30 days)
- collected liquids are not intended to be reinfused into the body nor reprocessed for eventual reinfusion

Intended uses	Rule	Class
Surgically invasive cannula to reach a wound site in the pleural cavity to drain the cavity	7	B
Non-invasive tubing to evacuate body liquids towards the collector	1	A
Non-invasive collector to receive the body liquids	1	A



SFDA

The clear conclusion here is that the manufacturer would have a choice of applying:

- Class B to the whole device or
- Carrying out separate conformity assessment procedures for the cannula on one hand and the tubing and collector on the other hand.

4.2.2.3 Software

Software, which drives a device or influences the use of a device, shall fall within the same class as the device. If the software is independent of any other device, it shall be classified in its own right.

4.2.2.4 Parts of the body

If the device is not intended to be used solely or principally in a specific part of the body, it shall be considered and classified on the basis of the most critical specified use.

Classification of the device will have to be determined on the basis of claims contained in the information provided with the device. The manufacturer must be sufficiently specific in that regard. If the manufacturer wants to avoid the particular higher classification, then it must clearly define on the labelling the intended purpose in such a way that the device falls into the lower class. The manufacturer must provide as a minimum requirement either appropriate positive or negative indications for use. For example, a catheter could be used within the central circulatory system, however an explicit exclusion must be documented in the intended use to ensure it would not be classified in the higher class.

4.2.2.5 Devices falling into several (sub-) rules

If several rules, or if, within the same rule, several sub-rules, apply to the same device based on the device's intended purpose, the strictest rule and sub-rule resulting in the higher classification shall apply.

For instance, a wound dressing incorporating collagen is covered by rules 4 (Class A, Class B or Class C depending on intended use) and 18 (Class D), therefore the higher classification (Class D) would apply. All rules must be considered, for instance if an active device is also surgically invasive, the relevant rules for surgically invasive devices must also be considered.

4.2.2.6 Concept of continuous use

In calculating the duration referred to in Section 5.2.1.1, continuous use shall mean:

- a) the entire duration of use of the same device without regard to temporary interruption of use during a procedure or temporary removal for purposes such as cleaning or disinfection of the device. Whether the interruption of use or the removal is temporary shall be established in relation to the duration of the use prior to and after the period when the use is interrupted or the device removed; and*
- b) the accumulated use of a device that is intended by the manufacturer to be replaced immediately with another of the same type.*

For example, a scalpel may be used on the same patient throughout an operation that may last for several hours. The uninterrupted use for an intended purpose, i.e. cutting tissue, will normally not last for more than a few seconds at a time. Therefore, a scalpel is a transient use device.

However, where usage of a device is discontinued in order for the device to be replaced immediately by the same or an identical device (e.g. replacement of a ureteric catheter) this shall be considered an extension of the continuous use of the device.

If it cannot be demonstrated that components of the device are totally eliminated in the interval between uses, this is also considered as an immediate replacement.

4.2.2.7 Devices allowing direct diagnosis

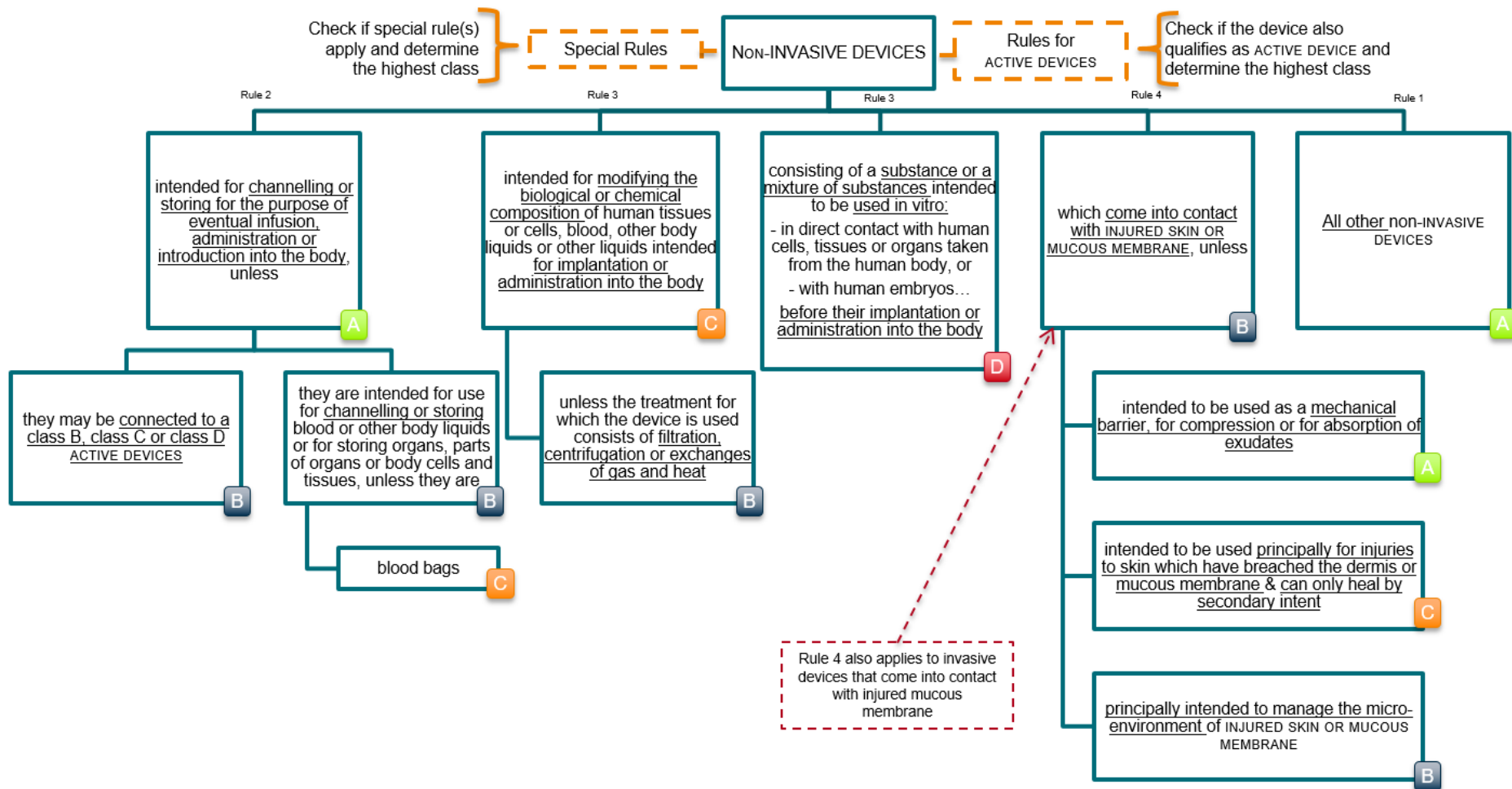
A device is considered to allow direct diagnosis when it provides the diagnosis of the disease or condition in question by itself or when it provides decisive information for the diagnosis.

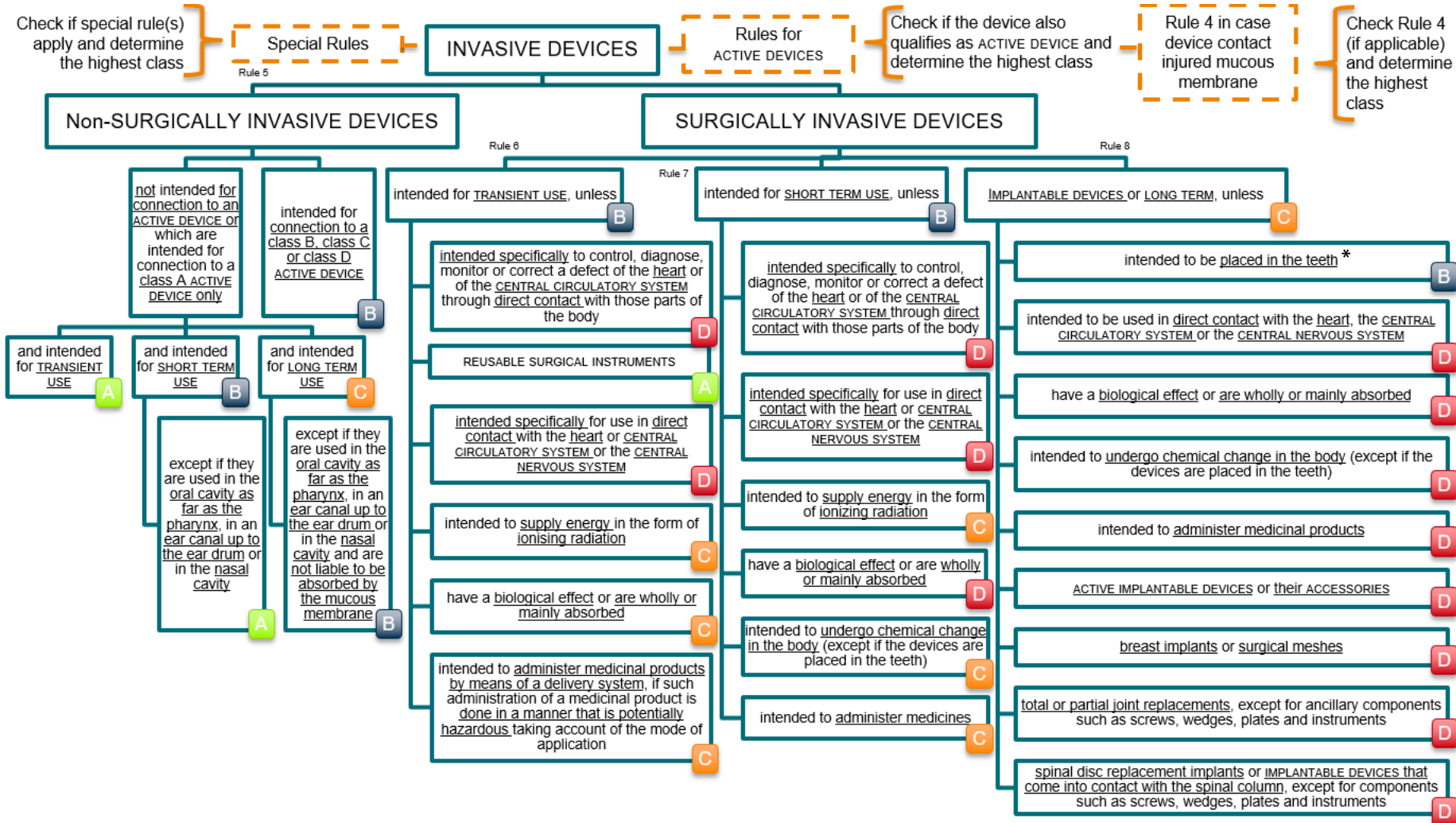
4.2.3 Explanation of the individual rules

The explanations are given in the following manner. This section begins with a graphical summary of the rules, as a preface to subsections on the individual rules. Each subsection starts with a general explanation of the rule followed by a tabular presentation of the rule and examples of devices to which it applies. Any special terms used are explained and practical issues related to the rule are clarified. It must be emphasized that even if a particular device type is given as an example, this does not mean that such devices are in all cases in the class indicated by the example. It is always possible that some manufacturer will assign to such a device an entirely different intended use than what was used in the context of the example.

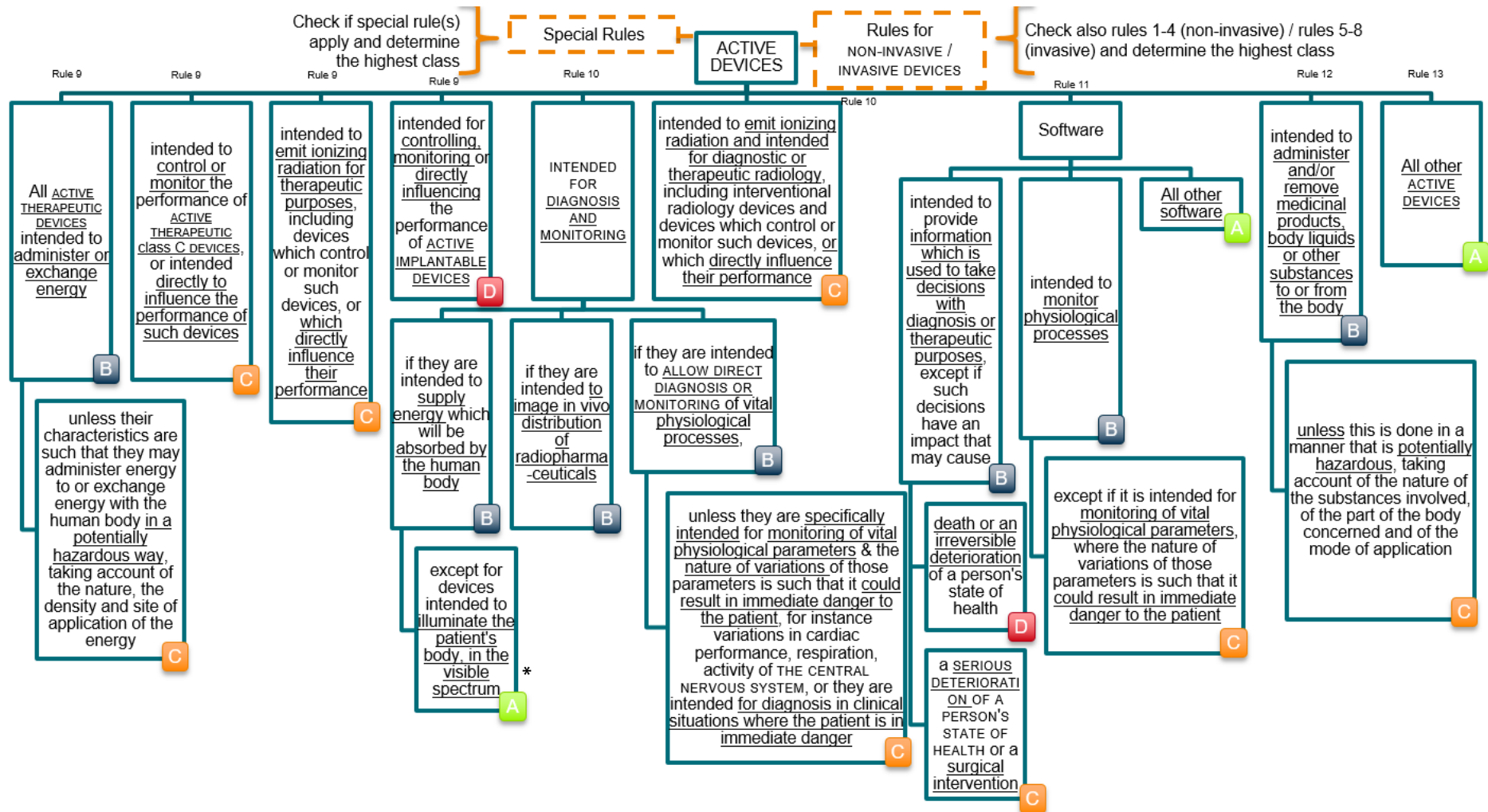
4.2.3.1 Classification guidance chart for initial identification of probable device class

Always confirm definitive classification by reading all rules in detail, and utilize additional assistance in this guidelines document as provided in the form of general explanations of rules and examples of devices.

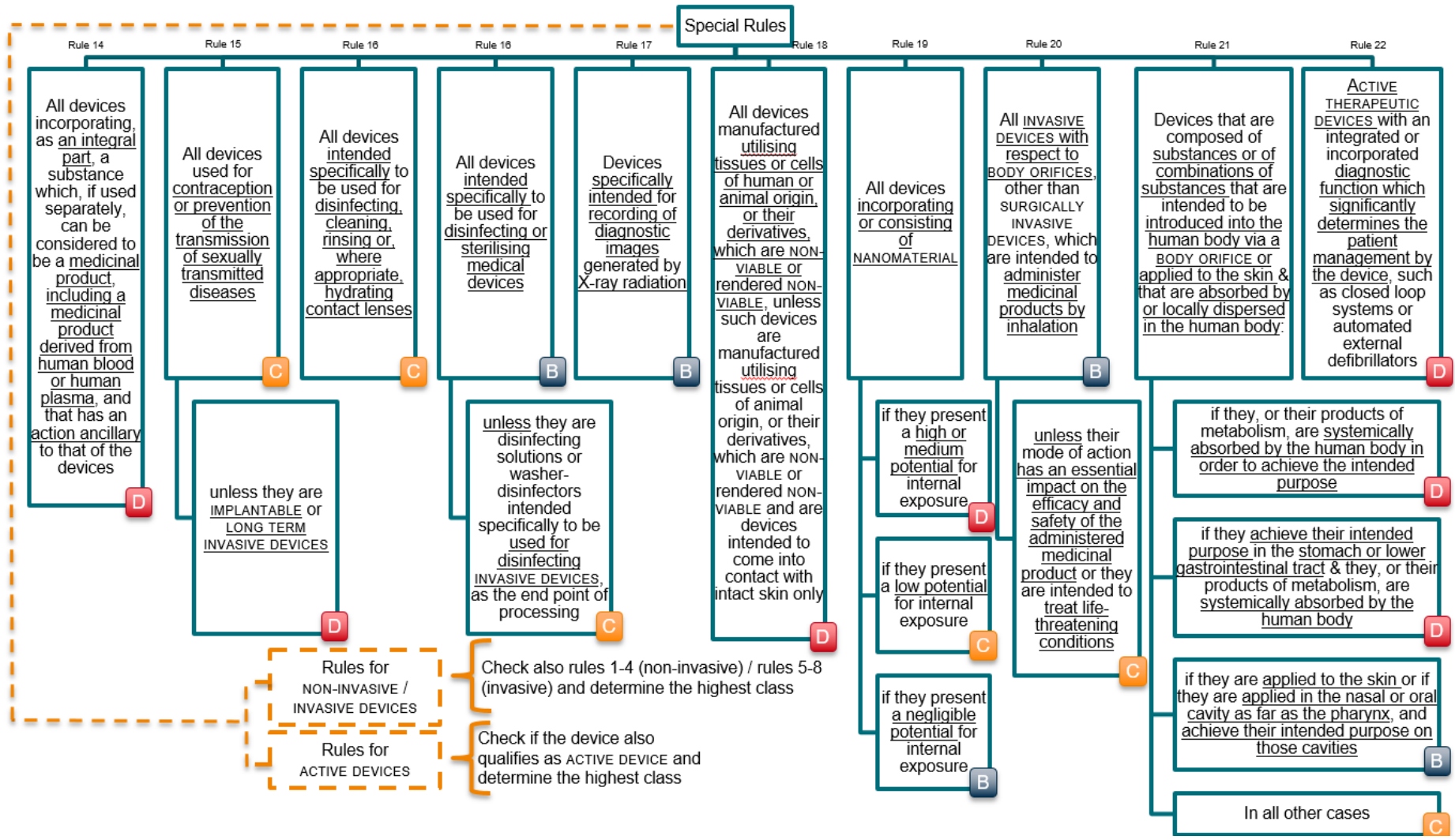




* or prepared tooth structure



* or near infra-red spectrum



4.2.3.2 General explanation of rules, practical issues and examples

4.2.3.2.1 Rule 1

This is a fallback rule applying to all devices that are not covered by a more specific rule.

This is a rule that applies in general to devices that come into contact only with intact skin or that do not touch the patient.

Some non-invasive devices are indirectly in contact with the body and can influence internal physiological processes by storing, channeling or treating blood, other body liquids or liquids which are returned or infused into the body or by generating energy that is delivered to the body. These must be excluded from the application of this Rule and be handled by another rule because of the hazards inherent in such indirect influence on the body.

RULE 1	Description & examples
All non-invasive devices are classified as class A, unless one of the rules set out hereinafter applies.	<ul style="list-style-type: none">• Body liquid collection devices intended to be used in such a way that a return flow is unlikely (e.g. to collect body wastes such as urine collection bottles, ostomy pouches, incontinence pads or collectors used with wound drainage devices). They may be connected to the patient by means of catheters and tubing• Devices used to immobilise body parts and/or to apply force or compression on them (e.g. non-sterile dressings used to aid the healing of a sprain, plaster of Paris, cervical collars, gravity traction devices, compression hosiery)• Devices intended in general for external patient support (e.g. hospital beds, patient hoists, walking aids, wheelchairs, stretchers, dental patient chairs)• Corrective glasses and frames• Stethoscopes for diagnosis• Eye occlusion plasters• Incision drapes• Conductive gels• Non-invasive electrodes (electrodes for EEG or ECG)• Image intensifying screens• Permanent magnets for removal of ocular debris• 3D printed surgical models used for treatment planning which are NOT placed in contact with the patient.

4.2.3.2.2 Rule 2

These types of devices must be considered separately from the non-contact devices of rule 1 because they may be indirectly invasive. They channel or store substances that will eventually be administered to the body. Typically, these devices are used in transfusion, infusion, extracorporeal circulation and delivery of anaesthetic gases and oxygen.

In some cases, devices covered under this rule are very simple gravity activated delivery devices.

If a device, e.g. tubing, can be used for a purpose that would cause it to be connected to an active device such a device will be automatically in Class B, unless the manufacturer clearly state that it should not be connected to an active device of Class B or higher.

RULE 2	Description & examples
<p>All non-invasive devices intended for channeling 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 B:</p> <p>a) If they may be connected¹ to a class B, class C or class D active device;</p> <p>b) If they are intended for use for channeling or storing blood or other body liquids or for storing organs, parts of organs or body cells and tissues,</p>	<ul style="list-style-type: none"> • Devices intended to be used as channels in active drug delivery systems, e.g. tubing intended for use with an infusion pump • Devices used for channeling, e.g. antistatic tubing for anaesthesia, anaesthesia breathing circuits, pressure indicator, pressure limiting devices, oxygen tubing and masks • Syringes & tubing for infusion pumps
<p>Except for blood bags; blood bags are classified as class C.</p> <p>In all other cases, such devices are classified as class A.</p>	<ul style="list-style-type: none"> • Devices intended to channel blood (e.g. in transfusion, extracorporeal circulation) • Devices intended for temporary storage and transport of organs for transplantation (i.e. containers, bags and similar products) • Devices intended for long term storage of biological substances and tissues such as corneas, sperm, human embryos, etc. (i.e. containers, bags and similar products) • Fridges specifically intended for storing blood , tissues etc.
	<p>Blood bags</p> <ul style="list-style-type: none"> • Devices that provide a simple channeling function, with gravity providing the force to transport the liquid, e.g. administration sets for infusion • Devices intended to be used for a temporary containment or storage function, e.g. cups and spoons specifically intended for administering medicines • Syringes without needles

¹ "May be connected to an active device". Such a connection is deemed to exist between a non-active device and an active device where the non-active device forms a link in the transfer of the substance between the patient and the active device and the safety and performance of one of the devices is influenced by the other device. For instance, this applies to tubing in an extracorporeal circulation system which is downstream from a blood pump and in the same blood flow circuit, but not directly in contact with the pump.

4.2.3.2.3 Rule 3

These types of devices must be considered separately from the non-contact devices of Rule 1 because they are indirectly invasive. They modify substances that will eventually be infused into the body. This rule covers mostly the more sophisticated elements of extracorporeal circulation sets, dialysis systems and autotransfusion systems as well as devices for extracorporeal treatment of body fluids which may or may not be immediately reintroduced into the body, including, where the patient is not in a closed loop with the device.

These devices are normally used in conjunction with an active medical device covered under Rule 9 or Rule 12. Filtration and centrifugation should be understood in the context of this rule as exclusively mechanical methods.

RULE 3	Description & examples
<p>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 C,</p>	<ul style="list-style-type: none"> • Devices intended to remove undesirable substances out of the blood by exchange of solutes such as hemodialysers • Devices intended to separate cells by physical means, e.g. gradient medium for sperm separation • Haemodialysis concentrates
<p>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 B.</p>	<ul style="list-style-type: none"> • Particulate filtration of blood in an extracorporeal circulation system. These are used to remove particles and emboli from the blood • Centrifugation of blood to prepare it for transfusion or autotransfusion • Removal of carbon dioxide from the blood and/or adding oxygen • Warming or cooling the blood in an extracorporeal circulation system
<p>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 D.</p>	<ul style="list-style-type: none"> • Devices for processing and preservation of human cells, tissues and organs • Some agents for transport, nutrition and storage of organs intended for transplantation may be qualified and regulated as medical devices provided that they meet the definition of a medical device, taking into consideration the principal intended action and intended purpose of the product • Media intended for use in the IVF / ART process to support the growth / storage of the embryo

4.2.3.2.4 Rule 4

This rule is intended to primarily cover wound dressings independently of the depth of the wound. The traditional types of products, such as those used as a mechanical barrier, are well understood and do not result in any great hazard. There have also been rapid technological developments in this area, with the emergence of new types of wound dressings for which non-traditional claims are made, e.g. management of the micro-environment of a wound to enhance its natural healing mechanism.

More ambitious claims relate to the mechanism of healing by secondary intent, such as influencing the underlying mechanisms of granulation or epithelial formation or preventing contraction of the wound. Some devices used on breached dermis may even have a life-sustaining or lifesaving purpose, e.g. when there is full thickness destruction of the skin over a large area and/or systemic effect.

Dressings containing medicinal products which act ancillary to the dressing fall within Class D under Rule 14.

Products covered under this rule are extremely claim sensitive, e.g. a polymeric film dressing would be in Class B if the intended use is to manage the micro-environment of the wound or in Class A if its intended use is limited to retaining an invasive cannula at the wound site. Consequently, it is impossible to say a priori that a particular type of dressing is in a given class without knowing its intended use as defined by the manufacturer. However, a claim that the device is interactive or active with respect to the wound healing process usually implies that the device is in Class C.

Most dressings that are intended for a use that is in Class B or C, also perform functions that are in Class A, e.g. that of a mechanical barrier. Such devices are nevertheless classed according to the intended use in the higher class.

For such devices incorporating a medicinal product or a human blood derivative see Rule 14 or animal tissues or derivatives rendered non-viable see Rule 18.

A skin might be considered as "injured" either because of pathological (e.g. diabetic ulcers) or external factors (e.g. burns).

Breached dermis: the wound exposes at least partly the subcutaneous tissue.

Secondary intent: the wound heals by first being filled with granulation tissue, subsequently the epithelium grows back over the granulation tissue and the wound contracts. In contrast primary intent implies that the edges of the wound are close enough or pulled together, e.g. by suturing, to allow the wound to heal.

RULE 4	Description & examples
<p>All non-invasive devices which come into contact with injured skin or mucous membrane & invasive devices that come into contact with injured mucous membrane are classified as:</p> <p>a) Class A if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates;</p> <p>b) Class C 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;</p> <p>c) Class B if they are principally intended to manage the micro-environment of injured skin or mucous membrane;</p> <p>d) Class B in all other cases.</p>	<p>Wound dressings, such as:</p> <ul style="list-style-type: none"> • Absorbent pads • Island dressings • Cotton wool • Wound strips • Adhesive bandages (sticking plasters, Band-Aid) • Gauze dressings which act as a barrier, maintain wound position or absorb exudates from the wound
	<p>Are principally intended to be used with severe wounds that have substantially and extensively breached the dermis, and where the healing process can only be by secondary intent such as:</p> <ul style="list-style-type: none"> • Dressings for chronic extensive ulcerated wounds • Dressings for severe burns having breached the dermis and covering an extensive area • Dressings for severe decubitus wounds • Dressings incorporating means of augmenting tissue and providing a temporary skin substitute • Dressings, pads or swabs intended for wound debridement
	<ul style="list-style-type: none"> • Have specific properties intended to assist the healing process by controlling the level of moisture at the wound during the healing process and to generally regulate the environment in terms of humidity and temperature, levels of oxygen and other gases and pH values or by influencing the process by other physical means
	<p>These devices may specify particular additional healing properties whilst not being intended for extensive wounds requiring healing by secondary intent.</p> <ul style="list-style-type: none"> • Adhesives for topical use • Polymer film dressings • Hydrogel dressings • Non-medicated impregnated gauze dressings

4.2.3.2.5 Rule 5

Invasiveness with respect to the body orifices (ear, mouth, nose, eye, anus, urethra and vagina) must be considered separately from invasiveness that penetrates through a cut in the body surfaces (surgical invasiveness). For short term use, a further distinction must be made between invasiveness with respect to the less vulnerable anterior parts of the ear, mouth and nose and the other anatomical sites that can be accessed through natural body orifices.

Surgically created stoma, which for example allows the evacuation of urine or faeces, should also be considered as a body orifice. Devices covered by this rule tend to be diagnostic and therapeutic instruments used in particular specialities (ENT, ophthalmology, dentistry, proctology, urology and gynaecology).

RULE 5	Description & examples
<p>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 A active device are classified as:</p> <p>a) Class A if they are intended for transient use;</p> <p>b) Class B if they are intended for short-term use,</p> <p>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 A;</p> <p>c) Class C if they are intended for long-term use,</p> <p>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 B.</p> <p>All invasive devices with respect to body orifices, other than surgically invasive devices, intended for connection to a class B, class C or class D active device, are classified as class B.</p>	<ul style="list-style-type: none"> • Handheld mirrors used in dentistry to aid in dental diagnosis and surgery • Dental impression materials • Tubes used for pumping the stomach • Impression trays • Enema devices • Examination gloves • Urinary catheters intended for transient use • Prostatic balloon dilation catheters <ul style="list-style-type: none"> • Short term corrective contact lenses • Tracheal tubes • Stents • Vaginal pessaries • Indwelling urinary catheters intended for short term use • Perineal reduction devices <ul style="list-style-type: none"> • Dressings for nose bleeds • Materials for manufacturing dentures <ul style="list-style-type: none"> • Urethral stents • Long term contact lenses • Tracheal cannulae • Urinary catheters intended for long term use • Artificial eyes <ul style="list-style-type: none"> • Orthodontic wires • Fixed dental prostheses • Fissures sealants <ul style="list-style-type: none"> • Tracheostomy or tracheal tubes connected to a ventilator • Blood oxygen analysers placed under the eye-lid • Powered nasal irrigators • Nasopharyngeal airways • Some enteral feeding tubes • Fibre optics in endoscopes connected to surgical lasers • Suction catheters or tubes for stomach drainage • Dental aspirator tips • Heat & moisture exchangers

4.2.3.2.6 Rule 6

This rule primarily covers three major groups of devices: devices that are used to create a conduit through the skin (needles, cannulae, etc.), surgical instruments (scalpels, saws, etc.) and various types of catheters, suckers, etc.

RULE 6	Description & examples
<p>All surgically invasive² devices intended for transient use are classified as class B unless they:</p> <p>a) Are intended specifically to control, diagnose, monitor or correct a defect³ 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 D;</p> <p>b) Are reusable surgical instruments, in which case they are classified as class A⁵;</p> <p>c) Are intended specifically for use in direct contact with the heart or central circulatory system or the central nervous</p>	<ul style="list-style-type: none"> • Suture needles, Hypodermic needles • Needles of syringes • Lancets • Suckers • Single use scalpels and single use scalpel blades • Support devices in ophthalmic surgery • Staplers • Surgical swabs • Drill bits connected to active devices • Surgical gloves • Etchants • Tester of artificial heart valves • Orthopaedic trials and jigs. • Heart valve occluders, sizers and holders • Swabs to sample exudates • Single use aortic punches <ul style="list-style-type: none"> • Cardiovascular catheters (e.g. angioplasty balloon catheters, stent delivery catheters/systems), including related guidewires, related introducers and dedicated⁴ disposable cardiovascular surgical instruments e.g. electrophysiological catheters, electrodes for electrophysiological diagnosis and ablation • Catheters containing or incorporating sealed radioisotopes, where the radioactive isotope is not intended to be released into the body, if used in the central circulatory system • Distal protection devices • Angioplasty balloon catheters • Coronary artery probes <ul style="list-style-type: none"> • Scalpels and scalpel handles, reamers, drill bits, scissors • Saws, that are not intended for connection to an active device • Retractors forceps, excavators and chisels • Sternum retractors for transient use <ul style="list-style-type: none"> • Neuro-endoscopes • Brain spatulas • Direct stimulation canulae • Spinal cord retractors

² "Surgically invasive device", "central circulatory system", "central nervous system" and "reusable surgical instruments" are defined terms. In particular, surgical instruments connected to an active device are not considered to be "reusable surgical instruments".

³ The expression "correct a defect" does not cover devices that are used accessorially in heart surgery procedures, e.g. clamps, aortic punch instruments. The first indent of this rule does not apply to aortic punches and similar cutting instruments which perform a similar function to a scalpel.

⁴ Dedicated means that the intended purpose of the device or accessory is to specifically control, diagnose, monitor or correct a defect of the heart or of the central circulatory system.

⁵ Surgical instruments which are not specifically intended for purposes described in the a), and irrespective of the site of application, are in class B, if they are intended for single use and in class A if they are reusable.

system, in which case they are classified as class D;

d) Are intended to supply energy in the form of ionising radiation in which case they are classified as class C;

e) Have a biological effect⁶ or are wholly or mainly absorbed⁷ in which case they are classified as class C; or

f) 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 hazardous⁸ taking account of the mode of application, in which case they are classified as class C.

• Spinal needles

Catheters containing or incorporating sealed radioisotopes, where the radioactive isotope as such is not intended to be released into the body, if used in the circulatory system, excluding the central circulatory system

Insufflation gases for the abdominal cavity

Devices for repeated self-application where dosage levels and the nature of the medicinal product are critical, e.g. insulin pens



⁶ Biological effect: All materials and devices have the potential to affect tissues following use in a surgically invasive procedure. A material is considered to have a biological effect if it actively and intentionally induces, alters or prevents a response from the tissues that is mediated by specific reactions at a molecular level. Such a device may be described as bioactive.

⁷ Wholly or mainly absorbed: 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.

⁸ The concept of "potentially hazardous manner" is related to the characteristics of the device and not the competence of the user.

4.2.3.2.7 Rule 7

These are mostly devices used in the context of surgery or post-operative care (e.g. clamps, drains), infusion devices (cannulae, needles) and catheters of various types.

RULE 7	Description & examples
<p>All surgically invasive devices intended for short-term use are classified as class B unless they:</p> <p>a) Are intended specifically to control, diagnose, monitor or correct a defect⁹ 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 D;</p> <p>b) 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 D;</p> <p>c) Are intended to supply energy in the form of ionizing radiation in which case they are classified as class C;</p> <p>d) Have a biological effect or are wholly or mainly absorbed in which case they are classified as class D;</p> <p>e) Are intended to undergo chemical change in the body in which case they are classified as class C, except if the devices are placed in the teeth; or</p> <p>f) Are intended to administer medicines¹⁰, in which case they are classified as class C.</p>	<ul style="list-style-type: none"> • Clamps • Skin closure devices • Temporary filling materials • Tissue stabilisers used in cardiac surgery
	<ul style="list-style-type: none"> • Cardiovascular catheters • Cardiac output probes • Temporary pacemaker leads • Thoracic catheters intended to drain the heart, including the pericardium • Carotid artery shunts • Ablation catheter
	<ul style="list-style-type: none"> • Neurological catheters • Cortical electrodes
	<ul style="list-style-type: none"> • Brachytherapy devices
	<ul style="list-style-type: none"> • Absorbable sutures • Biological/tissue adhesives • Absorbable haemostatic sponge
	<ul style="list-style-type: none"> • Surgical adhesive
	<ul style="list-style-type: none"> • Infusion cannulae

⁹ The expression “correct a defect” does not cover devices that are used accessorially in heart surgery, e.g. tissue stabilizers.

¹⁰ Administration of medicines is more than just channelling, it implies also storage and/or influencing the volume and rate of the medicine delivered. Implanted capsules for the slow release of medicines are medicines and not medical devices.

4.2.3.2.8 Rule 8

These are mostly implants in the orthopaedic, dental, ophthalmic and cardiovascular fields as well as soft tissue implants such as implants used in plastic surgery.

RULE 8	Description & examples
<p>All implantable devices and long-term surgically invasive devices are classified as class C unless they:</p> <p>a) Are intended to be placed in the teeth¹³, or on a prepared tooth structure, in which case they are classified as class B;</p> <p>b) 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 D;</p> <p>c) Have a biological effect or are wholly or mainly absorbed, in which case they are classified as class D;</p> <p>d) Are intended to undergo chemical change¹⁴ in the body in which case they are classified as class D, except if the devices are placed in the teeth;</p> <p>e) Are intended to administer medicinal products, in which case they are classified as class D;</p> <p>f) Are active implantable devices or their accessories, in which cases they are classified as class D;</p>	<ul style="list-style-type: none"> • Ligaments • Shunts • Stents and valves (e.g. pulmonary) • Nails and plates • Intra-ocular lenses • Internal closure devices (including vascular closure devices¹¹) • Tissue augmentation implants • Peripheral vascular catheters • Peripheral vascular grafts and stents • Penile implants • Non-absorbable sutures, bone cements and maxillo-facial implants¹²
	<ul style="list-style-type: none"> • Bridges and crowns • Dental filling materials and pins • Dental alloys, ceramics and polymers
	<ul style="list-style-type: none"> • Prosthetic heart valves • Aneurysm clips • Vascular prosthesis and stents • Central vascular catheters • Spinal stents • CNS electrodes • Cardiovascular sutures • Permanent and retrievable vena cava filters • Septal occlusion devices • Intra-aortic balloon pumps • External left ventricular assisting devices
	<ul style="list-style-type: none"> • Absorbable sutures • Adhesives and implantable devices claimed to be bioactive through the attachment of surface coatings such as phosphorylcholine
	<ul style="list-style-type: none"> • Surgical adhesives for long term use
	<ul style="list-style-type: none"> • Rechargeable non-active drug delivery system
	<ul style="list-style-type: none"> • Cochlear implant system • Implantable defibrillator • Pacemakers

¹¹ For closure of arteriotomies in the peripheral vascular system. (please refer to definition of central circulatory system)

¹² These products are implants because in normal conditions a significant amount of the substance remains at the surgical site after the procedure. If these devices contain animal tissues or derivatives of animal tissues, they are covered by Rule 18.

¹³ Implants without bioactive coatings intended to secure teeth or prostheses to the maxillary or mandibular bones are in Class C following the general rule. Hydroxyapatite is considered as having biological effect only if so claimed and demonstrated by the manufacturer.

¹⁴ The clause about chemical change under this rule does not apply to products such as bone cements where the chemical change takes place during the placement and does not continue in long term.

g) Are breast implants or surgical meshes, in which cases they are classified as class D;
h) Are total or partial joint replacements, in which case they are classified as class D, with the exception of ancillary components such as screws, wedges, plates and instruments;
i) 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 D with the exception of components such as screws, wedges, plates and instruments.

- Neuro stimulators
- Breast implants
- Surgical meshes
- Total or partial joint replacements (hips, knees. Shoulders, elbows, fingers, wrists, ankles, toes)
- Spinal disc replacement implants
- Implantable devices that come into contact with the spinal column such as spinal fusion devices



4.2.3.2.9 Rule 9

Devices classified by this rule are mostly electrical equipment used in surgery such as lasers and surgical generators. In addition, there are devices for specialized treatment such as radiation treatment. Another category consists of stimulation devices, although not all of them can be considered as delivering dangerous levels of energy considering the tissue involved.

RULE 9	Description & examples
<p>All active therapeutic devices intended to administer or exchange energy are classified as class B</p> <p>Unless their characteristics are such that they may administer energy to or exchange energy with the human body in a potentially hazardous way¹⁵, taking account of the nature, the density and site of application of the energy, in which case they are classified as class C.</p> <p>All active devices intended to control or monitor the performance of active therapeutic class C devices, or intended directly to influence the performance of such devices are classified as class C.</p> <p>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 C.</p> <p>All active devices that are intended for controlling, monitoring or directly influencing the performance of active</p>	<ul style="list-style-type: none"> • Muscle stimulators • External bone growth stimulators • TENS devices • Eye electromagnets • Electrical acupuncture • Cryosurgery equipment • Heat exchangers, except the types described below • Powered dermatomes • Powered drills • Dental hand pieces • Phototherapy for skin treatment and for neonatal care • Hearing aids • Equipment for physiotherapy
	<ul style="list-style-type: none"> • Lung ventilators • Incubators for babies • Warming blankets • Blood warmers • Electrically powered heat exchangers (for example, those used with patients incapable of reacting, communicating and/or who are without a sense of feeling) • High-frequency electrosurgical generators, and electrocautery equipment, including their electrodes • External pacemakers and defibrillators • Electroconvulsive therapy equipment • Surgical lasers • Lithotriptors, surgical ultrasound devices
	<ul style="list-style-type: none"> • External feedback systems for active therapeutic devices • Afterloading control devices
	<p>Ionizing radiation</p> <ul style="list-style-type: none"> • Radioactive sources for afterloading therapy • Therapeutic cyclotrons and linear accelerators • Therapeutic X-ray sources
	<ul style="list-style-type: none"> • Programmers/controllers for implantable pacemakers and implantable cardioverter defibrillator

¹⁵ The decision as to whether a medical device administers or exchanges energy to and from the human body in a potentially hazardous way should take into account the following factors. The concept of "potentially hazardous" is dependent on the type of technology involved and the intended application of the device to the patient and not on the measures adopted by the manufacturer in view of good design management (e.g. use of technical standards, risk analysis). For instance, all devices intended to emit ionizing radiation, all lung ventilators and lithotriptors should be in Class C. However, the manufacturer's obligation to comply with design requirements and solutions adopted, such as use of standards, exist independently from the classification system.

implantable devices are classified as class D.



4.2.3.2.10 Rule 10

This primarily covers a whole range of widely used equipment in various fields, e.g. ultrasound diagnosis, capture of physiological signals and therapeutic and diagnostic radiology.

RULE 10	Description & examples
<p>Active devices intended for diagnosis and monitoring are classified as class B:</p> <p>a) 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, or near infra-red spectrum, in which case they are classified as class A;</p> <p>b) If they are intended to image in vivo distribution of radiopharmaceuticals;</p> <p>c) If they are intended to allow direct diagnosis or monitoring of vital physiological processes¹⁶,</p> <p>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 C.</p> <p>Active devices intended to emit ionizing radiation and intended for diagnostic or therapeutic radiology, including interventional radiology¹⁷ devices and devices which control or monitor¹⁸ such devices, or which directly influence their performance, are classified as class C.</p>	<ul style="list-style-type: none"> • Magnetic resonance equipment • Pulp testers • Evoked response stimulators • Diagnostic ultrasound
	<ul style="list-style-type: none"> • Examination lights
	<ul style="list-style-type: none"> • Gamma cameras • Positron emission tomography and single photon emission computer tomography
	<ul style="list-style-type: none"> • Electrocardiographs for screening/diagnosis with no monitoring purpose • Electroencephalographs • Cardioscopes with or without pacing pulse indicators • Electronic thermometers • Electronic stethoscopes • Electronic blood pressure measuring equipment
	<ul style="list-style-type: none"> • Patient monitoring and alarm devices (e.g. Electrocardiographs, blood pressure, temperature, oxygen saturation used in treatment setting) • Biological sensors • Blood gas analysers used in open heart surgery • Cardioscopes • Apnoea monitors used in any setting including in home care
<ul style="list-style-type: none"> • Diagnostic X-ray sources 	

¹⁶ Vital physiological processes and parameters include, for example respiration, heart rate, cerebral functions, blood gases, blood pressure and body temperature. Medical devices intended to be used for continuous surveillance of vital physiological processes in anaesthesia, intensive care or emergency care are in Class C, whilst medical devices intended to be used to obtain readings of vital physiological signals in routine check ups and in self-monitoring are in Class B. A thermal imaging device intended to monitor blood flow is not considered to be a temperature measuring device.

¹⁷ Therapeutic interventional radiology refers to diagnosis being carried out during surgical procedures.

¹⁸ This refers to active devices for the control, monitoring or influencing of the emission of ionizing and not to the subsequent processing, recording or viewing of the resulting image.

4.2.3.2.11 Rule 11

This rule applies to stand-alone software.

RULE 11	Description & examples
<p>Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes is classified as class B, except if such decisions have an impact that may cause:</p> <p>a) Death or an irreversible deterioration of a person's state of health, in which case it is in class D;</p> <p>b) A serious deterioration of a person's state of health or a surgical intervention, in which case it is classified as class C.</p> <p>Software intended to monitor physiological processes is classified as class B, 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 C.</p> <p>All other software is classified as class A.</p>	<ul style="list-style-type: none"> • Software to diagnose sleep apnoea
	<ul style="list-style-type: none"> • Software to select dose of cytostatic drugs • Software provides critical and significance information for treatment or diagnosis.
	<ul style="list-style-type: none"> • Software suggesting diagnoses based on test results • Software which uses information from glucose monitoring to provide direction on administration of insulin for management of diabetes
	<ul style="list-style-type: none"> • Software monitoring of heart rate data intended as an aid
	<ul style="list-style-type: none"> • Software monitoring of physiological parameters during a surgical operation
	<ul style="list-style-type: none"> • Software used to make biomechanical measurements to aid rehabilitation • Software intended to support conception by calculating the user's fertility status based on a validated statistical algorithm

4.2.3.2.12 Rule 12

This rule is intended to primarily cover drug delivery systems and anaesthesia equipment.

RULE 12	Description & examples
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 B, 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 C.	<ul style="list-style-type: none">• Suction equipment• Feeding pumps• Jet injectors for vaccination <ul style="list-style-type: none">• Infusion pumps• Ventilators• Anaesthesia machines• Anaesthetic vaporisers• Dialysis equipment• Blood pumps for heart-lung machines• Hyperbaric chambers• Pressure regulators for medical gases• Medical gas mixers• Moisture exchangers in breathing circuits if used on unconscious or non-spontaneously breathing patients



4.2.3.2.13 Rule 13

This is a fallback rule to cover all active devices not covered by the previous rules.

RULE 13	Description & examples
All other active devices are classified as class A.	<ul style="list-style-type: none">• Active diagnostic devices intended to optically view the body such as surgical microscopes• Devices intended in general for external patient support (e.g. hospital beds, patient hoists, wheelchairs, dental patient chairs)• Active diagnostic devices intended for thermography• Dental curing lights



4.2.3.2.14 Rule 14

This rule is intended to cover combination devices that contain a medicinal substance incorporated into the device for the purpose of assisting the functioning of that device. However, this rule does not cover those devices incorporating substances which under other circumstances may be considered as medicinal substances, but which are incorporated into the device exclusively for the purpose of maintaining certain characteristics of the device and which are not liable to act on the body. The primary function of the device does not rely on the pharmacological, metabolic or immunological effect of the medicine. If the latter is the case, the product is a medicinal product rather than a device and not covered by this guidance.

Note 1:

RULE 14	Description & examples
<p>All devices incorporating, as an integral part¹⁹, a substance which, if used separately, can be considered to be a medicinal product, as defined in “SFDA Products Classification Guidance”, including a medicinal product derived from human blood or human plasma, as defined in “SFDA Products Classification Guidance”, and that has an action ancillary to that of the devices, are classified as class D.</p>	<ul style="list-style-type: none"> • Antibiotic bone cements • Condoms with spermicide • Heparin coated catheters • Endodontic materials with antibiotics • Dressings incorporating an antimicrobial agent where the purpose of such an agent is to provide ancillary action on the wound including silver impregnated dressings • Contraceptive intrauterine devices (IUDs) containing copper or silver • Drug eluting stents, e.g. coronary, pulmonary • Surgical sealants containing human serum albumin • Catheters coated with an anticoagulant or an antibiotic agent • Sponge impregnated with antibiotics • Medicated root canal sealant



¹⁹ "Integral part" means that the device and the medicinal substance are physically or chemically combined at the time of administration (i.e. use, implantation, application etc.) to the patient.

4.2.3.2.15 Rule 15

These intended uses relate to special cases of human vulnerability that cannot be covered by the normal criteria of time, invasiveness and organic function.

Although this rule covers two very different device applications, some devices may perform both functions, e.g. condoms.

Devices intended to prevent the sexual transmission of the HIV are also covered by this rule.

RULE 15	Description & examples
All devices used for contraception or prevention of the transmission of sexually transmitted diseases are classified as class C, Unless they are implantable or long term invasive devices, in which case they are classified as class D.	<ul style="list-style-type: none">• Condoms• Contraceptive diaphragms
	<ul style="list-style-type: none">• Contraceptive intrauterine devices (IUDs)²⁰



²⁰ Intrauterine contraceptives whose primary purpose is to release progestogens are not medical devices

4.2.3.2.16 Rule 16

This rule covers substances and other equipment used principally in a medical environment to disinfect medical devices as well as fluids for cleaning, disinfection or hydration of contact lenses.

RULE 16	Description & examples
<p>All devices intended specifically to be used for disinfecting, cleaning, rinsing or, where appropriate, hydrating contact lenses are classified as class C.</p>	<ul style="list-style-type: none"> • Contact lens solutions • Comfort solutions
<p>All devices intended specifically to be used for disinfecting or sterilising medical devices are classified as class B,</p>	<ul style="list-style-type: none"> • Disinfectants specifically intended for non-invasive medical devices and equipment such as sterilizers specifically intended to sterilize medical devices in a medical environment and washer disinfectors • Washers-disinfectors intended specifically for disinfecting non-invasive medical devices
<p>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 C.</p>	<ul style="list-style-type: none"> • Denture disinfecting products • Washers-disinfectors for endoscopes • Disinfectants for the fluid pathways of haemodialysis equipment • Disinfectants for ocular prosthesis, intraosseous transcutaneous amputation prosthesis, surgical equipment and invasive dental equipment
<p>This rule does not apply to devices that are intended to clean devices other than contact lenses by means of physical action²¹ only.</p>	<p>Cleaning with no disinfection or sterilization claims.</p>



²¹ This rule does not apply to mechanical means of cleaning of devices, such as brushes and ultrasound. Such products will only fall under this guidance if they are specifically intended for use with medical devices.

4.2.3.2.17 Rule 17

This refers to primary recording media such as X-ray films and not to media used for subsequent reproduction.

RULE 17	Description & examples
Devices specifically intended for recording of diagnostic images generated by X-ray radiation are classified as class B.	<ul style="list-style-type: none"><li data-bbox="715 389 938 421">• X-ray films<li data-bbox="715 421 1161 452">• Photostimulable phosphor plates



4.2.3.2.18 Rule 18

This rule covers devices that contain or are made of animal tissues that have been rendered non-viable or derivatives from such tissues also being non-viable, i.e. where there is no longer any capacity for cellular metabolic activity. Devices containing viable animal tissues and/or any human tissues or derivatives are excluded from the scope of this guidance.

The manufacture of some devices may use industrial raw materials which contain small amounts of tallow or tallow derivatives (e.g. stearates in polymers). Such substances are not considered as derivatives of animal tissues for the purpose of this rule which therefore does not apply.

Devices made of non-viable animal tissue that comes into contact with intact skin only (e.g. leather components of orthopaedic appliances) are in Class A in accordance to Rule 1.

RULE 18	Description & examples
All devices manufactured utilising tissues or cells of human or animal origin, or their derivatives²², which are non-viable or rendered non-viable, are classified as class D, 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 skin²³ only. In which case they are class A.	<ul style="list-style-type: none">• Biological heart valves• Porcine xenograft dressings• Implants and dressings made from collagen• Devices utilising hyaluronic acid of animal origin



²² Derivatives are products that are processed from animal tissues and exclude substances such as milk, silk, beeswax, hair, lanolin.

²³ Intact skin includes the skin around an established stoma unless the skin is breached.

4.2.3.2.19 Rule 19

The use of nanomaterials in medical devices can vary considerably. Examples are the use of free nanomaterials as a medical device which is administered to the patient (e.g. iron oxide or gold nanomaterials for heat therapy against cancer), free nanomaterials in a paste-like formulation (e.g. dental filling composites), free nanomaterials added to a medical device (e.g. nanosilver as antibacterial agent in wound dressings), fixed nanomaterials forming a coating on implants to increase biocompatibility (e.g. nanohydroxyapatite) or to prevent infection (e.g. nanosilver), or embedded nanomaterials to strengthen biomaterials (e.g. carbon nanotubes in a catheter wall). In all these cases the potential exposure to the nanomaterials should be considered. It is additionally recognized that wear-and-tear of medical devices may generate nano-sized particles even when the medical device itself does not contain nanomaterials.

Humans may be exposed to nanomaterials from medical devices through various routes. Depending on the relevant exposure route based on the use of a specific medical device, the nanomaterials will encounter various barriers before they are taken up by the body. Patients and users (health care professionals) may be exposed, although the potential of exposure of patients and/or users will differ depending on the particular device and the way it is used. In general, the highest potential for exposure is associated with devices that consist of “free” nanomaterials or that are subject to the release/loosening of nanomaterials present as coatings on the surface of medical devices. In addition, exposure to nanomaterials from medical devices may also result from degradation or wear processes, when nanomaterials are fixed on the surface (e.g. as coating on implants) or are embedded within the material of the medical device.

Examples of devices in current clinical practice:

Non-invasive surface contacting medical devices

These are medical devices, which come into contact only with the intact skin. Examples are antibacterial gowns and textiles to cover patients in the operating theatre, which contain silver nanoparticles.

Invasive surface contacting medical devices

These are medical devices, which come into contact with breached or otherwise compromised skin. Examples are wound treatment products (wound dressings) containing nano-sized silver particles and metal oxide particles which are used for improved antibacterial and anti-fungal activity.

Invasive external communicating medical devices

These are medical devices that come into contact with the blood path, either indirectly or with circulating blood, and devices in contact with tissue/bone/dentin. Examples include:

- Catheters with a nanosilver coating for bladder drainage, haemodialysis and local administering of anaesthesia
- Catheters with nanotopographical morphology imprinted onto the exposed surface
- Polymer based dental composite filler materials and dental cements containing nanoparticles
- Surgical and dental instruments with nanostructures used to enhance the cutting behaviour and wear resistance of cutting instruments, e.g. scalpels, needles, catheters, burs for cutting bone or teeth
- Instruments with nanostructures used to create non-sticky surfaces to facilitate handling and placement of materials

Invasive implantable medical devices

These are medical devices which are 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 are intended to remain in place after the procedure. Examples include:

- Carbon nanotubes in bone cements for fixation of implanted prostheses
- Bone fillers with hydroxyapatite and tricalcium phosphate nanoparticles which facilitate rapid integration with the bone of the patient
- Surface coatings. The surface of implants can be modified with the aid of nanotechnologies to enable them to integrate better in the body (improved biocompatibility). In addition, coatings can be used for their antibacterial activity.
 - Joint prosthetics (hip, knee) with nanohydroxyapatite coating
 - Coronary stents with a diamond-like nano composite coating made of ultra-thin polymer

RULE 19

All devices incorporating or consisting of nanomaterial are classified as:

- a) Class D if they present a high or medium potential for internal exposure;
- b) Class C if they present a low potential for internal exposure;
- c) Class B if they present a negligible potential for internal exposure.



4.2.3.2.20 Rule 20

Devices used to deliver therapeutic agents as aerosols are based on one of the three platforms: nebulizers, pressurized metered-dose inhaler (pMDI), and dry powder inhalers (DPIs).

The effectiveness of an aerosol therapy is largely dependent on how much of the medication will reach the intended site of deposition.

The major problems with the use of inhaler devices are the deposition of aerosolized particles in the oropharyngeal region and upper airways and the lack of coordination between the device activation and inhalation due to lack of patient training.

RULE 20	Description & examples
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 B, 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 C.	Nebulisers to be used on conscious and spontaneously breathing patients where failure to deliver the appropriate dosage characteristics is not potentially hazardous
	Nebulisers where the failure to deliver the appropriate dosage characteristics could be hazardous
	Metered dose inhalers for treatment of acute asthma



4.2.3.2.21 Rule 21

Self-care medical devices are composed of substances or combination of substances.

They include, amongst others, products such as nasal solution primarily used for sufferers, often infants, with cold symptoms and blocked noses, lozenges to relieve throat discomfort, dentifrices for sensitive teeth, verruca and wart removers, gels for vaginal discomfort, other personal lubricants, cough syrups, products used for the reduction of bloating, denture cleansers and adhesives, creams to treat or prevent minor skin irritations or anti-flatulence products.

These are classified as devices in light of their mode of action which is not pharmacological, immunological or metabolic but relies on chemico-physical processes such as local pH changes, sequestering actions of molecules, and physical barrier formation.

Substances are treated as medicinal products in case the mode of active is pharmacological, immunological or metabolic.

RULE 21	Description & examples
<p>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:</p> <p>a) Class D if they, or their products of metabolism, are systemically absorbed by the human body in order to achieve the intended purpose;</p> <p>b) Class D 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;</p> <p>c) Class B 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;</p> <p>d) Class C in all other cases.</p>	<p>Any device that is claimed to achieve its intended purpose through absorption or dispersion.</p> <p>Gastrointestinal gas suppressant Anti-obesity capsules which expand in the stomach to suppress appetite</p> <ul style="list-style-type: none"> • lozenges • Nasal sprays • Cold therapy gel • Cold sore gel • Antisnoring mucosa lubricant • Ear drops

4.2.3.2.22 Rule 22

PHYSIOLOGIC CLOSED-LOOP CONTROLLERS in ME EQUIPMENT and ME SYSTEMS are expected to provide a successful strategy to improve PATIENT safety and reduce healthcare costs and also fall under this rule.

RULE 22	Description & examples
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 D.	<ul style="list-style-type: none">• Closed loop systems• Automated external defibrillators



4.3 In vitro diagnostic medical devices

4.3.1 Definitions related to classification

'Specimen receptacle' means a device, whether of a vacuum-type or not, specifically intended by its manufacturer for the primary containment and preservation of specimens derived from the human body for the purpose of in vitro diagnostic examination.

'Device for self-testing' means any device intended by the manufacturer to be used by lay persons, including devices used for testing services offered to lay persons by means of information society services.

'Device for near-patient testing' means any device that is not intended for self-testing but is intended to perform testing outside a laboratory environment, generally near to, or at the side of, the patient by a health professional.

'Companion diagnostic' means a device which is essential for the safe and effective use of a corresponding medicinal product to:

- identify, before and/or during treatment, patients who are most likely to benefit from the corresponding medicinal product; or
- identify, before and/or during treatment, patients likely to be at increased risk of serious adverse reactions as a result of treatment with the corresponding medicinal product.

'Calibrator' means a measurement reference material used in the calibration of a device.

'Control material' means a substance, material or article intended by its manufacturer to be used to verify the performance characteristics of a device.

4.3.2 Implementing rules

4.3.2.1 Intended purpose

Application of the classification rules shall be governed by the intended purpose of the devices.

Where a manufacturer states multiple intended purposes for a device, and as a result the device falls into more than one class, it shall be classified in the higher class.

4.3.2.2 Combination with another device

If the device in question is intended to be used in combination with another device, the classification rules shall apply separately to each of the devices.

4.3.2.3 Accessories

Accessories for an in vitro diagnostic medical device shall be classified in their own right separately from the device with which they are used.

4.3.2.4 Software

Software, which drives a device or influences the use of a device, shall fall within the same class as the device. If the software is independent of any other device, it shall be classified in its own right.

4.3.2.5 Calibrators

Calibrators intended to be used with a device shall be classified in the same class as the device.

4.3.2.6 Control materials

Control materials with quantitative or qualitative assigned values intended for one specific analyte or multiple analytes shall be classified in the same class as the device.

4.3.2.7 Multiple rules

The manufacturer shall take into consideration all classification and implementation rules in order to establish the proper classification for the device.

If several classification rules apply to the same device, the rule resulting in the higher classification shall apply.

4.3.2.8 First line, confirmatory and supplemental assays

Each of the classification rules shall apply to first line assays, confirmatory assays and supplemental assays.

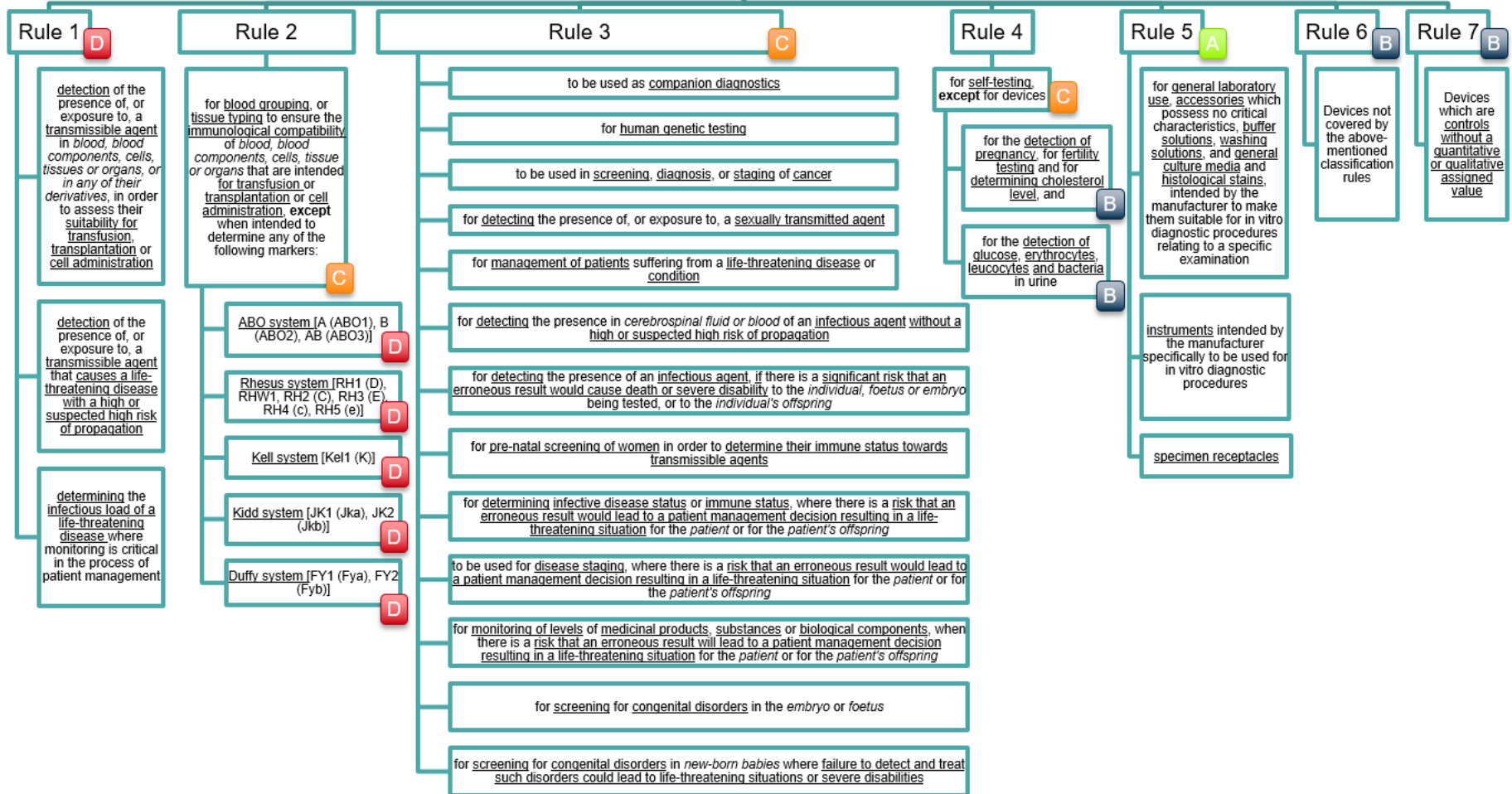
4.3.3 Explanation of the individual rules

The explanations are given in the following manner. This section begins with a graphical summary of the rules, as a preface to subsections on the individual rules. Each subsection starts with a general explanation of the rule followed by a tabular presentation of the rule and examples of devices to which it applies. Any special terms used are explained and practical issues related to the rule are clarified. It must be emphasized that even if a particular device type is given as an example, this does not mean that such devices are in all cases in the class indicated by the example. It is always possible that some manufacturer will assign to such a device an entirely different intended use than what was used in the context of the example.

4.3.3.1 Classification guidance chart for initial identification of probable device class

Always confirm definitive classification by reading all rules in detail, and utilize additional assistance in this guidelines document as provided in the form of general explanations of rules and examples of devices.

IVD Medical Devices



4.3.3.2 General explanation of rules, practical issues and examples

4.3.3.2.1 Rule 1

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.

RULE 1	Description & examples
<p>Devices intended to be used for the following purposes are classified as class D:</p> <p>a) Detection of the presence of, or exposure to, a transmissible agent in blood, blood components, cells, tissues or organs, or in any of their derivatives, in order to assess their suitability for transfusion, transplantation or cell administration;</p> <p>b) Detection of the presence of, or exposure to, a transmissible agent that causes a life-threatening disease with a high or suspected high risk of propagation;</p>	<p>All tests intended to be used for blood, organ and tissue donor screening, including screening and confirmatory assays for:</p> <ul style="list-style-type: none"> • Human immunodeficiency virus (HIV) • Hepatitis C virus (HCV) • Hepatitis B virus • HTLV I/II • Syphilis <p>Any additional assays used to screen donors on a supplementary basis, such as those used to determine Cytomegalovirus status or to screen for Malaria</p> <ul style="list-style-type: none"> • Tests intended to be used to screen for HIV, either at the point of care or for self-testing. • Tests intended for the diagnosis of infection with, or exposure to: <ul style="list-style-type: none"> • Severe acute respiratory syndrome-associated coronavirus (SARS-CoV) • Highly virulent pandemic influenza • Variola virus (Smallpox virus) • Viral haemorrhagic fevers, such as Ebola virus or Marburg virus • All tests intended for the diagnosis of infection with, or exposure to: <ul style="list-style-type: none"> • HIV 1 & 2 • Hepatitis C virus • Hepatitis B virus* • HTLV I/II <p>Note: Applies to first-line assays, confirmatory assays and supplemental assays.</p> <p>*Assays for Hepatitis B markers that are intended by the manufacturer to be used as an aid in the diagnosis of acute or chronic infection, or exposure to Hepatitis B, e.g.:</p> <ul style="list-style-type: none"> • Hepatitis B surface antigen (HBsAg) • Hepatitis B core IgM antibodies (anti-HBcore IgM) • Hepatitis B core total antibodies (anti-HBcore tot) • Hepatitis B virus nucleic acid detection (HBV NAT) • Other tests for Hepatitis B, including anti-HBs would be considered Class D IVDs if the manufacturer's intended purpose for the device included aiding in the diagnosis of Hepatitis B.
<p>c) Determining the infectious load of a life-threatening disease where monitoring</p>	<p>Viral load assays for HIV, HBV, HCV</p>

is critical in the process of patient management.



4.3.3.2.2 Rule 2

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.

RULE 2	Description & examples
<p>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 or cell administration, are classified as class C, except when intended to determine any of the following markers:</p> <p>a) ABO system [A (ABO1), B (ABO2), AB (ABO3)] in which case they are classified as class D.</p> <p>b) Rhesus system [RH1 (D), RHW1, RH2 (C), RH3 (E), RH4 (c), RH5 (e)] in which case they are classified as class D.</p> <p>c) Kell system [Kel1 (K)] in which case they are classified as class D.</p> <p>d) Kidd system [JK1 (Jka), JK2 (Jkb)] in which case they are classified as class D.</p> <p>e) Duffy system [FY1 (Fya), FY2 (Fyb)] in which case they are classified as class D.</p>	<ul style="list-style-type: none"> • IVDs intended for testing for red blood cell antigens or antibodies for: <ul style="list-style-type: none"> • Cw or V from the Rhesus system • Cellano (k) from the Kell blood group system • Any markers from MNS or Cartwright blood group systems • All IVDs intended for use in tissue typing to detect antigens and antibodies for any human leukocyte antigens • IVDs intended for subtyping previously determined ABO system A group reactive patients (i.e. A1, A2, A3 etc.) • Tests intended for the quantitative determination of antibodies to Rhesus system blood group antigens (i.e. anti-D) <p>IVDs intended for detecting red blood cell antigens, antibodies or genetic markers specific to the high risk blood group:</p> <ul style="list-style-type: none"> • ABO system [A (ABO1), B (ABO2), AB (ABO3)] <p>IVDs intended for detecting red blood cell antigens, antibodies or genetic markers specific to the high risk blood group:</p> <ul style="list-style-type: none"> • Rhesus system [RH1 (D), RHW1, RH2 (C), RH3 (E), RH4 (c), RH5 (e)] <p>IVDs intended for detecting red blood cell antigens, antibodies or genetic markers specific to the high risk blood group:</p> <ul style="list-style-type: none"> • Kell system [Kel1 (K)] <p>IVDs intended for detecting red blood cell antigens, antibodies or genetic markers specific to the high risk blood group:</p> <ul style="list-style-type: none"> • Kidd system [JK1 (Jka), JK2 (Jkb)] <p>IVDs intended for detecting red blood cell antigens, antibodies or genetic markers specific to the high risk blood group:</p> <ul style="list-style-type: none"> • Duffy system [FY1 (Fya), FY2 (Fyb)]

4.3.3.2.3 Rule 3

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 3	Description & examples
<p>Devices are classified as class C if they are intended:</p> <p>a) For detecting the presence of, or exposure to, a sexually transmitted agent;</p> <p>b) For detecting the presence in cerebrospinal fluid or blood of an infectious agent without a high or suspected high risk of propagation;</p> <p>c) For detecting the presence of an infectious agent, if there is a significant risk that an erroneous result would cause death or severe disability to the individual, foetus or embryo being tested, or to the individual's offspring;</p>	<p>Tests intended to detect the presence or exposure to a sexually transmitted agent, such as:</p> <ul style="list-style-type: none"> • Chlamydia trachomatis • Neisseria gonorrhoeae • Syphilis (Treponema pallidum) • Donovanosis (Klebsiella (Calymmatobacterium) granulomatis) • Herpes simplex virus 1 & 2 • Lymphogranuloma venereum (C. trachomatis L-1, L-2, L-3) • Human papillomavirus • Trichomoniasis (Trichomonas vaginalis) <p>Tests intended to detect (in cerebrospinal fluid or blood) the presence of an infectious agent that poses a high personal risk and has a risk of limited propagation, including tests for the:</p> <ul style="list-style-type: none"> • direct detection of Cryptococcus neoformans antigens • detection of N. meningitidis in CSF or blood • detection of Haemophilus influenzae type B (Hib) antigen • detection of IgM antibodies to malaria parasites • detection of Prion diseases • detection of Hendra virus <p>• Tests that are intended to:</p> <ul style="list-style-type: none"> • confirm the presence or identity of methicillin-resistant Staphylococcus aureus (MRSA), either directly from a clinical specimen or from a cultured isolate • detect transmissible agents that cause serious infectious diseases such as influenza, typhoid fever and pertussis • specifically detect/identify Salmonella typhi, including serotyping reagents intended to identify Salmonella typhi at the subspecies level (e.g., a serotyping kit intended to discriminate between S. typhi and S. paratyphi) • detect Shiga toxin-producing E. coli or Verotoxin-producing E. coli (STEC or VTEC) including serotyping reagents to specifically identify E.coli 0157:H7 (e.g., 0157 and H7 antisera) • detect Chlamydia pneumoniae • Influenza A including tests intended to: • screen for influenza A (e.g., detection of matrix protein) • detect or type an influenza A infection by different hemagglutinin subtypes and neuraminidase subtypes (e.g., H1 through H18 and N1 through N11 respectively) • detect or type certain influenza A strains (e.g., H1N1, H5N1)

d) For pre-natal screening of women in order to determine their immune status towards transmissible agents;

Screening tests intended to determine prenatal immune status for infections that may cause illness in pregnant women and birth defects, or serious infections in newborns, such as the detection of antibodies for:

- Toxoplasma gondii
- Rubella virus
- Cytomegalovirus (CMV)
- Herpes simplex virus 1 & 2
- Measles virus
- Treponema pallidum

If tests to detect immune status for these infections are not specifically intended for prenatal screening, they are classified according to other rules.

e) For determining infective disease status or immune status, where there is a risk that an erroneous result would lead to a patient management decision resulting in a life-threatening situation for the patient or for the patient's offspring;

Such as tests for the detection of:

- Enteroviruses, CMV IgG and HSV in transplant patients

f) To be used as companion diagnostics;

- biomarkers
- EGFR TEST

g) To be used for disease staging, where there is a risk that an erroneous result would lead to a patient management decision resulting in a life-threatening situation for the patient or for the patient's offspring;

Cardiac markers, Cyclosporin, Prothrombin time

h) To be used in screening, diagnosis, or staging of cancer;

- CANCER marker

i) For human genetic testing;

All tests intended for human genetic testing (whether testing for an inherited or acquired genetic marker), including:

- prenatal genetic screening
- tests for detecting the Philadelphia chromosome
- tests for Huntington's disease
- test for cystic fibrosis
- FISH probe to detect the BCR-ABL translocation

j) For monitoring of levels of medicinal products, substances or biological components, when there is a risk that an erroneous result will lead to a patient management decision resulting in a life-threatening situation for the patient or for the patient's offspring;

• Tests intended for therapeutic monitoring of immunosuppressive medicines such as, cyclosporin and tacrolimus, due to the impact of an incorrect result on a patient and the potential for adverse transplantation outcome

k) For management of patients suffering from a life-threatening disease or condition;

HCV viral load, HIV Viral Load and HIV and HCV geno- and subtyping

l) For screening for congenital disorders in the embryo or foetus;

• Software that is supplied as a 'stand-alone' IVD, for example software for the interpretation of results obtained as part of a first trimester screening assessment to determine foetal risk of trisomy 21.

- Screening tests for:
 - Spina Bifida,
 - Down Syndrome
- Non-Invasive Pre-natal Testing (NIPT) for fetal aneuploidies e.g. T13, T18, T21

m) For screening for congenital disorders in new-born babies where failure to detect and treat such disorders could lead to life-

Hemoglobinopathies (sickle cell disease)

threatening situations or severe disabilities.



4.3.3.2.4 Rule 4

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.

RULE 4	Description & examples
<p>a) Devices intended for self-testing are classified as class C,</p> <p>Except for devices for the detection of pregnancy, for fertility testing and for determining cholesterol level, and devices for the detection of glucose, erythrocytes, leucocytes and bacteria in urine, which are classified as class B.</p> <p>b) Devices intended for near-patient testing are classified in their own right.</p>	<ul style="list-style-type: none"> • System for the self-monitoring of blood glucose <p>Each device is classified individually, with the highest class applying to the overall system:</p> <ul style="list-style-type: none"> • The glucose meter is classified as a Class A IVD as per rule 5 • The glucose reagent test strip is a Class C IVD because an incorrect result obtained when self-testing for blood glucose may lead to a life-threatening situation • The lancet is a Class B medical device <p>Prothrombin time reagent test strips for the self-monitoring of the effects of anticoagulation therapy</p> <p>NOTE: A self-test for HIV is a Class D IVD as it is a screening test for a serious disease and Classification Rule 1 b) applies (i.e., higher classification rule applies)</p> <ul style="list-style-type: none"> • Device for detection of pregnancy (pregnancy self-test) • Device for fertility self-testing • Device for determining cholesterol level • Devices for the detection of glucose, erythrocytes, leucocytes and bacteria in urine • Urine self-test strips to detect glucose and other general urine chemistry analytes <p>POC</p>



4.3.3.2.5 Rule 5

These devices present a low individual risk and no or minimal public health risk

RULE 5	Description & examples
<p>The following devices are classified as class A:</p> <p>a) Products for general laboratory use, accessories which possess no critical characteristics, buffer solutions, washing solutions, and general culture media and histological stains, intended by the manufacturer to make them suitable for in vitro diagnostic procedures relating to a specific examination;</p> <p>b) Instruments intended by the manufacturer specifically to be used for in vitro diagnostic procedures;</p> <p>c) Specimen receptacles.</p>	<ul style="list-style-type: none"> • Selective/differential microbial media • Identification kits for cultured microorganisms • Washing solutions intended for specific IVD examinations • Buffer solutions intended for specific IVD examinations • Histological stains <p>• Microscope counting chambers, such as haemocytometers and chambered urinalysis slides labelled as being intended for the microscopic examination of urine and other body fluids.</p> <p>Note: Plain ground-glass microscope slides, although intended for an application related to microscopic analysis, are not IVDs unless specifically intended for diagnostic use.</p> <ul style="list-style-type: none"> • Manual, automated or semi-automated instruments intended for use as an IVD such as an enzyme immunoassay analyser or an ESR analyser • Specimen containers intended for the collection of urine, faeces, cells or tissue specimens for subsequent in vitro examination



4.3.3.2.6 Rule 6

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.

RULE 6	Description & examples
<p>Devices not covered by the above-mentioned classification rules are classified as class B.</p>	<ul style="list-style-type: none"> • A foetal cell staining kit intended for performing a Kleihauer stain to identify candidates required to receive more than one dose of anti-D immunoglobulin • A ready-to-use Romanowski staining kit intended for use in haematology for staining peripheral blood smears to perform white cell differentiation and evaluation of red cell morphology • A non-assay specific bacterial or viral RNA nucleic acid extraction kit intended for the extraction of pathogenic nucleic acid from a clinical specimen • Most biochemistry tests for blood gases, hormones, vitamins, enzymes, metabolic markers and substrates • IVDs for performing coagulation testing, including activated partial thromboplastin time (APTT), factor assays and prothrombin time testing (other than prothrombin time for self-testing, which is captured as a Class C IVD by rule 4) • Cell culture lines for the culture of viruses present in clinical specimens • Screening tests intended to presumptively detect Salmonella at the genus/species level such as individually supplied serotyping reagents that are not intended to identify an individual subspecies/serotype in their own right (e.g., polyvalent and monovalent O antisera) • Biochemical tests for establishing the presumptive identification of microbiological culture isolates, or for determining antimicrobial susceptibility of microbiological culture isolates • Tests used to detect transmissible agents that have public health importance but pose a moderate personal risk because they generally cause self-limiting disease: <ul style="list-style-type: none"> • Cryptosporidiosis, Campylobacter • Hepatitis A virus, Salmonella enteritidis • Mumps, Varicella zoster virus (unless intended for prenatal screening) • Barmah Forest virus, Chikungunya virus • Ross River virus, Ornithosis • Tests to detect infection by: <ul style="list-style-type: none"> • Helicobacter pylori, Clostridium difficile • Adenovirus, Rotavirus • Giardia lamblia

4.3.3.2.7 Rule 7

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

RULE 7	Description & examples
Devices which are controls without a quantitative or qualitative assigned value are classified as class B.	Run controls for hospital lab QC programs



5 Revision History

Rev	Description of Change	Updated by	Date changed

