
MEDICAL DEVICES: Guidance document

MEDDEV 2.4/1 Rev.8

July 2001

**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 December 1999 as MEDDEV. 2.4/1 rev. 6

1. PURPOSE AND PHILOSOPHY OF MEDICAL DEVICE CLASSIFICATION	3
2. PRACTICAL RELEVANCE OF CLASSIFICATION.....	
2.1. General requirements.	
2.2. Conformity assessment	
2.3. Clinical data.....	
2.4. Labelling	
2.5. Miscellaneous.....	
3. HOW TO CARRY OUT CLASSIFICATION	
3.1. Basic definitions	
3.2. Application rules.....	
3.3. How to use the rules and the decision tree	
3.4. Practical example	
3.5. Handling of interpretational problems.....	
4. EXPLANATIONS OF INDIVIDUAL RULES	
4.1. Graphical summary - Guidance chart	
4.2. General explanation of rules/Practical issues/Examples.....	

APPENDICES:

1. Annex IX of the Medical Device Directive

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 there 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 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).

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

2.2. Conformity Assessment

CONFORMITY ASSESSMENT PROCEDURES	CLASSES					
	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

The Medical Devices Directive states that 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. This rule applies in particular in the case of implantable devices and devices in class III (Annex X, 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. Instructions for use

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).

3. HOW TO CARRY OUT CLASSIFICATION

The manufacturer should first decide if the product concerned is a medical device as defined in the Directive 93/42 or an accessory to such a medical device and if it therefore comes within the scope of this Directive.

Active implantable devices and devices for in vitro diagnosis are covered by separate directives, which do not apply the classification rules reviewed in these Guidelines.

3.1. Basic definitions

The classification rules are based on terms related to duration of contact with the patient, degree of invasiveness and the part of the body affected by the use of the device. These terms are defined in Section I of Annex IX of the Directive and reproduced below, together with some additional guidance.

3.1.1. Time

3.1.1.1. 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.

3.1.1.2 Concept of continuous use

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.

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.

3.1.2. Invasiveness

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.

There are two exceptions to this:

A surgically created stoma used in colostomy and ileostomy or **permanent** 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 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.

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.

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

3.1.3. Active devices

Definition of active medical device (Annex IX Sect. I clause 1.4):

Any medical device the 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 or in 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 or in 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. 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. 2.1/2).

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. However, heating/cooling pads which act by chemical action (e.g. endothermic or exothermic reaction) are active devices as they are converting chemical energy into heat energy and or vice versa.

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 or radioactive implants as defined in article 1 of Directive 90/385/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.
- Standalone software, e.g. software which is used for image enhancement is regarded as driving or influencing the use of a device and so falls automatically into the same class. Other standalone software, which is not regarded as driving or influencing the use of a device, is classified in its own right.

3.3. How to use the rules

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.

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.

4.1 Graphical summary – medical devices classification guidance chart for initial identification of probable device class

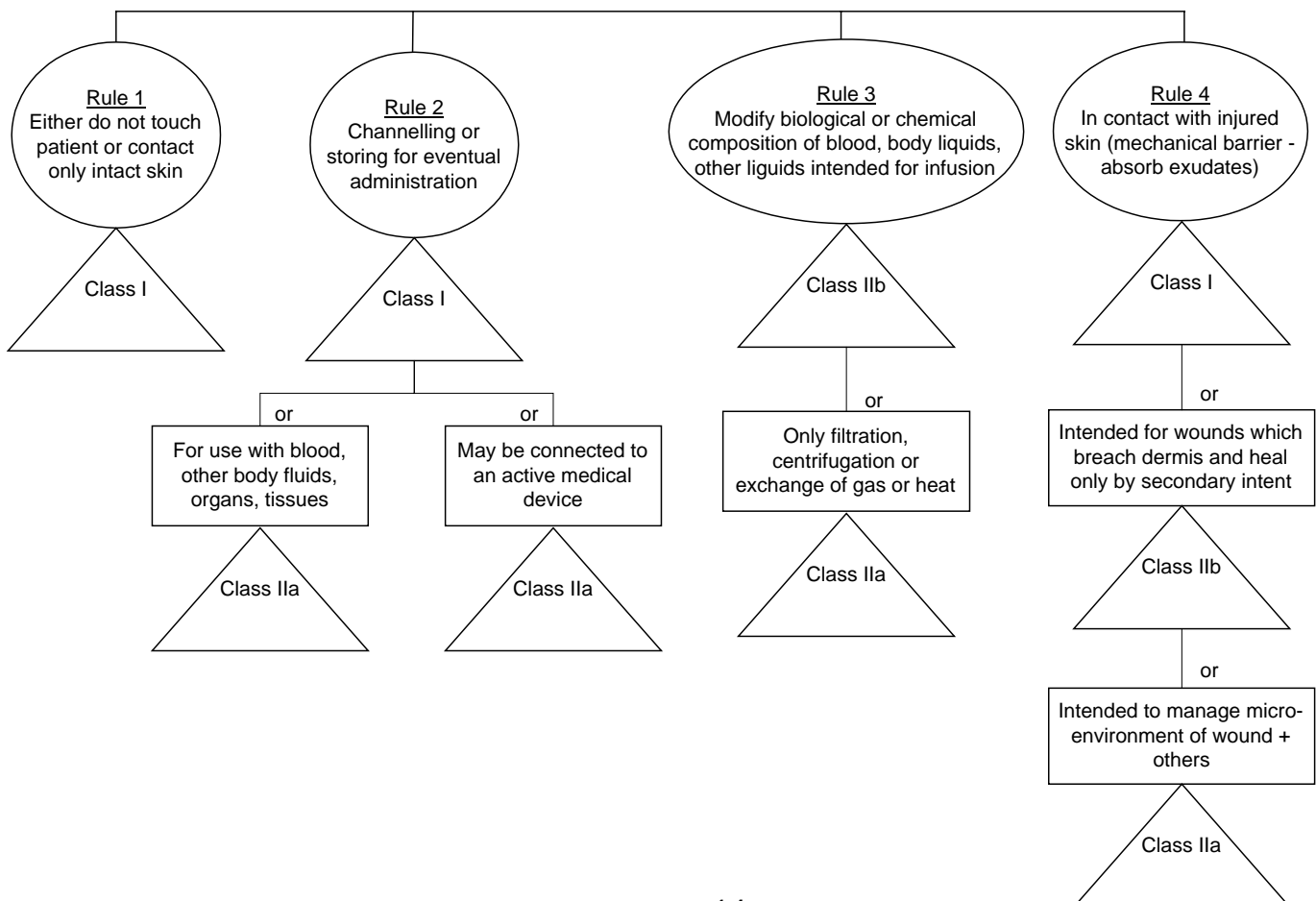
Note:

Always confirm definitive classification by reading all rules in detail, and utilise additional assistance in this guidelines document as provided in the form of general explanations of rules and examples of devices (see section 4.2)

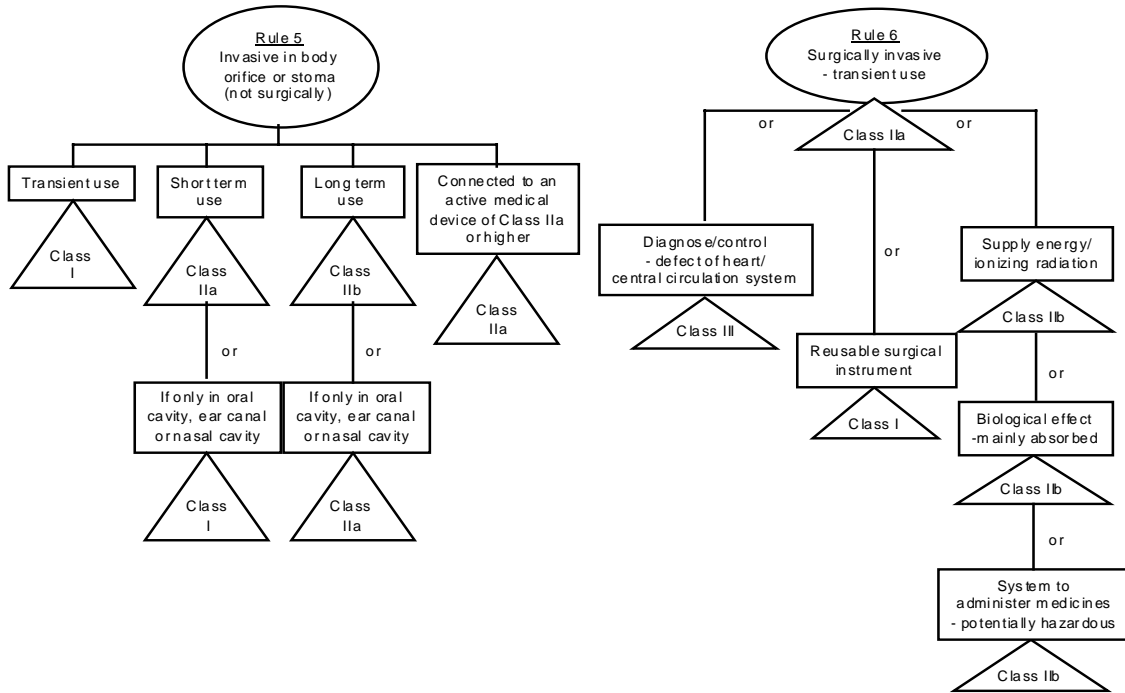
SUBJECTS
Non invasive devices – Rules 1, 2, 3, 4
Invasive devices – Rules 5, 6, 7, 8
Active devices – Rules 9, 10, 11, 12
Special rules – Rules 13, 14, 15, 16, 17, 18

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

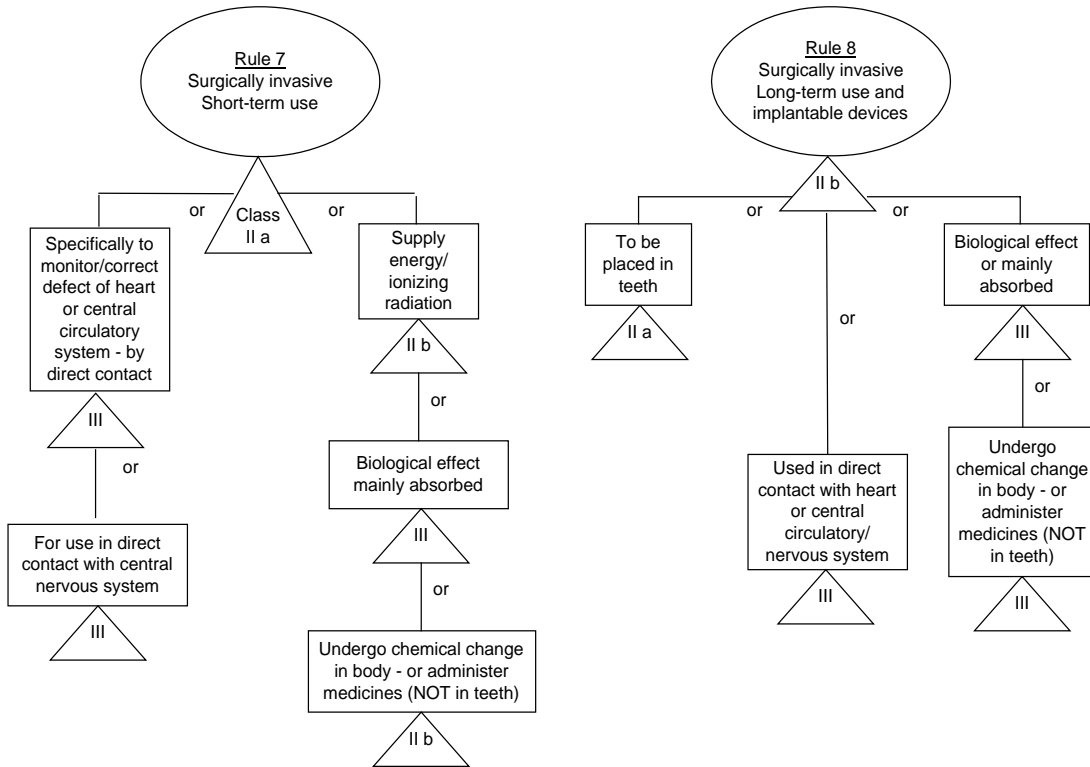
NON INVASIVE DEVICES



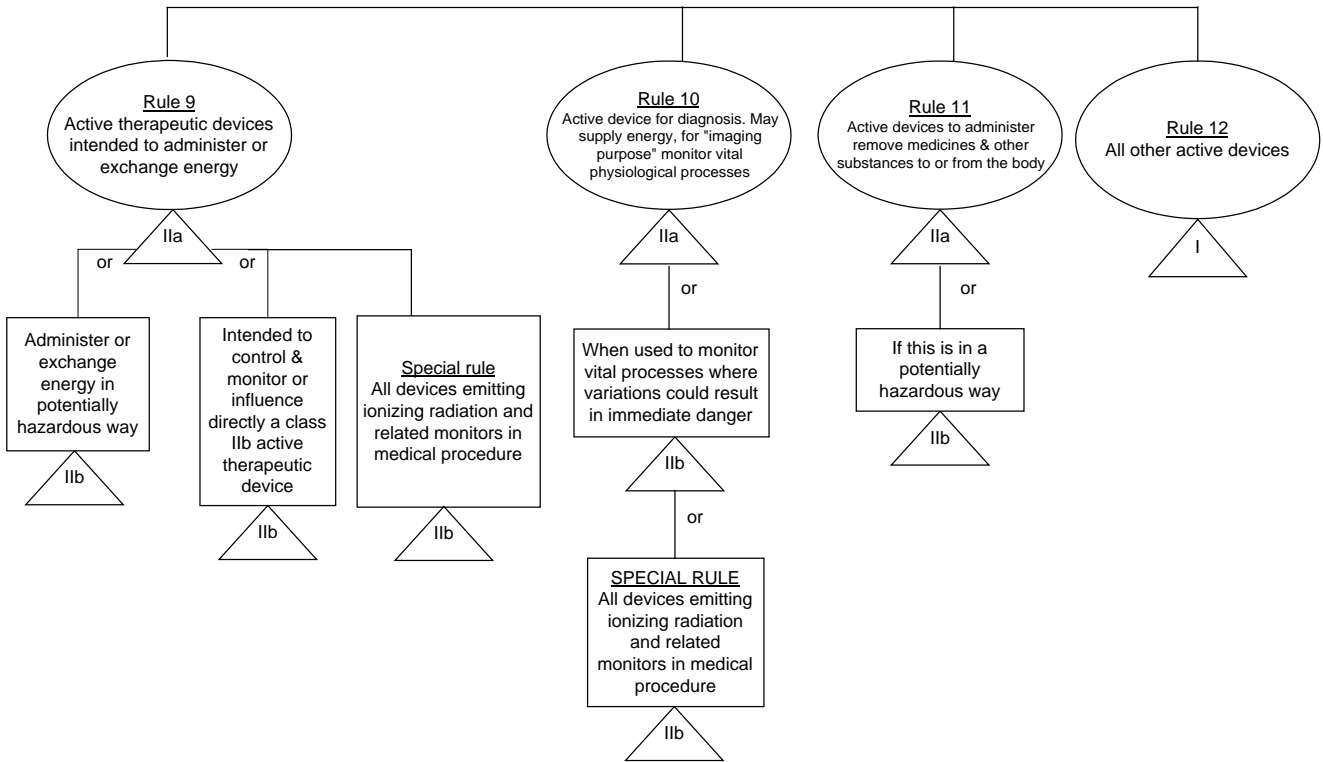
INVASIVE DEVICES



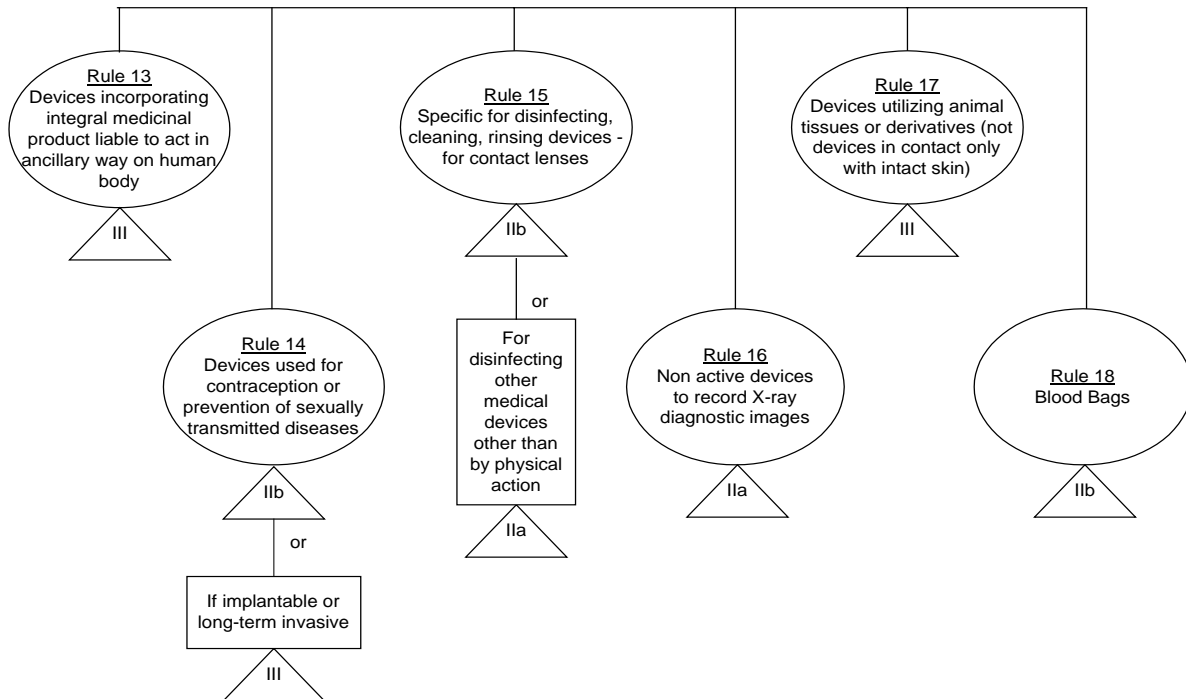
INVASIVE DEVICES



ACTIVE DEVICES



SPECIAL RULES



End Part 1

.....

Part 2 :See next document (starting with page 16 again).

.....