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GUIDELINES FOR THE CLASSIFICATION OF MEDICAL DEVICES

The present Guidelines are part of a set of Guidelines relating to questions of application of EC-Directives on medical devices. They are legally not binding. The Guidelines have been carefully drafted through a process of intensive consultation of the various interested parties (competent authorities, Commission services, industries, other interested parties) during which intermediate drafts were circulated and comments were taken up in the document. Therefore, this document reflects positions taken by representatives of interested parties in the medical devices sector.

Note : this document is a revision of an earlier document published in March 1996 as MEDDEV. 10/93 rev. 5

Additions have been indicated in bold larger text

Pages

1. PURPOSE AND PHILOSOPHY OF MEDICAL DEVICE CLASSIFICATION

It is not feasible economically nor justifiable in practice to subject all medical devices to the most rigorous conformity assessment procedures available. A graduated system of control is more appropriate. [In such a system, the level of control corresponds to the level of potential hazard inherent in the type of device concerned.] A medical device classification system is therefore needed, in order to channel medical devices into the proper conformity assessment route.

In order to ensure that conformity assessment under the Medical Device Directive functions effectively from January 1995, manufacturers should be able to know as early as possible in which class their product is. Identification of the class of each individual type of device by a committee procedure would have taken too long to achieve this goal. It was therefore decided to set up a system of classification rules within the directive, so that each manufacturer could classify its own devices.

A simple set of classification rules based on technical features of medical devices existing now and in the future is impossible, because of the vast number and the changing nature of variables involved. The human body, however, is a relatively unchanging element of the equation. The European legislator established therefore a classification concept which is essentially based on potential hazards related to the use and possible failure of devices taking account of technology used and of health policy considerations. This approach in turn allows the use of a small set of criteria that can be combined in various ways: duration of contact with the body, degree of invasiveness and local vs. systemic effect.

It is recognized that although the existing rules will adequately classify the vast majority of existing devices, a small number of difficult cases may arise. Such cases may in particular include the determination of the borderline between two classes. In addition their may be devices that cannot be classified by the existing rules because of their unusual nature or situations where the classification would result in the wrong level of conformity assessment in light of the hazard represented by the device.

2. PRACTICAL RELEVANCE OF CLASSIFICATION

2.1. General requirements

All devices must:

- meet the essential requirements irrespective of the class of the device (see also Annex VIII I of the Directive)
- be subject to the reporting requirements under the medical device vigilance system;
- be CE marked (except custom-made devices and devices intended for clinical investigation).

<u>Note</u>: If Annex VIII applies (custom made devices and devices intended for clinical investigation) then all its requirements apply irrespective of the class of the device

2.2. Conformity Assessment

CONFORMITY ASSESSMENT PROCEDURES	**CLASSES**					
ANNEXES	I	I sterile	I meas.	II A	II B	III
II (+ Sect.4)						√
II (- Sect. 4)				√	√	
III					√	√
IV		√	√	√	√	√
V		√	√	√	√	√
VI		√	√	√	√	
VII	√	√	√	√		

2.3. Clinical data

2.3.1. Clinical evaluation

As a general rule, confirmation of conformity with the requirements concerning the characteristics and performances referred to in sections 1 and 3 of Annex I of Directive 93/42/EEC under the normal conditions of use of the device and the evaluation of the undesirable side-effects must be based on clinical data in particular in the case of implantable devices and devices in class III (Annex IX, section 1.1)

2.3.2. Clinical investigation

Clinical investigation with Class III devices and implantable and long-term invasive devices falling within Class II A or II B may start 60 days after their notification to the Competent Authority unless a negative decision from the Competent Authority has been received within this timeframe. (Art. 15)

2.4. Labelling

Instructions for use are not required for Class I and II A devices if these devices can be used safely without such instructions (Annex I Sect. 13.1.).

2.5. Miscellaneous

The manufacturer, or persons responsible for marketing of a Class I product and designated by the manufacturer, must notify their address and the devices concerned to the Competent Authority of the Member State where they have their registered place of business (Art. 14).

Class I custom made devices need not to be accompanied by the statement referred to in Annex VII (Art. 4).

3. HOW TO CARRY OUT CLASSIFICATION

The manufacturer should first gain assurance that the product concerned is a medical device or an accessoryand that it comes within the scope of the Medical Device Directive.

3.1. Basic definitions

The classification rules are based on terms related to duration of contact with the patient, degree of invasiveness and the anatomy affected by the use of the device. These are explained in Section I of the Annex 9 of the Directive and are appended to this document. Whilst these definitions are self-explanatory, the following additional advice may be helpful.

3.1.1. Time

Annex IX

Duration

Transient

Normally intended for continuous use for less than 60 minutes

Short term

Normally intended for continuous use for not more than 30 days

Long term

Normally intended for continuous use for more than 30 days

Concepts of duration such as transient, short term and long term are defined in terms of continuous use. Continuous use must be understood as an uninterrupted actual use for the intended purpose. For instance, 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.

3.1.2. Invasiveness

Annex IX

Invasive devices

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

Body orifice

Any natural opening in the body, as well as the external surface of the eyeball, or any permanent artificial opening, such as a stoma.

Surgically invasive device

An invasive device which penetrates inside the body through the surface of the body, with the aid or in the context of a surgical operation.

For the purposes of this Directive devices other than those referred to in the previous subparagraph and which produce penetration other than through an established body orifice, shall be treated as surgically invasive devices.

Implantable device

Any device which is intended:

- **to be totally introduced into the human body or,**
- **to replace an epithelial surface or the surface of the eye**

by surgical intervention which is intended to remain in place after the procedure
Any device intended to be partially introduced into the human body through surgical intervention and intended to remain in place after the procedure for at least 30 days is also considered an implantable device.

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.

There are two exceptions to this:

- A surgically created stoma used in colostomy and ileostomy **or tracheostomy** is considered to be a natural 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 "natural body orifice". Devices introduced into such an opening are surgically invasive.

- A device that administers energy to the body should not be considered as invasive if only energy penetrates the body and not the device itself. Energy as such is not a device and therefore it cannot be classified. Only the device generating the energy must be classified. However, if a device administers a substance, whether this substance is a medicine or a medical device, such substance must be assessed in its own right (e.g. substances administered by a jet injector).

One of the key elements in defining what is 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 explantation are two different surgical procedures.
Some partially implanted devices are deemed to be implants. For instance, if an operation is carried out to specifically to place an infusion port into the body, then such an infusion port would remain after the procedure and consequently be an implant.

However, a suture used for skin wound closure that is taken out prior to 30 days is not an implant.

3.1.3. Active devices

~~The definition of an active medical device contains the concept that "medical devices intended to transmit energy, substances or other elements between an active medical device and the patient, without any significant change, are not considered to be active medical devices."~~

Definition of active medical device:

Any medical device operation of which depends on a source of electrical energy or any source of power other than that directly generated by the human body or gravity and which acts by converting this energy. Medical devices intended to transmit energy, substances or other elements between an active medical device and the patient, without any significant change, are not considered to be active medical devices.

The concept "act by converting energy" includes conversion of energy in the device and/or conversion at the interface between the device and the tissues.

The concept of "significant changes" includes changes in the nature, level and density of energy (see rule 9). This means that for instance an electrode is not an active device under this classification system as long as the energy input is intended to be the same as the energy output. For instance, Resistance in a wire that causes minor changes between input and output cannot be considered to constitute "significant change". **For example: electrodes used in electrosurgery for cutting tissues or cauterisation are active devices because their operation depends on energy provided by a generator and their action is achieved by conversion of energy at the interface between the device and the tissue. Electrodes intended for E.C.G. or E.E.G are normally not active devices because they do not normally act by conversion of energy at the interface with the body or in the electrode.** However, it should be understood that an electrode, which is an accessory of an active implant, is covered under the relevant directive for active implants. Further information on this issue can be found in "Guidelines relating to the application of the Council Directive 90/385/EEC on active implantable medical devices (Med.Dev. 5/93)".

The application of energy from the human body does not make a device "active" unless that energy is stored within the device for subsequent release. For instance, energy generated by human muscle and applied to the plunger of a syringe (thus causing a substance to be delivered to a

patient) does not make this syringe an "active device". However, if a drug delivery system depends upon manual winding to preload a spring which is subsequently released to deliver a substance, then the device incorporating the spring is an "active device".

Medical devices using prestored gases and/or vacuum as a power source are regarded as active devices, e.g. gas mixers with anesthesia machines and gas powered suction pumps.

Heating/cooling pads intended only to release stored thermal energy are not active devices because they do not act by conversion of energy.

Radioactive sources that are intended to deliver ionizing radiation are regarded as active medical devices, unless they are radiopharmaceuticals as defined in article 2 of Directive 89/343/EEC.

3.1.4 Devices with a measuring function

See Meddev 2.1/5

3.2. Application rules

In terms of further interpretation of the decision rules, the following should be considered:

- It is the intended purpose 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.

- 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 in the maze of the many threads of sutures 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.

- 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.

- 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. Similarly combination 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.

- Accessories must be classified separately from their parent device.

- If a given device can be classified according to several rules, then the highest possible class applies. For instance, a wound dressing incorporating collagen is covered by rules 4 (Class I, Class IIa or *Class IIb* depending on *intended use*) and *17 (Class III*).

- If the device is not intended to be used solely or principally in a specific part of the body, it must 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 a device to be "specifically intended" 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 be intended to be used principally for the purpose that is accepted in general medical practice.

- Multi-application equipment such as laser printers and identification cameras, which may be used in combination with medical devices, are not medical devices unless their manufacturer places them on the market with specific intended purpose as medical devices.

3.3. How to use the rules and the decision tree

The manufacturer must take into consideration all the rules in order to establish the proper classification for his device. It is quite conceivable for instance that one of the general rules that are not specific to active devices, nevertheless applies to such a device. All the device characteristics must be taken into consideration. The characteristic or combination of characteristics in accordance with the intended purpose of the device that rates the highest class determines the class for the device as a whole.

For further clarity, a decision tree in the form of a flow chart is included in Appendix 2.

3.4. Practical example

Example: a 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.
It is assumed here that the device is used for a short term duration, i.e. that uninterrupted intended use is more than 60 minutes and less than 30 days. It is furthermore assumed that the collected liquids are not intended to be re infused into the body nor reprocessed for eventual re infusion and that the device is not intended to be connected to a powered suction system.

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

The clear conclusion here is that the manufacturer would have a choice of applying Class II A 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.

3.5. Handling of interpretational problems.

In case the manufacturer is unsure how its devices should be classified, it should first consult a Notified Body. In case doubts remain or there is a disagreement with the Notified Body, the relevant Competent Authority should be approached in accordance with Art. 9 of the Directive. In addition, the Directive provides Community wide mechanisms, including a committee procedure, to address problems related to classification.

4. EXPLANATIONS OF 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 GENERAL EXPLANATION OF RULES/PRACTICAL ISSUES/EXAMPLES

Rule 1 - Devices that either do not touch the patient or contact intact skin only
General explanation of the rule

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.

RULE 1	**EXAMPLES**
All non-invasive devices are in Class I, unless one of the rules set out hereinafter applies.	- 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 immobilize 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, frames, stethoscopes for diagnosis, eye occlusion plasters, incision drapes, conductive gels, non-invasive electrodes, image intensifying screens, software intended for image processing - **electrodes for EEG or ECG**

Practical issues of classification

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.

Non-invasive receptacles intended for biological samples for in vitro diagnostic examination are not covered by this Directive.

4.1 GRAPHICAL SUMMARY - MEDICAL DEVICES CLASSIFICATION

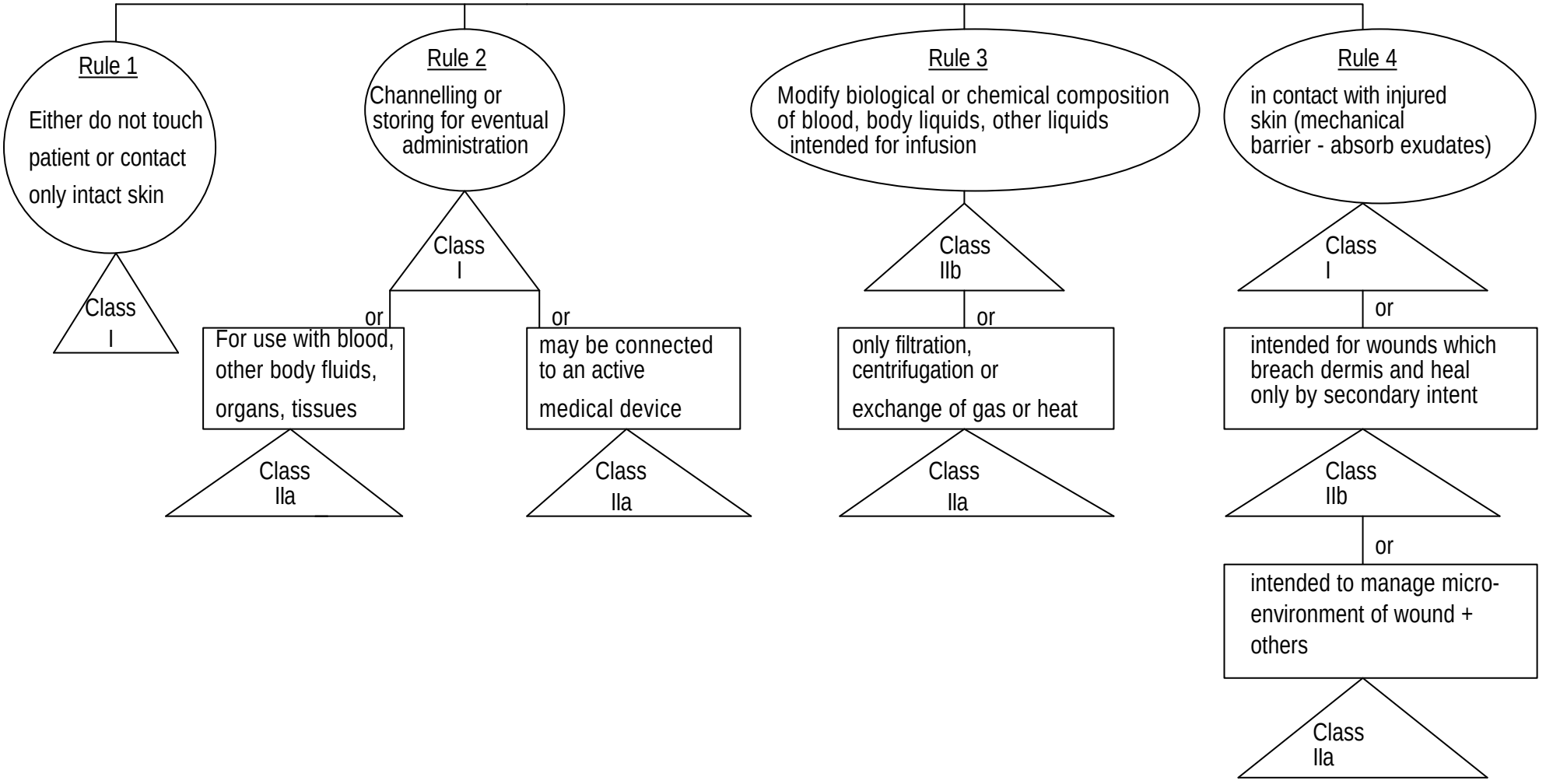
GUIDANCE CHART FOR INITIAL IDENTIFICATION OF PROBABLE DEVICE CLASS

Note : always confirm definitive classification by reading actual applicable 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 (pages 12 to 35)

INDEX	SUBJECTS
Page 14b	Non invasive devices - Rules 1, 2, 3, 4
Page 14c	Invasive devices - Headings
Page 14d	Invasive devices - Rules 5, 6
Page 14e	Invasive devices - Rules 7, 8
Page 14f	Active devices - Rules 9, 10, 11, 12
Page 14g	Special rules - Rules 13, 14, 15, 16, 17, 18

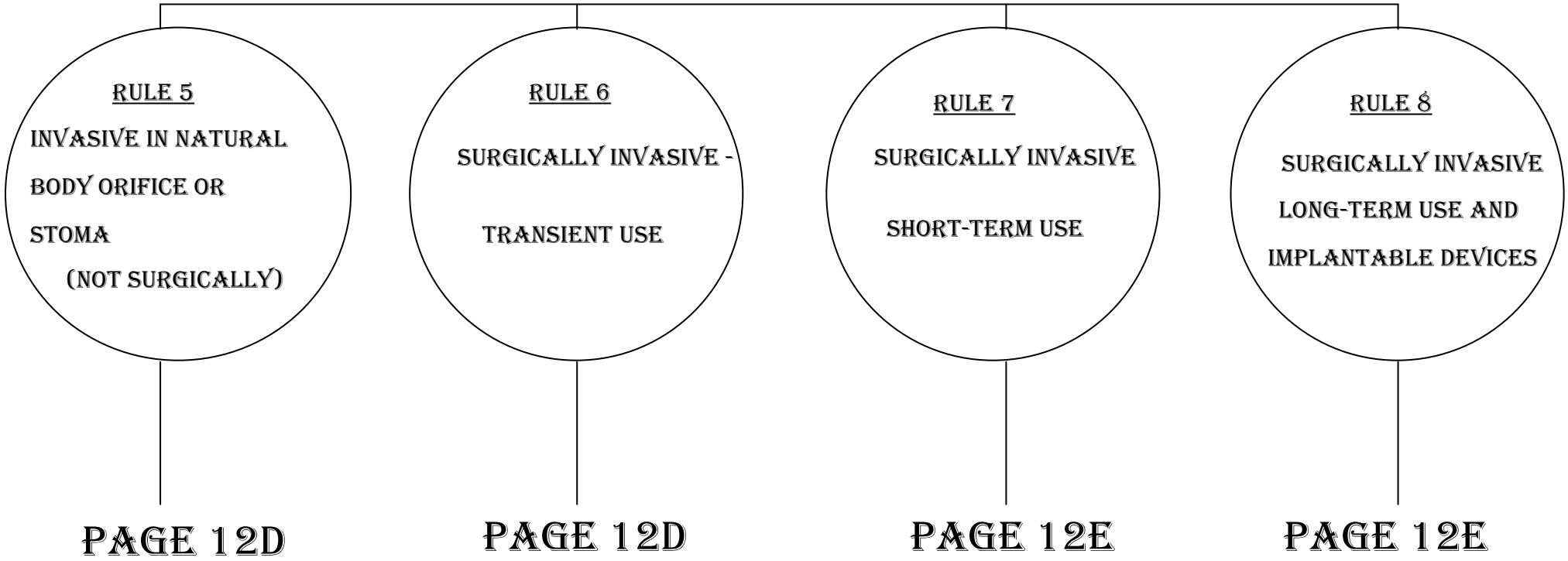
Remember ! the characteristics or combination of characteristics in accordance with the intended purpose of the device that rates the highest class determines the class for the device as a whole.

NON INVASIVE DEVICES



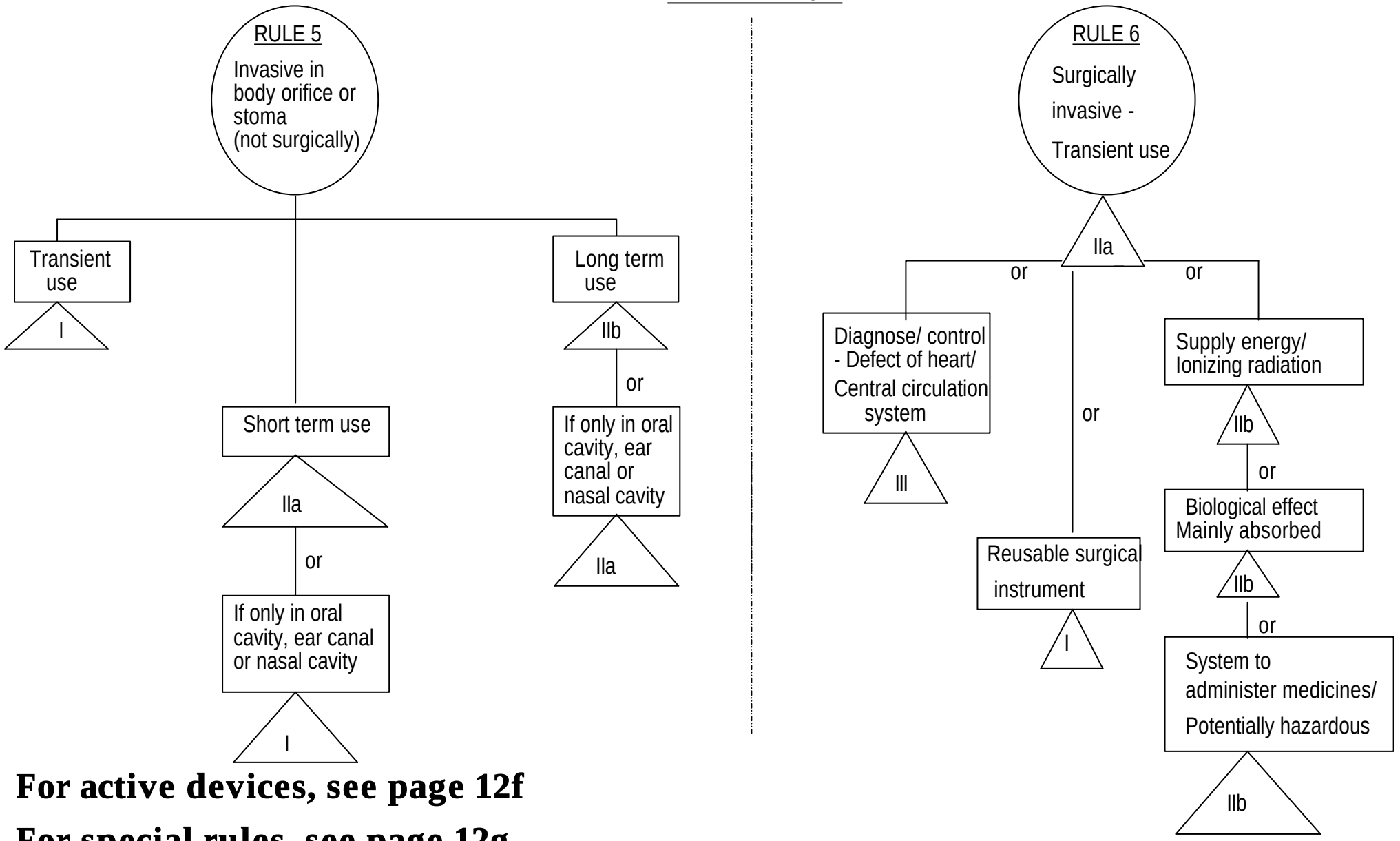
For invasive devices, see page **14c, 14d, 14e**
For active devices, see page **14f**
For special rules, see page **14g**

INVASIVE DEVICES



PAGE 12D PAGE 12D PAGE 12E PAGE 12E

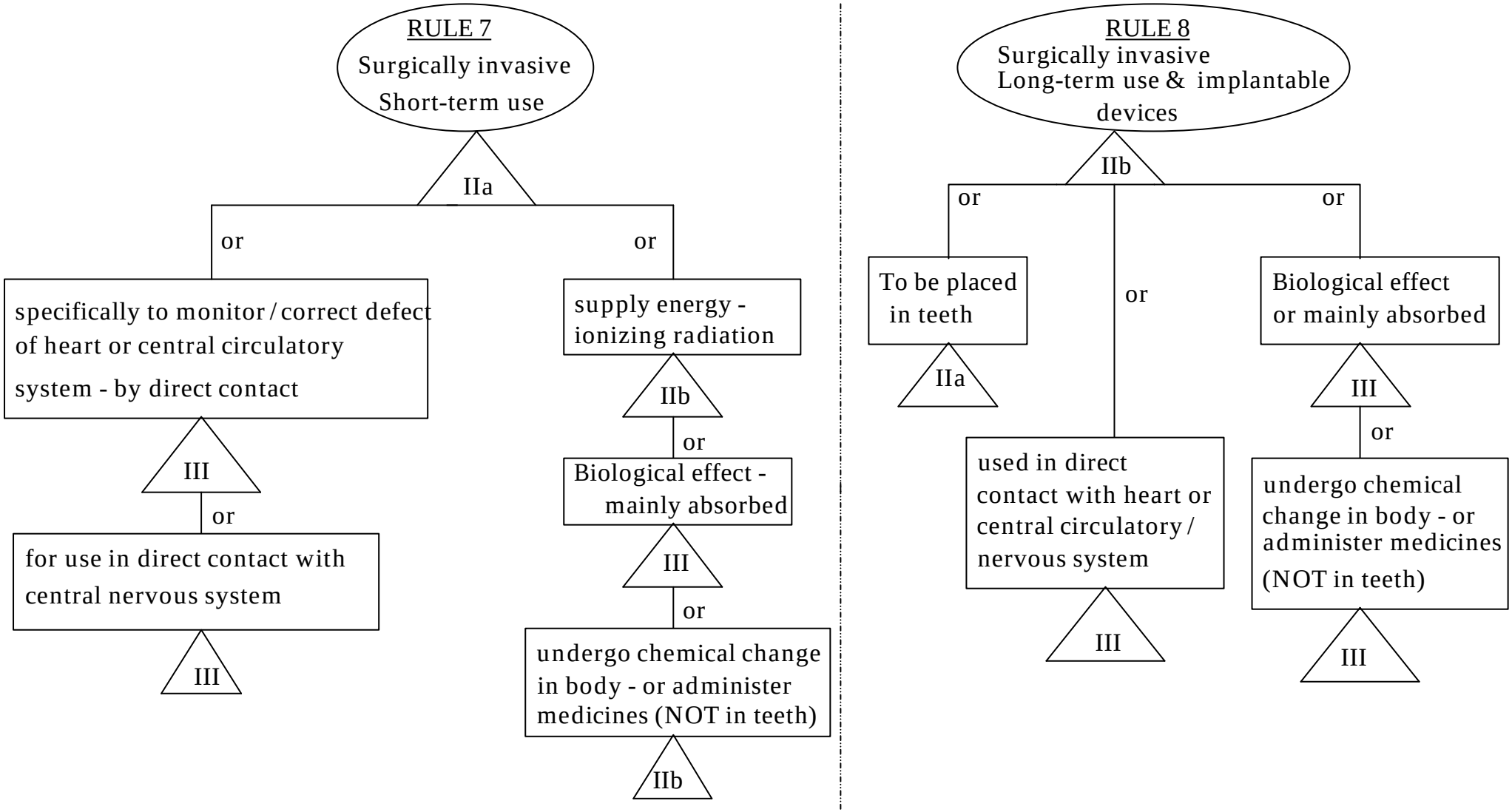
INVASIVE DEVICES



For active devices, see page 12f

For special rules, see page 12g

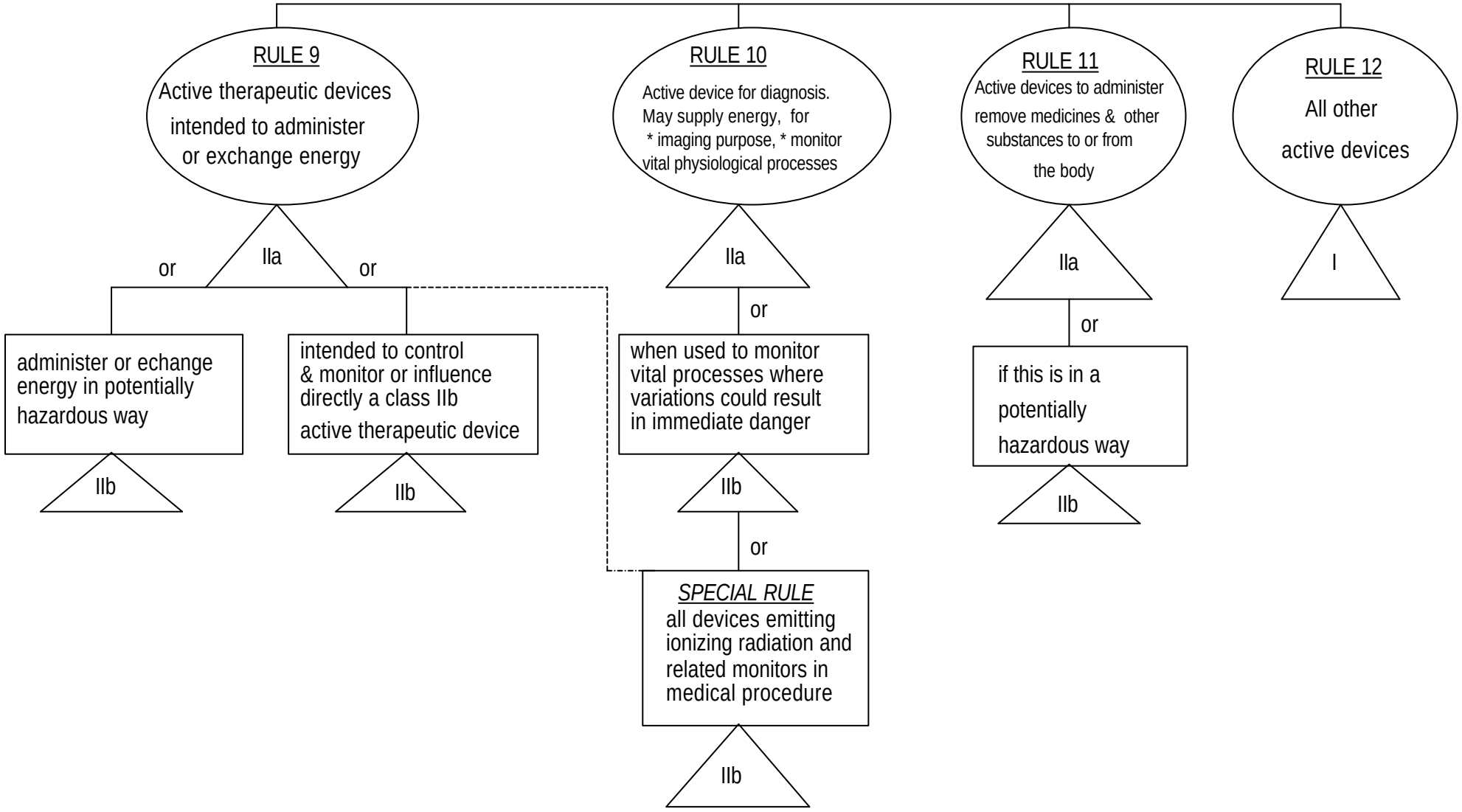
INVASIVE DEVICES



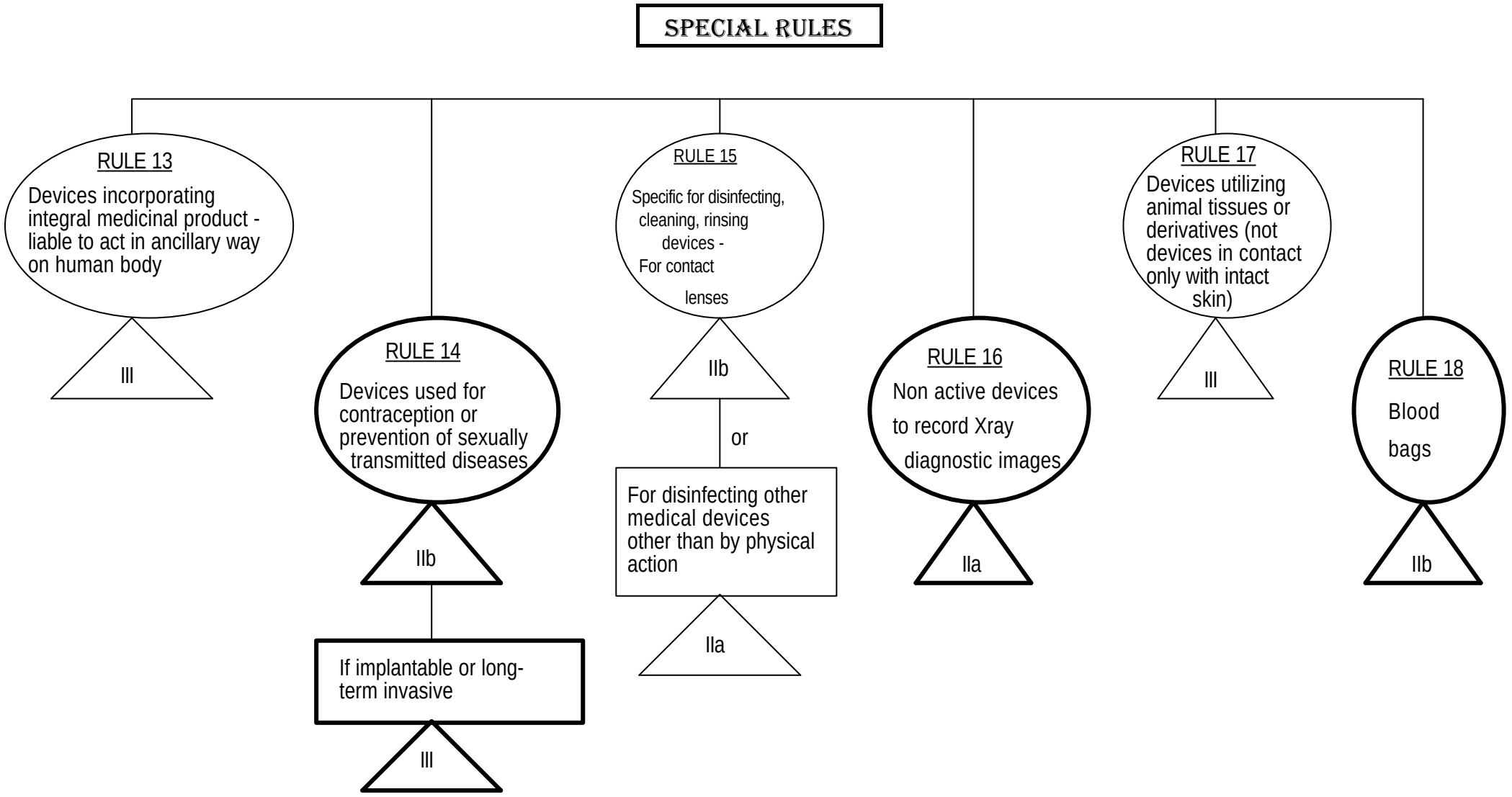
For active devices, see page 12f

For special devices, see page 12g

ACTIVE DEVICES



For special rules, see page 12g



THESE SPECIAL RULES OVERRIDE OTHER RULES

Rule 2 - Channeling or storing for eventual administration

General explanation of the rule

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 be eventually delivered into the body. Typically these devices are used in transfusion, infusion, extracorporeal circulation, delivery of anaesthetic gases and oxygen.

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

RULE 2	EXAMPLES
All non-invasive devices intended for channeling or storing blood, body liquids or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the body are in Class IIa: - if they may be connected[1] to an active medical device in Class IIa or a higher class,	- 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 anesthesia, anesthesia breathing circuits and pressure indicator, pressure limiting devices **and pipes for distribution networks for medical gases in hospitals** - Syringes for infusion pumps.
- if they are intended for use for storing or channelling blood or other body liquids or for storing organs, parts of organs or body tissues (are in Class II a)	- Devices intended to channel blood (e.g. in transfusion, extracorporeal circulation). - Devices intended for temporary storage and transport of organs for transplantation - Devices intended for long term storage of biological substances and tissues such as corneas, sperm, human embryos, etc.
in all other cases they are in Class I.	- Devices that provide a simple channeling function, with gravity providing the force to transport the liquid, e.g. tubing used in gravity drips for saline solution and medicines. - Devices intended to be used for a temporary containment or storage function such as cups and spoons specifically intended for administering medicines. - Syringes without needles

Practical issues of classification

Blood bags are covered as an exception under a separate rule (see rule 18).

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 II A, unless the manufacturer clearly state that it should not be connected to an active device of Class II A or higher.

Explanation of special concepts

Note 1: "May be connected to an active device". Such connection is deemed to exist between a non-active device and an active device where a 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.

Note 2: Primary packaging for medicinal products are normally not medical devices

Rule 3 - Devices that modify biological or chemical composition of blood, body liquids or other liquids

General explanation of the rule

These types of devices must be considered separately from the non-contact devices of rule 1 because they are indirectly invasive. They treat or modify substances that will be eventually delivered 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 not be reintroduced immediately, **where the patient is not in a closed loop with the device,** into the body.

RULE 3	**EXAMPLES**
All non-invasive devices intended for modifying the biological or chemical composition of blood, other body liquids or other liquids intended for infusion into the body are in Class IIb,	- Devices intended to remove undesirable substances out of the blood by exchange of solutes such as hemodyalizers. - Devices intended to separate cells.
unless the treatment consists of filtration, centrifugation or exchange of gas or heat, in which case they are in Class IIa.	- 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.

Practical issues of classification

These devices are normally used in conjunction with an active medical device covered under rule 9 or rule 11.

Filtration and centrifugation should be understood in the context of this rule as exclusively mechanical methods.

Rule 4 - Devices in contact with injured skin

General explanation of the rule

This rule is intended to cover primarily wound dressings independently of the depth of the wound. The traditional types of products (e.g. 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 life-saving purpose, e.g. when there is full thickness destruction of the skin over a large area and/or systemic effect.

RULE 4	**EXAMPLES**
All non-invasive devices which come into contact with injured skin: - are in Class I if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates,	- Wound dressings, such as absorbent pads, island dressings, cotton wool, wound strips and gauze dressings to act as a barrier or to maintain the wound positionally or to absorb exudates from the wound.
- are in Class IIb if they are intended to be used principally with wounds which have breached the dermis and can only heal by secondary intent	- 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: - dressings for chronic extensive ulcerated wounds - dressings for severe burns having breached the dermis and covering an extensive area - dressings for severe decubitis wounds - dressings incorporating means of augmenting tissue and providing a temporary skin substitute
- are in Class IIa in all other cases, including devices principally intended to manage the micro-environment of a wound.	- 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 . - These devices may specify particular additional healing properties whilst not being intended for extensive wounds requiring healing by secondary intent. - Adhesives for topical use. - Polymer film dressings, hydrogel dressings and non-medicated impregnated gauze dressings.

Practical issues of classification

Products covered under this rule are extremely claim sensitive, e.g. a polymeric film dressing would be in Class II A if the intended use is to manage the micro-environment of the wound and in Class I 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 II B.

Most dressings that are intended for a use that is in Class II A or II B, also perform functions that are in Class I, 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 medicines see rule 13 or animal tissues see rule 17.

Explanation of special concepts

- 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 5 Devices invasive in body orifices

General explanation of the rule

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). 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.

The surgically created stoma, which **for example** allows the evacuation of urine or faeces, should be also considered as a body orifice.

Devices are covered by this rule tend to be diagnostic and therapeutic instruments used in particular specialities (ENT, ophthalmology, dentistry, proctology, urology and gynecology).

RULE 5	**EXAMPLES**
All invasive devices with respect to body orifices, other than surgically invasive devices and which are not intended for connection to an active medical device:	
- are in Class I if they are intended for transient use,	- Handheld mirrors used in dentistry to aid in dental diagnosis and surgery, dental impression materials, tubes used for pumping the stomach, impression tray, enema devices, examination gloves and prostatic balloon dilation catheters.
- are in Class IIa if they are intended for short term use,	- Contact lenses, urinary catheters, tracheal tubes, stents, vaginal pessaries and perineal reeducation devices.

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 a nasal cavity , in which case they are in Class I,	- Dressings for nose bleeds, dentures removable by the patient.
- are in Class IIb if they are intended for long term use,	- Urethral stents.
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 a nasal cavity and are not liable to be absorbed by the mucous membrane, in which case they are in Class IIa.	- Orthodontic wire, fixed dental prostheses, fissures sealants.
All invasive devices with respect to body orifices, other than surgically invasive devices, intended for connection to an active medical device in Class IIa or a higher class, are in Class IIa.	- Tracheostomy or tracheal tubes connected to a ventilator, blood oxygen analysers placed under the eye-lid, powered nasal irrigators, nasopharyngeal airways, ~~heat and moisture exchangers,~~ some enteral feeding tubes, fibreoptics in endoscopes connected to surgical lasers, suction catheters or tubes for stomach drainage.

Rule 6 - Surgically invasive devices for transient use

General explanation of the rule

This rule covers principally 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	EXAMPLES
All surgically invasive[1] devices intended for transient use are in Class IIa unless they are:	- Needles used for suturing, needles of syringes, lances, suckers, single use scalpels, support devices in ophtalmic surgery, staplers, surgical swabs, drill bits connected to active devices, surgical gloves, etchants**, single use aortic punches (see note 2), tester of artificial heart valves, heart valve occluder, heart valve sizers and holders**
- intended specifically to diagnose, monitor or correct a defect [2] of the heart or of the central circulatory system[1] through direct contact with these parts of the body, in which case they are in Class III [3]	- Cardiovascular catheters (e.g. angioplasty balloon catheters), including related guidewires and dedicated disposable cardiovascular surgical instruments. **- Coronary artery probes**
- reusable surgical instruments[1], in which case they are in Class I[3],	- Scalpels, drill bits, saws, that are not intended for connection to an active device, and retractors *forceps, excavators and chisels*.
- intended to supply energy in the form of ionizing radiation in which case they are in Class IIb,	**- Catheters containing or incorporating radioisotopes where the radioactive isotope as such is not intended to be released into the body unless the 1st indent of the rule applies**
- intended to have a biological[4] effect or to be wholly or mainly absorbed[4] in which case they are in Class IIb,	

- intended to administer medicines by means of a delivery system, if this is done in a manner that is potentially hazardous[5] taking into account of the mode of application, in which case they are Class IIb.	- Devices for repeated self-application where dosage levels and the nature of the medicinal product are critical, e.g. insulin pens.

Explanations of special concepts

Note 1:

Terms such as "surgically invasive device", "central circulatory system" and "reusable surgical instruments" are defined in Section I of Annex IX of the Directive. In particular surgical instruments connected to an active device are not considered to be reusable surgical instruments.

Note 2*:* The expression "correct a defect" does not cover devices that are used accessorily in heart surgery, e.g. clamps **and tissue stabilisers. The first indent of this rule does not apply to aortic punches and similar cutting instruments which perform a similar function to a scalpel and which do not give rise to additional hazards to those of a scalpel.**

Note 3: Surgical instruments which are not specifically intended for purposes described in the first indent, and irrespective of the site of application, are in class IIA, if they are intended for single use and in class I if they are reusable.

Note 4:
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 a response from the tissues that is mediated by specific reactions at a molecular level. Such a device may be described as bioactive.
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.

Note 5*:* The concept of "potentially hazardous manner" is related to the characteristics of the device and not the competence of the user.

Rule 7 - Surgically invasive devices for short-term use

General explanation of the rule

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	EXAMPLES
All surgically invasive devices intended for short term use are in Class IIa unless they are intended:	- Clamps, infusion cannulae, skin closure devices, temporary filling materials. **- Tissue stabilisers used in cardiac surgery**
- either specifically to diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class III,	- Cardiovascular catheters, cardiac output probes and temporary pacemaker leads. **- Thoracic catheters intended to drain the heart, including the pericardium** **- Temporary vera cava filter**
- or specifically for use in direct contact with the central nervous system, in which case they are in Class III,	- Neurological catheters, cortical electrodes and connonoid paddles.
- or to supply energy in the form of ionizing radiation in which case they are in Class IIb,	- Brachytherapy devices.
- intended to have a biological effect or to be wholly or mainly absorbed in which case they are in Class III,	- Absorbable sutures and biological adhesives.
- or to undergo chemical change in the body, except if the devices are placed in the teeth, or to administer medicines[1], in which case they are Class IIb.	- Adhesives

Practical issues of classification

Note 1: Administration of medicines is more than just channeling, 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.

Rule 8 - Surgically invasive devices for long-term use and implantable devices

General explanation of the rule

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	EXAMPLES
All implantable devices and long-term surgically invasive devices are in Class IIb unless they are intended:	- Prosthetic joint replacements, ligaments, shunts, stents, nails, plates, intra-ocular lenses, internal closure devices, tissue augmentation implants, infusion ports, peripheral vascular grafts, penile implants, non-absorbable sutures, bone cements and maxillo-facial implants, visco-elastic surgical devices intended specifically for ophthalmic anterior segment surgery [1].
- to be placed in the teeth[2], in which case they are in Class IIa,	- Bridges, crowns, dental filling materials and pins, dental alloys, ceramics and polymers.
- to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are Class III,	- Prosthetic heart valves, aneurysm clips, vascular prostheses, spinal stents, vascular stents, CNS electrodes and cardiovascular sutures. **- Permanent vena calva filters**
- to have a biological effect or to be wholly or mainly absorbed, in which case they are in Class III,	- Absorbable sutures,adhesives and implantable devices claimed to be bioactive through the attachment of surface coatings such as phosphorylcholine.
- or to undergo chemical change[3] in the body, except if the devices are placed in the teeth, or to administer medicines, in which case they are in Class III.	- Rechargeable non-active drug delivery systems.

Practical issues of classification

Note 1 : 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 17.

Note 2: Implants without bioactive coatings intended to secure teeth or prostheses to the *maxillary or mandibular* bones are in Class II B following the general rule. Hydroxy-apatite is considered as having biological effect only if so claimed and demonstrated by the manufacturer.

Note 3: 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.

Rule 9 - Active therapeutic devices intended to administer or exchange energy

General explanation of the rule

Devices classified by this rule are mostly electrical equipment used in surgery such as lasers and surgical generators. In addition there are devices for specialised 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	**EXAMPLES**
All active therapeutic devices intended to administer or exchange energy are in Class IIa	Electrical, magnetic and electromagnetic energy - Muscle stimulators and external bone growth stimulators, TENS devices and eye magnets, **electrical accupuncture** Thermal energy - Warming blankets except for unconscious patients, cryosurgery equipment**, heat exchangers** . Mechanical energy - Powered *d*ermatomes, powered drills and dental hand pieces. Light - Phototherapy for skin treatment and for neonatal care Sound - Hearing aids

unless their characteristics are such that they may administer or exchange energy to and from the human body in a potentially hazardous way[1], taking account of the nature, the density and the site of application of the energy, in which case they are in Class IIb.	Kinetic energy - Lung ventilators Thermal energy - Incubators for babies, warming blankets for unconscious patients, blood warmers**, heat exchangers used in intensive care** Electrical energy - High-frequency electrosurgical generators, electrocautery equipment **including their electrodes**, external pacemakers, external defibrillators, electroconvulsive therapy equipment Coherent light - Surgical lasers Ultrasound - Lithotriptors, **surgical ultrasound devices** Ionizing radiation - Radioactive sources for afterloading therapy, therapeutic cyclotrons, linear accelerators, therapeutic X-ray sources.
All active devices intended to control and monitor the performance of active therapeutical devices in Class IIb or intended to influence directly the performance of such devices are in Class IIb.	- External feedback systems for active therapeutic devices, afterloading control devices.

Explanation of special concepts

Note 1: 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 IIB. However, the manufacturer's obligation to comply with design requirements and solutions adopted, such as use of standards, exist independently from the classification system.

Rule 10 - Active devices for diagnosis.

General explanation of the rule

This covers principally a whole range of widely used equipment in the fields ultrasound diagnosis and capture of physiological signals as well as therapeutic and diagnostic radiology.

RULE 10	EXAMPLES
Active devices intended for diagnosis are in Class IIa:	
- if they are intended to supply energy which will be absorbed by the human body, except for devices used to illuminate the patient's body, in the visible spectrum,	- Magnetic resonance equipment, pulp testers, evoked response stimulators, diagnostic ultrasound.
- if they are intended to image in vivo distribution of radiopharmaceuticals,	- Gamma cameras, positron emission tomography and single photon emission computer tomography.
- if they are intended to allow direct diagnosis or monitoring of vital physiological processes[1],	- Electrocardiographs, electroencephalographs, cardioscopes with or without pacing pulse indicators[2] **- Electronic thermometers**
unless they are specifically intended for monitoring of vital physiological parameters, where the nature of variations is such that it could result in immediate danger to the patient, for instance variations in cardiac performance, respiration, activity of CNS in which case they are in Class IIb.	- Intensive care monitoring systems, biological sensors, blood gas analysers used in open heart surgery, cardioscopes and apnea monitors[1], including those in home care.

Active devices intended to emit ionizing radiation and intended for diagnostic and therapeutic interventional radiology[3] including devices which control or monitor[4] such devices, or which directly influence their performance, are in Class II B.	- *Diagnostic* X-ray sources.

Examples of special concepts:

Note 1: Vital physiological processes and parameters, e.g. 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 anesthesia, intensive care or emergency care are in Class IIB, 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 IIA. A thermal imaging device intended to monitor blood flow is not considered to be a temperature measuring device.

Note 2: Devices specifically intended to monitor AIMDs fall under the AIMD Directive.

Note 3: Therapeutic interventional radiology refers to diagnosis being carried out during surgical procedures

Note 4: 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.

Rule 11 - Active devices to administer, remove medicines and other substances to or from the body

General explanation of the rule

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

RULE 11	EXAMPLES
All active devices intended to administer and/or remove medicines, body liquids or other substances to or from the body are in Class IIa,	- Suction equipment, feeding pumps. **- Jet injectors for vaccination**
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 in Class IIb.	- Infusion pumps, ventilators, anesthesia machines, anesthetic vaporisers, dialysis equipment, blood pumps for heart-lung machines, hyperbaric chambers, pressure regulators for medical gases, **medical gas mixers, moisture exchangers in breathing circuits** **- Nebulisers where the failure to deliver the appropriate dosage form could be hazardous.**

Rule 12 All other active devices

General explanation of the rule

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

RULE 12	EXAMPLES
All other active devices are in Class I.	- Active diagnostic devices intended to illuminate the patient's body in the visible spectrum such as examination lights or to optically view the body such as surgical microscopes. - Devices intended in general for external patient support (e.g. hospital beds, patient hoists, walking aids, wheelchairs, stretchers, dental patient chairs). - Active diagnostic devices intended for thermography. - Active devices intended for recording, processing or viewing of diagnostic images. - Dental curing lights.

4. Special rules

Rule 13 - Devices incorporating a medicinal substance

General explanation of the rule

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 at maintaining certain characteristics of the device and which are not liable to act on the body. For instance antimicrobial agents for the preservation of solutions for contact lenses.** The primary function of the device does not rely on the pharmacological effect of the medicine. If the latter is the case, the product is a medicine rather than a device and not covered by this Directive.

RULE 13	EXAMPLES
All devices incorporating, as an integral part[1], a substance which, if used separately, can be considered to be a medicinal product as defined in Article 1 of the Directive 65/65/EEC, and which is liable to act on the human body with action ancillary to that of the devices, are in Class III.	- Antibiotic bone cements, [medicated dressings], condoms with spermicide, heparin coated catheters, endodontic materials with antibiotics. **- Opthalmic irrigation solutions intended inter alia to support the metabolism of the endothelial cells of the cornea** **- Dressings incorporating an antimicrobial agent where the purpose of such an agent is to provide ancillary action on the wound**

Note 1: "Integral part" means that the device and the medicinal substance form one physical unit.

Rule 14 - Devices used for contraception or prevention of sexually transmitted diseases

General explanation of the rule

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 14	EXAMPLES
All devices used for contraception or the prevention of the transmission of sexually transmitted diseases are in Class IIb,	- Condoms, contraceptive diaphragms.
unless they are implantable or long term invasive devices, in which case they are in Class III.	- Contraceptive intrauterine devices (IUDs)[1] .

Note 1: Intrauterine contraceptives whose primary purpose is to release progestogens are medicines and not medical devices.

Rule 15 - Specific disinfecting, cleaning and rinsing devices

General explanation of the rule

This rule is principally intended to cover various contact lens fluids. It also covers substances used principally in a medical environment to disinfect medical devices.

RULE 15	EXAMPLES
All devices intended specifically to be used for disinfecting, cleaning, rinsing or, when appropriate hydrating contact lenses are in Class IIb.	- Contact lens solutions, comfort solutions.
All devices intended specifically to be used for disinfecting medical devices are in Class IIa.	- Disinfectants specifically intended for instance for endoscopes **or haemodyalysis apparatus**, sterilizers specifically intended to sterilize medical devices in a medical environment **and washer disinfecters.**
This rule does not apply to products that are intended to clean medical devices other than contact lenses by means of physical action[1].	

Practical issues of classification

Note 1: This rule does not apply to mechanical means of cleaning of devices, such as brushes and ultrasound. Such products will only fall under this directive if they are specifically intended for use with medical devices.

Rule 16 - Non-active devices to record X-ray diagnostic images

RULE 16	EXAMPLES
Non-active devices specifically intended for recording of X-ray diagnostic images are in Class II A.	X-ray films, photostimulable phosphor plates

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

Rule 17 - Devices utilizing animal tissues or derivatives

Explanation of the rule

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 non-inactivated animal tissues and/or any human tissues or derivatives are excluded from the scope of this Directive.

The manufacture of some devices may use industrial raw materials which contain small amounts of substances derived from animal tissues (e.g. tallow) through a chemical/physical process which is likely to destroy the structure of the original molecules. Where such substances (e.g. stearates in plastics) are not intended to have any specific effect in relation with the medical function of the device and are unlikely to be released into the body, then, such substances should not be considered as of directives animal tissues. This is justified by the fact that the intensive industrial processing of the substance has removed the original characteristics which are specific to the animal tissue as well as the risk of transmission of pathogens.

RULE 17	EXAMPLES
All devices manufactured utilizing animal tissues or derivatives[1] rendered non-viable are Class III except where such devices are intended to come into contact with intact skin only.	- Biological heart valves, porcine xenograft dressings, catgut sutures, implants and dressings made from collagen.

Practical classification issues

- Devices made of non-viable animal tissue that come into contact with intact skin only (e.g. leather components of orthopedic appliances) are in Class I in accordance to rule 1.

[Note 1 : derivatives are products that are processed from animal tissues and exclude substances such as milk, silk, beeswax, hair, lanolin]

Rule 18 - Blood bags

General explanation of the rule

This is a special rule that covers only blood bags.

RULE 18	EXAMPLES
By derogation from other rules, blood bags are in Class IIb.	Blood bags (including those **containing or** coated with an anticoagulant). Where blood bags have a function greater than for storing purposes and include systems for preservation other than anti-coagulants then other rules (e.g. rule 13) may apply

Note: Blood bags are described in the European Pharmacopoeia in the monograph on "Containers for Blood and Blood Components".