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DG HEALTH AND CONSUMER
Directorate B, Unit B2 "Cosmetics and medical devices"

MEDICAL DEVICES: Guidance document
-
Classification of medical devices

MEDDEV 2. 4/1 Rev. 9
June 2010

GUIDELINES RELATING TO THE APPLICATION OF
THE COUNCIL DIRECTIVE 93/42/EEC ON MEDICAL DEVICES

Foreword

The present MEDDEV is part of a set of guidelines relating to questions of application of EU Directives on medical devices. They are not legally binding. Only the European Court of Justice can give an authoritative interpretation of Community Law.

This MEDDEV contains guidance for the application of the classification rules for medical devices as set out in Annex IX of Directive 93/42/EEC[1], as amended. It is for the national Competent Authorities and national Courts to take legally binding decisions on a case-by-case basis.

Directive 93/42/EEC, as amended, allows for derogation from the classification rules outlined in its Annex IX in light of technical progress or on information gathered from post-market experience with the device.

[1] OJ L 169, 12.7.1993, p. 1

This MEDDEV has been revised after consultation with various interested parties (*e.g.* Competent Authorities, Commission services, industry and other stakeholders) and therefore this document reflects a consensus view on the classification of medical devices.

Active implantable medical devices and *in vitro* diagnostic medical devices are covered by separate Directives, which do not apply the classification rules reviewed in this MEDDEV.

Note: This document is a revision of an earlier document published in July 2001 as MEDDEV 2.4/1 rev 8. It includes information pertaining to the changes in classification resulting from the amending and implementing Directives issued since the last revision of this document in 2001, including derogation of the classification rules in the case of breast implants and hip, knee and shoulder joint replacements and requirements related to devices containing human blood derivatives and medical devices manufactured utilising tissues of animal origin. In addition this guidance document takes account of the changes arising from Directive 2007/47/EC[2] which further amends Directive 93/42/EEC and became applicable as from 21st March 2010.

[2] OJ L 247, 21.9.2007, p. 21

CONTENTS	Pages
1. PURPOSE AND PHILOSOPHY OF MEDICAL DEVICE CLASSIFICATION **2. PRACTICAL RELEVANCE OF CLASSIFICATION** 2.1. General requirements 2.2. Conformity assessment 2.3. Clinical evaluation and investigation 2.4. Instructions for use 2.5. Miscellaneous **3. HOW TO CARRY OUT CLASSIFICATION** 3.1. Basic definitions 3.2. Application of the classification rules 3.3. How to use the rules 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	

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 apply to medical devices an appropriate conformity assessment procedure.

In order to ensure that conformity assessment under the Medical Device Directive functions effectively, manufacturers should be able to determine the classification of their product as early as possible in device development. It was therefore decided to set up a system of classification rules within the Directive, so that each manufacturer could classify its own devices.

The classification of medical devices is a 'risk based' system based on the vulnerability of the human body taking account of the potential risks associated with the devices. This approach allows the use of a set of criteria that can be combined in various ways in order to determine classification, *e.g.* duration of contact with the body, degree of invasiveness and local vs. systemic effect. These criteria can then be applied to a vast range of different medical devices and technologies. These are referred to as the 'classification rules' and are set out in Annex IX of Directive 93/42/EEC. They correspond, to a large extent, to the classification rules established by the Global Harmonization Task Force (GHTF) in the guidance document GHTF/SG1/N15:2006[3].

It is recognized that although the existing rules will adequately classify the vast majority of existing devices, a small number of products may be more difficult to classify. Such cases may in particular include devices which are borderline cases between two different classes of medical devices. 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 (see also section 3.5).

2. PRACTICAL RELEVANCE OF CLASSIFICATION

2.1. General requirements

Irrespective of the class of the device, all devices must:

- meet the essential requirements, including the requirements regarding the information to be supplied by the manufacturer (Annex I of the Directive 93/42/EEC);
- be subject to the reporting requirements under the medical device vigilance system;

[3] http://www.ghtf.org/documents/sg1/SG1-N15-2006-Classification-FINAL.pdf

- be CE marked (except custom-made devices and devices intended for clinical investigation, in which case they should comply with the provisions of Annex VIII of Directive 93/42/EEC regarding the statement on devices for special purposes.

2.2. Conformity Assessment

Conformity assessment is the method by which a manufacturer demonstrates that their devices comply with the requirements of Directive 93/42/EEC. The classification of the medical device will have an impact on the conformity assessment route that the manufacturer should follow in order to affix the CE marking on the medical device.

CONFORMITY ASSESSMENT PROCEDURES	**CLASSES**					
ANNEXES	**I**	**I Sterile**	**I measure**	**IIa**	**IIb**	**III**
II (+ section 4)						√
II (- section 4)		√	√	√	√	
III					√	√
IV		√	√	√	√	√
V		√	√	√	√	√
VI		√	√	√	√	
VII	√	√	√	√		

Technical documentation relating to products in class IIa and class IIb must be reviewed by a notified body of the basis of a programme of representative sampling in the context of Annexes II, V and VI of Directive 93/42/EEC.

2.3. Clinical evaluation and investigation

As part of the Essential Requirements, a **clinical evaluation** in accordance with Annex X must be conducted for all medical devices. (Annex I part I, 6a of Directive 93/42/EEC).

The Medical Devices Directive states in Annex X 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.
In addition, according to Annex X Section 1.1a of Directive 93/42/EEC "*in the case of implantable devices and devices in class III clinical investigations shall be performed unless it is duly justified to rely on existing clinical data".*
For further guidance on clinical evaluation see MEDDEV 2.7.1 Rev.3[4].

Pursuant to article 15.1, in case of devices intended for **clinical investigation**s, the manufacturer shall notify the Competent Authorities of the Member States in which the investigations are to be conducted in accordance with section 2.2 of Annex VIII.
Clinical investigations with Class III devices and implantable and long-term invasive devices falling within Class IIa or IIb may start 60 days after the manufacturer's notification to the Competent Authority unless the Competent Authority has notified a decision to the contrary based on considerations of public health or public policy within this timeframe (article 15.2). For further details see article15 of Directive 93/42/EEC.

2.4. Instructions for use

Instructions for use are not required for Class I and IIa devices if these devices can be used safely without any such instructions (Annex I Section 13.1. of Directive 93/42/EEC).

2.5. Miscellaneous

The manufacturer of a Class I medical device, or his relevant authorised representative in the European Union designated by him, must notify their address and a description of the devices concerned to the Competent Authority of the Member State where they have their registered place of business (Article 14, paragraphs 1 and 2 of Directive 93/42/EEC).

For medical devices of classes IIa, IIb and III, Member States may request to be informed of all data allowing for identification of such devices together with the label and the instructions for use when such devices are put into service within their territory (second sub-paragraph of Article 14, paragraph 1, of Directive 93/42/EEC).

3. HOW TO CARRY OUT CLASSIFICATION

[4] http://ec.europa.eu/enterprise/sectors/medical-devices/files/meddev/2_7_1rev_3_en.pdf

The manufacturer should first decide if the product concerned is a medical device as defined in Directive 93/42/EEC or an accessory to such a medical device, if it is not excluded from the scope of this Directive and if it therefore comes within the scope of this Directive.

3.1. Basic definitions

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. Intended purpose is defined in Article 1 paragraph 2(g) of Directive 93/42/EEC. The other terms are defined in chapter I section 1 of Annex IX of Directive 93/42/EEC.

These definitions are reproduced below, together with some additional guidance.

3.1.1. Intended purpose

"Intended purpose" means the use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions and/or in promotional materials.

3.1.2. Time

3.1.2.1. 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.

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.

3.1.2.2 Concept of continuous use

In calculating the duration referred to in Section 1.1 of Chapter I of Annex IX to Directive 93/42/EEC, continuous use means "*an uninterrupted actual use of the device for the intended purpose. However where usage of a device is discontinued in order for the device to be replaced immediately by the same or an identical device this shall be considered as an extension of the continuous use of the device*" (Section 2.6 of Chapter II of Annex IX to Directive 93/42/EEC).

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 is totally eliminated in the interval between uses, this is also considered as an immediate replacement.

3.1.3. 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 of 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.

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.

Reusable surgical instrument

Instrument intended for surgical use by cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar procedures, without connection to any active medical device and which can be reused after appropriate procedures have been carried out (Section 1.3 of Annex IX of Directive 93/42/EEC).

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 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 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.

Critical anatomical locations

For the purposes of the Directive 93/42/EEC, '***central circulatory system***' means the following vessels:

arteriae pulmonales, aorta ascendens, arcus aorta, 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, vena cava inferior.

For the purposes of the Directive 93/42/EEC the '***central nervous system***' means *brain, meninges and spinal cord*.

3.1.4. Active medical devices

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. Stand alone software is considered to be an active medical device.

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". However, 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[5].

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 anaesthesia 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 ionising radiation are regarded as active medical devices, unless they are radiopharmaceuticals as defined in article 1 of Directive 2001/83/EC or radioactive implants as defined in article 1 of Directive 90/385/EEC.

3.1.5 Devices with a measuring function

Information on devices with a measuring function can be found in MEDDEV 2.1/5[6]

3.1.6 Procedure packs

[5] http://ec.europa.eu/enterprise/sectors/medical-devices/files/meddev/2_1-2___04-1994_en.pdf
[6] http://ec.europa.eu/enterprise/sectors/medical-devices/files/meddev/2_1_5____06-1998_en.pdf

Procedure packs per Article 12 of Directive 93/42/EEC normally do not require classification as each device in the procedure pack keeps its own CE marking and classification.

However, in cases where the procedure pack incorporates devices which do not bear a CE marking, or where the chosen combination of devices is not compatible in view of their original intended use, the system or procedure pack shall be treated as a device in its own right and as such be subjected to the relevant procedure pursuant to Article 11 of Directive 93/42/EEC.

For a procedure pack that is a device in its own right, the classification is normally determined by the intended use. In those cases where the intended use of the procedure pack is not specific enough to determine the classification, the classification of the pack is at the level of the highest classified device included in the pack, where applicable taking into account the new intended use of the device.

3.2. Application of the classification rules

In terms of further interpretation of the classification 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. *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.
- 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 CE marked in its own right as a separate device in such instances.

- 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, provided that they are also CE marked separately.
- Accessories are classified in their own right separately from the device with which they are used (Annex IX Section 2.2 of Directive 93/42/EEC).
- 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). 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.
- 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 have the intended use which is principally used and 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.
- Due to its complexity, classification of standalone software will be covered in a specific guidance document.

3.3. How to use the rules

The manufacturer must take into consideration all the rules in order to establish the proper classification for its 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.

By derogation to the classification rules set out in Annex IX of Directive 93/42/EEC, the manufacturers must also take account of additional Directives which may affect the classification of their device or the conformity route to be followed, *e.g.*

- Directive 2003/12/EC[7] on the reclassification of breast implants in the framework of Directive 93/42/EEC concerning medical devices.

- Directive 2005/50/EC[8] on the reclassification of hip, knee and shoulder joint replacements in the framework of Council Directive 93/42/EEC concerning medical devices.

- Directive 2003/32/EC[9] introducing detailed specifications as regards the requirements laid down in Council Directive 93/ 42/EEC with respect to medical devices manufactured utilising tissues of animal origin.

3.4. Practical example

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 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	IIa
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.

[7] OJ L 28, 4.2.2003, p. 43
[8] OJ L 210, 12.8.2005, p. 41
[9] OJ L 105, 26.4.2003, p. 18

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 (*i.e.* the Competent Authority to which the notified body is subject) should be approached in accordance with Article 9 of Directive 93/42/EEC.

In addition, Directive 93/42/EEC provides Community wide mechanisms, including a committee procedure, to address problems related to classification.

Complex classification issues may be referred to the 'Borderline and Classification Medical Devices Expert Group' for resolution. Consensus positions on classification reached by this Expert Group are published for reference in the Manual on Borderline and Classification[10].

In addition, MEDDEV 2.1/3 rev 3[11] provides with useful information relating to devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product or a human blood derivative, and which is liable to act on the human body with action ancillary to that of the devices.

[10] http://ec.europa.eu/enterprise/medical_devices/borderline_classification_en.htm
[11] http://ec.europa.eu/enterprise/sectors/medical-devices/files/meddev/2_1_3_rev_3-12_2009_en.pdf

4. EXPLANATIONS OF INDIVIDUAL RULES

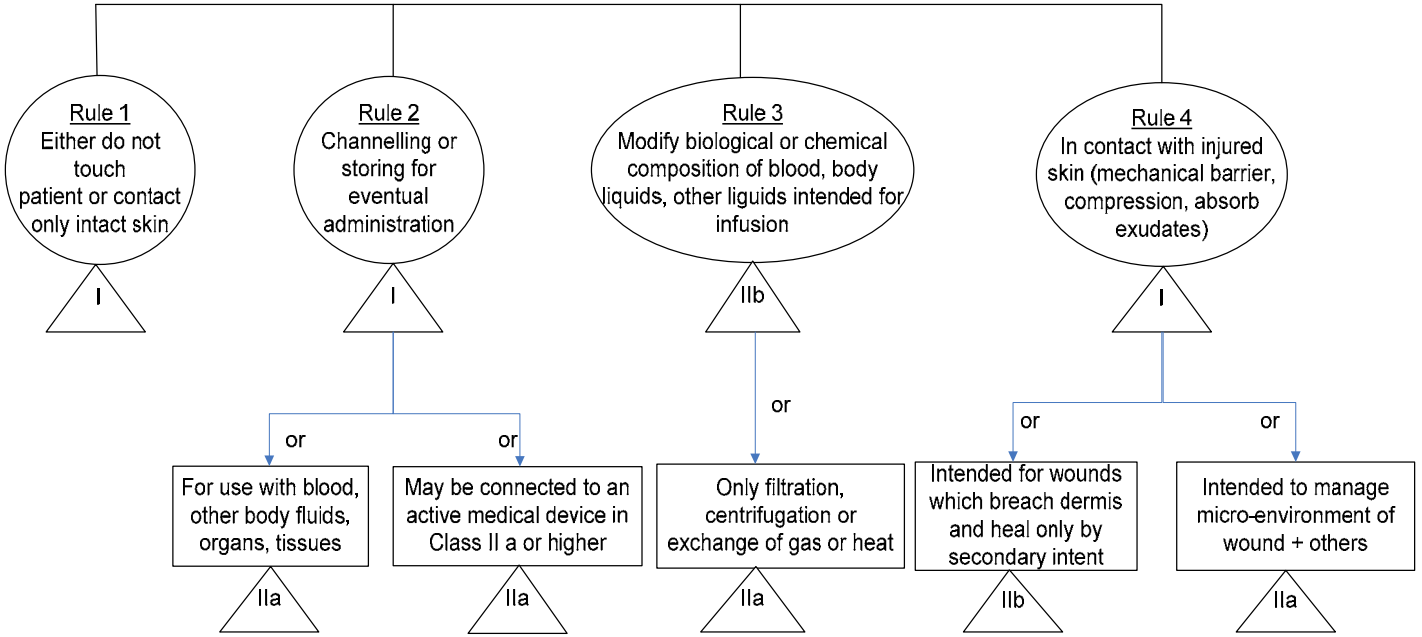
The explanations are given in the following manner. This section begins with a graphical summary of the rules, as a preface to subsections on the individual rules. Each subsection starts with a general explanation of the rule followed by a tabular presentation of the rule and examples of devices to which it applies. Any special terms used are explained and practical issues related to the rule are clarified. It must be emphasised 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.

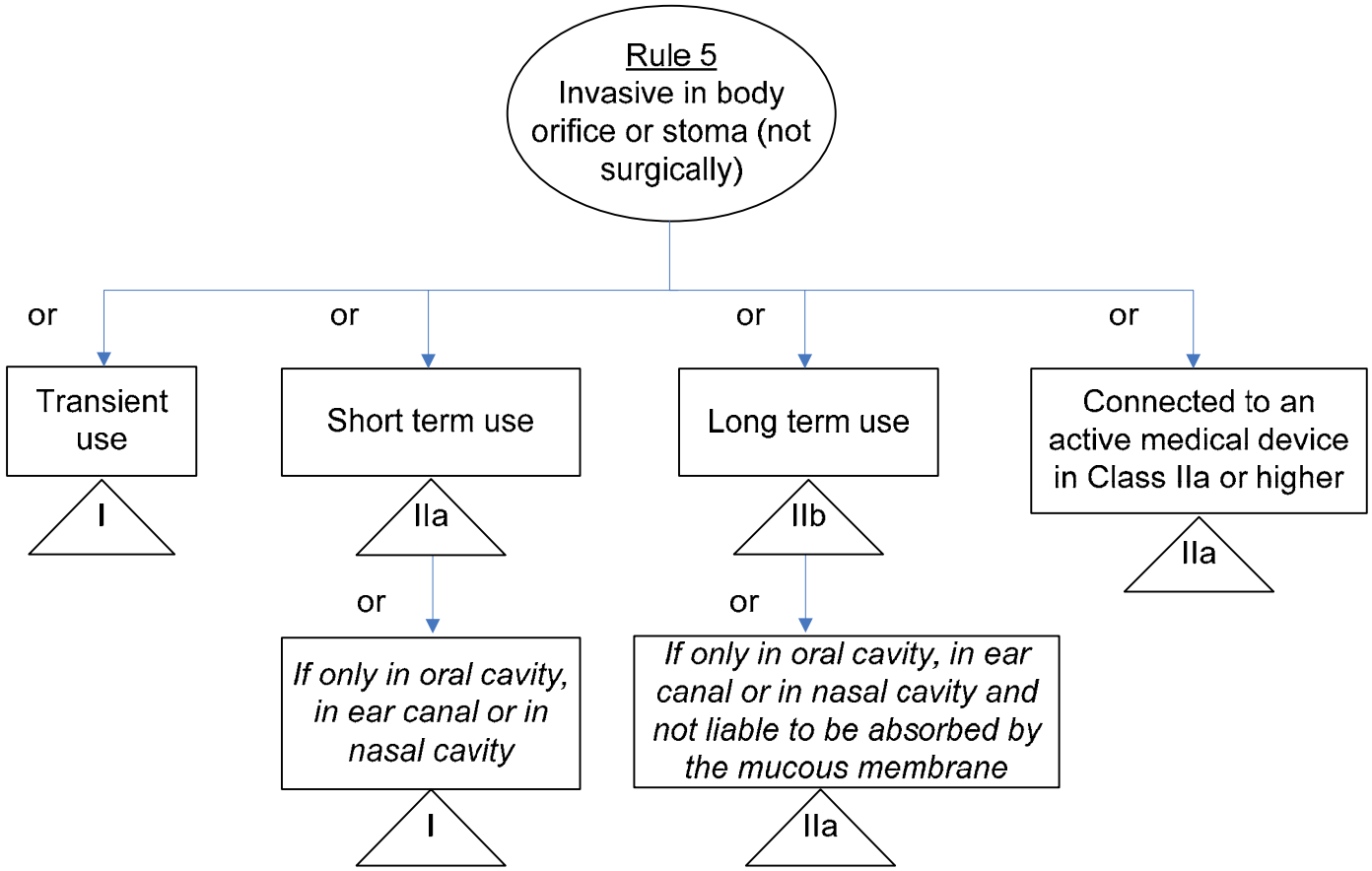
4.1 Graphical summary – medical devices classification guidance chart for initial identification of probable device class

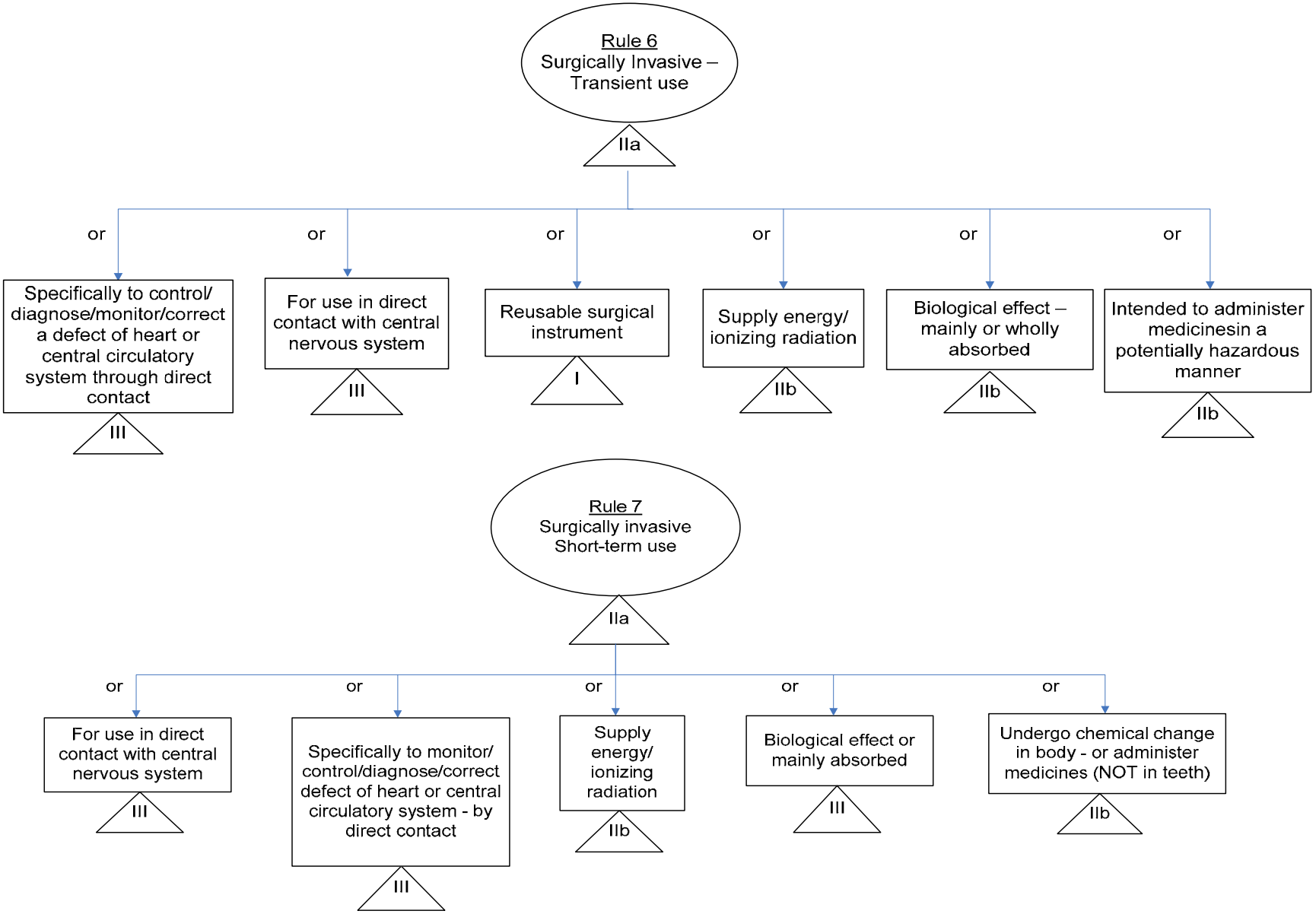
Note: Always confirm definitive classification by reading all rules in detail, and utilise additional assistance in this guidelines document as provided in the form of general explanations of rules and examples of devices (see section 4.2)

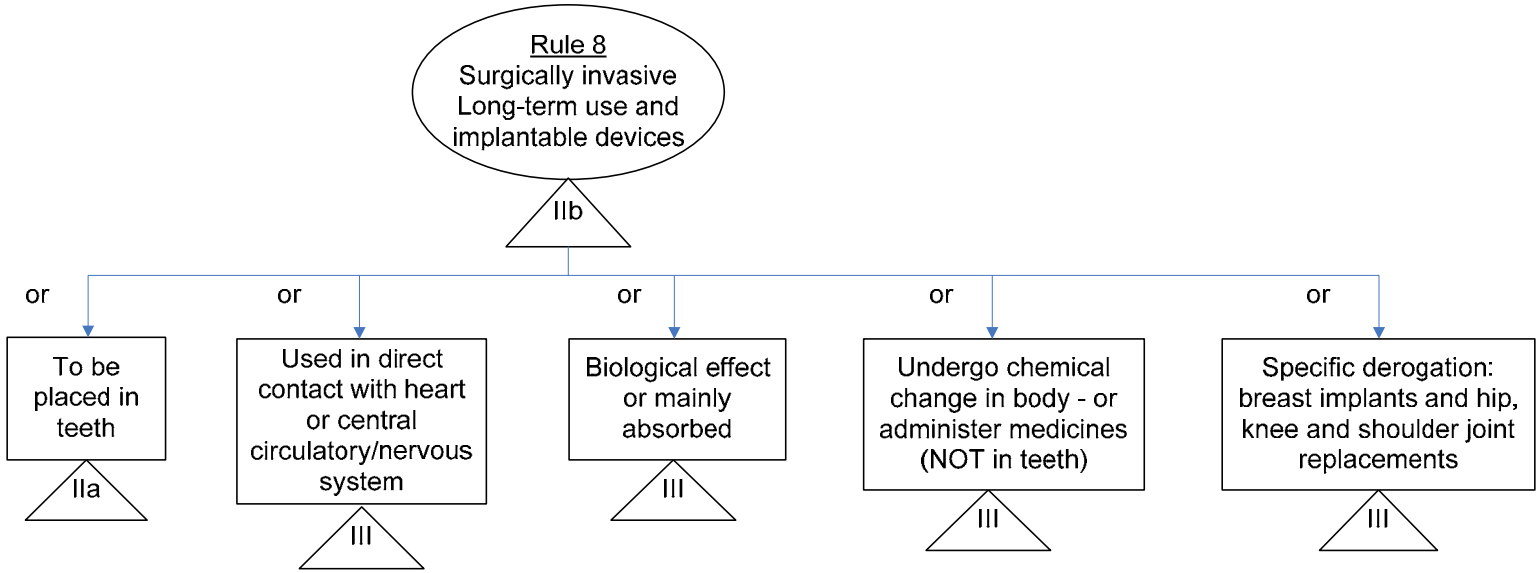
SUBJECTS
Non invasive devices – Rules 1, 2, 3, 4
Invasive devices – Rules 5, 6, 7, 8
Active devices – Rules 9, 10, 11, 12
Special rules – Rules 13, 14, 15, 16, 17, 18

NON INVASIVE DEVICES

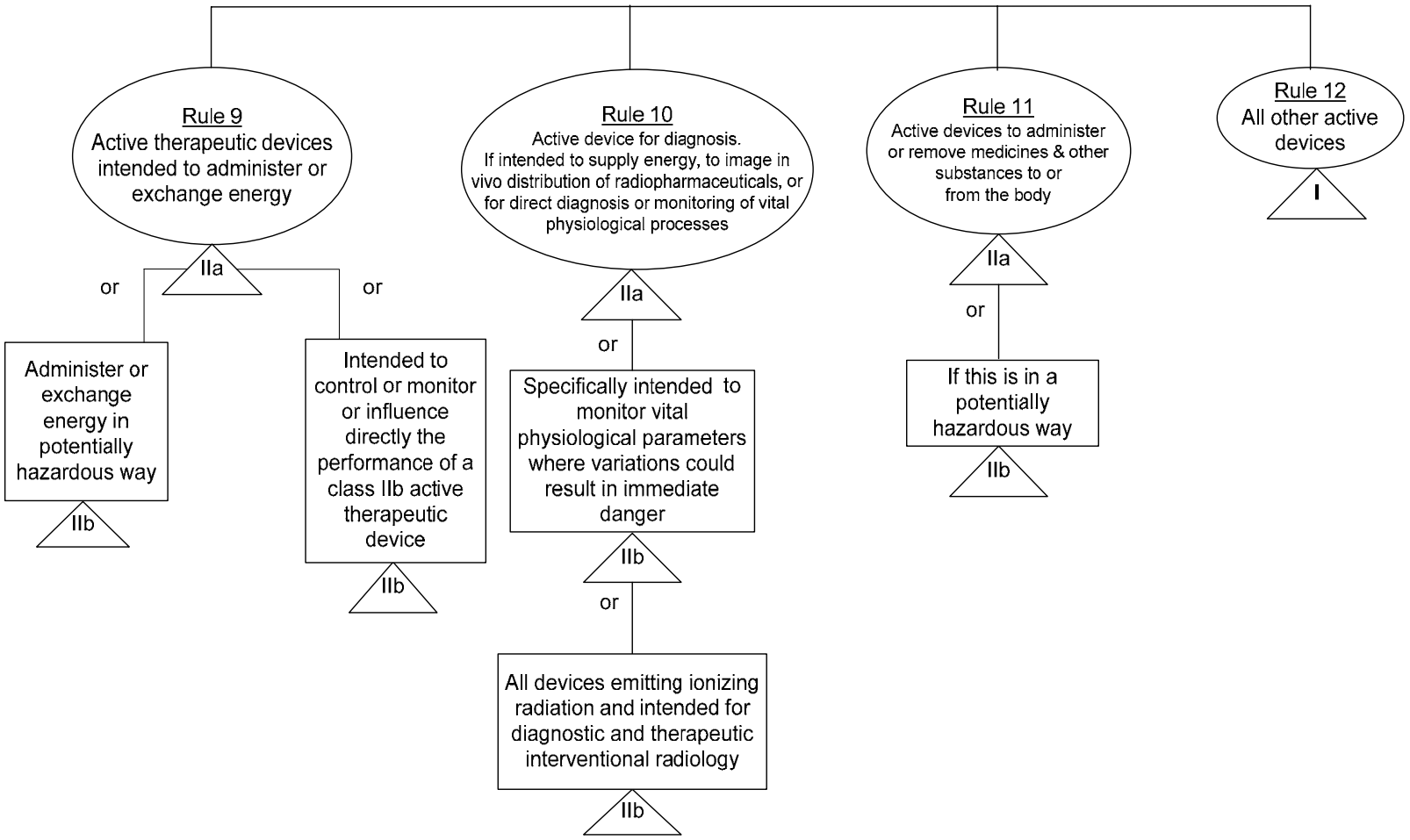



Rule 5
Invasive in body orifice or stoma (not surgically)
or
Transient use
I
or
Short term use
IIa
or
If only in oral cavity, in ear canal or in nasal cavity
I
or
Long term use
IIb
or
If only in oral cavity, in ear canal or in nasal cavity and not liable to be absorbed by the mucous membrane
IIa
or
Connected to an active medical device in Class IIa or higher
IIa

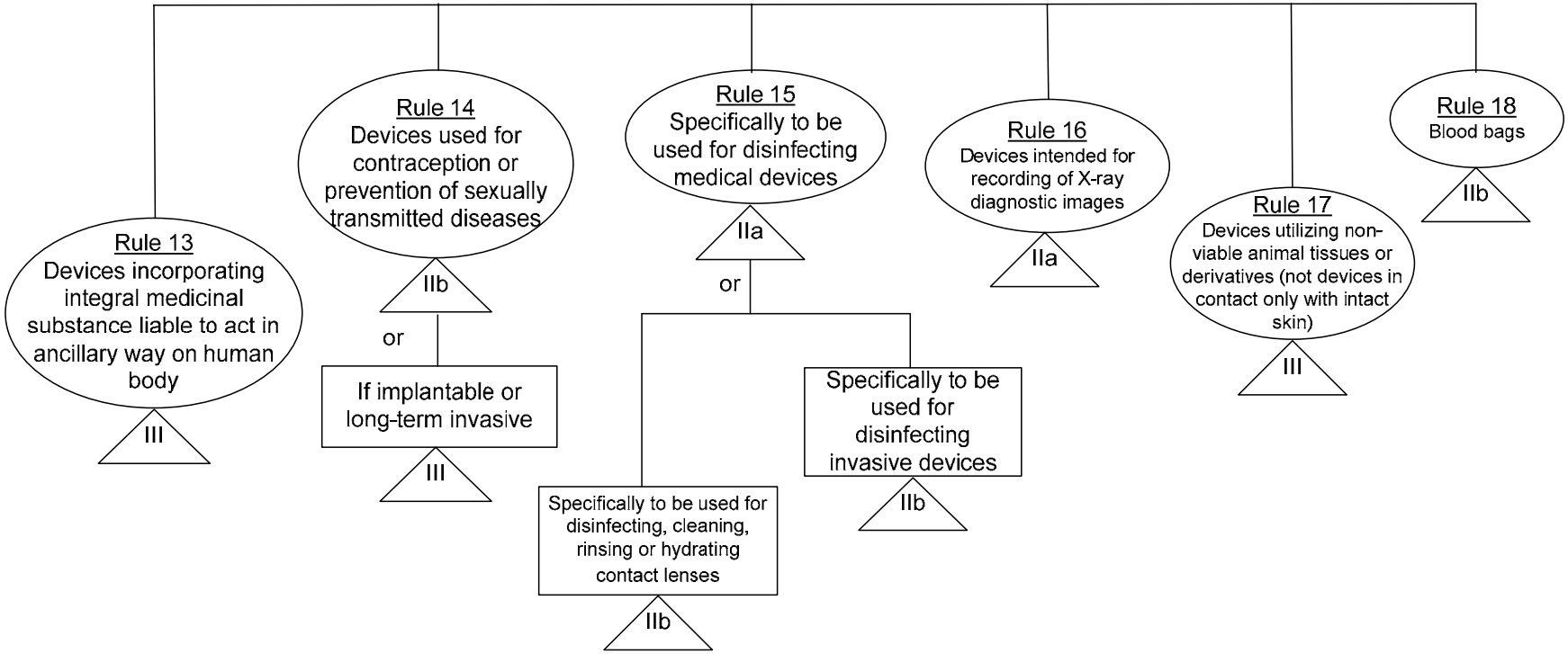

Rule 6
Surgically Invasive – Transient use
IIa
or
Specifically to control/ diagnose/monitor/correct a defect of heart or central circulatory system through direct contact
III
or
For use in direct contact with central nervous system
III
or
Reusable surgical instrument
I
or
Supply energy/ ionizing radiation
IIb
or
Biological effect – mainly or wholly absorbed
IIb
or
Intended to administer medicinesin a potentially hazardous manner
IIb
Rule 7
Surgically invasive Short-term use
IIa
or
For use in direct contact with central nervous system
III
or
Specifically to monitor/ control/diagnose/correct defect of heart or central circulatory system - by direct contact
III
or
Supply energy/ ionizing radiation
IIb
or
Biological effect or mainly absorbed
III
or
Undergo chemical change in body - or administer medicines (NOT in teeth)
IIb


Rule 8
Surgically invasive
Long-term use and
implantable devices
IIb
or
To be placed in teeth
IIa
or
Used in direct contact with heart or central circulatory/nervous system
III
or
Biological effect or mainly absorbed
III
or
Undergo chemical change in body - or administer medicines (NOT in teeth)
III
or
Specific derogation: breast implants and hip, knee and shoulder joint replacements
III

ACTIVE DEVICES



SPECIAL RULES



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 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

Practical issues of classification

Some non-invasive devices are indirectly in contact with the body and can influence internal physiological processes by storing, channelling 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 2 - Channelling 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 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.

RULE 2	EXAMPLES
All non-invasive devices intended for channelling 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 channelling, *e.g.* antistatic tubing for anaesthesia, anaesthesia breathing circuits, pressure indicator, pressure limiting devices - 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	- 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
- in all other cases they are in Class I.	- Devices that provide a simple channelling 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

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

Explanation of special concepts

Note 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.

Rule 3 – Non-invasive devices that modify biological or chemical composition of blood, body liquids or other liquids intended for infusion into the body

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 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.

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 hemodialysers - Devices intended to separate cells by physical means, *e.g.* gradient medium for sperm separation - Haemodialysis concentrates
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 - Non-invasive devices which come into contact with injured skin

General explanation of the rule

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 III under Rule 13.

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, adhesive bandages (sticking plasters, band-aid) and gauze dressings which act as a barrier, maintain wound position or 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 - 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 IIa if the intended use is to manage the micro-environment of the wound or 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 IIb.
Most dressings that are intended for a use that is in Class IIa or IIb, 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 a medicinal product or a human blood derivative see Rule 13 or animal tissues or derivatives rendered non-viable 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.
- A skin might be considered as "injured" either because of pathological (*e.g.* diabetic ulcers) or external factors (*e.g.* burns)

Rule 5 - Devices invasive with respect to 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). 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	**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 or which are intended for connection to an active medical device in Class I:	
- 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 trays - Enema devices - Examination gloves - Urinary catheters intended for transient use - Prostatic balloon dilation catheters
- are in Class IIa if they are intended for short term use	- Short term corrective contact lenses - Tracheal tubes - Stents - Vaginal pessaries - Indwelling urinary catheters intended for short term use
except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in a nasal cavity , in which case they are in Class I,	- Dressings for nose bleeds - Materials for manufacturing dentures

- are in Class IIb if they are intended for long term use,	- Urethral stents - Long term corrective contact lenses - Tracheal cannulae - Urinary catheters intended for long term use
except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in a nasal cavity and are not liable to be absorbed by the mucous membrane, in which case they are in Class IIa.	- Orthodontic wires - 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 - Some enteral feeding tubes - Fibre optics in endoscopes connected to surgical lasers - Suction catheters or tubes for stomach drainage - Dental aspirator tips

Rule 6 - Surgically invasive devices intended for transient use (< 60 minutes)

General explanation of the rule

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	**EXAMPLES**
All surgically invasive[1] devices intended for transient use are in Class IIa unless they are:	- Needles used for suturing - 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 - Heart valve occluders, sizers and holders - Swabs to sample exudates - Single use aortic punches (see note 2)
- intended specifically to control, 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, stent delivery catheters/systems), including related guidewires, related introducers and dedicated[4] 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
- reusable surgical instruments[1], in which case they are in Class I[3]	- Scalpels and scalpel handles

	- Reamers - Drill bits - Saws, that are not intended for connection to an active device - Retractors forceps, excavators and chisels - Sternum retractors for transient use
- intended specifically for use in direct contact with the central nervous system, in which case they are in Class III	- Neuro-endoscopes - Brain spatulas - Direct stimulation canulae - Spinal cord retractors - spinal needles
- intended to supply energy in the form of ionizing radiation in which case they are in Class IIb,	- 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
- intended to have a biological[5] effect or to be wholly or mainly absorbed[6] 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[7] taking 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", “central nervous system” and "reusable surgical instruments" are defined in Section I of Annex IX of Directive 93/42/EEC. 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 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.

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: 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.

Note 5: 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.

Note 6: 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 7*:* 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 intended for short-term use *(>60 minutes, <30 days)*

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[2] used in cardiac surgery
- either specifically to control**,** diagnose, monitor or correct a defect[2] 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 - Temporary pacemaker leads - Thoracic catheters intended to drain the heart, including the pericardium - Carotid artery shunts - Ablation catheter
- or specifically for use in direct contact with the central nervous system, in which case they are in Class III,	- Neurological catheters - Cortical electrodes
- or to supply energy in the form of ionising 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 - Biological adhesives
- or to undergo chemical change in the body, except if the devices are placed in the teeth, or to administer medicines1, in which case they are Class IIb.	- Adhesives

Practical issues of classification

Note 1: 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.

Note 2: The expression “correct a defect” does not cover devices that are used accessorily in heart surgery, *e.g.* tissue stabilisers.

Rule 8 - Implantable devices and long-term surgically invasive devices (> 30 days)

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 not covered by Directive 2005/50/EC - Ligaments - Shunts - Stents and valves (*e.g.* pulmonary) - Nails and plates - Intra-ocular lenses - Internal closure devices.(including vascular closure devices[2]) - Tissue augmentation implants - Peripheral vascular catheters - Peripheral vascular grafts and stents - 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*[3], in which case they are in Class IIa,	- Bridges and 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 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
- 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*[4] 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
- Directive 2003/12/EC introduced a derogation from this rule, reclassifying breast implants in Class III	- Breast implants
Directive 2005/50/EC introduced a derogation from this rule, reclassifying hip, knee and shoulder joint replacements in Class III	- Total hip, knee and shoulder joint replacement*s* systems and components of systems[12]

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: For closure of arteriotomies in the peripheral vascular system. (please refer to definition of central circulatory system)
Note *3*: Implants without bioactive coatings intended to secure teeth or prostheses to the maxillary or mandibular bones are in Class IIb following the general rule. Hydroxy-apatite is considered as having biological effect only if so claimed and demonstrated by the manufacturer.

Note 4: 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.

[12] http://ec.europa.eu/enterprise/sectors/medical-devices/files/guide-stds-directives/final_reclass_note_12jan2007_en.pdf

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	<u>Electrical and/or magnetic and electromagnetic energy</u> - Muscle stimulators - External bone growth stimulators - TENS devices - Eye electromagnets - Electrical acupuncture <u>Thermal energy</u> - Cryosurgery equipment. - Heat exchangers**,** except the types described below <u>Mechanical energy</u> - Powered dermatomes - Powered drills - Dental hand pieces. <u>Light</u> - Phototherapy for skin treatment and for neonatal care <u>Sound</u> - Hearing aids <u>Ultrasound</u> - Equipment for physiotherapy
unless their characteristics are such that they may administer or exchange	<u>Kinetic energy</u>

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.	- Lung ventilators <u>Thermal energy</u> - 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) <u>Electrical energy</u> - High-frequency electrosurgical generators, and electrocautery equipment, including their electrodes - External pacemakers and defibrillators - Electroconvulsive therapy equipment. <u>Coherent light</u> - Surgical lasers <u>Ultrasound</u> - Lithotriptors, surgical ultrasound devices <u>Ionizing radiation</u> - Radioactive sources for afterloading therapy - Therapeutic cyclotrons and linear accelerators - Therapeutic X-ray sources
All active devices intended to control or monitor the performance of active therapeutic 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 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	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 - Electronic stethoscopes - Electronic blood pressure measuring equipment.
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 and alarm devices (*e.g.* blood pressure, temperature, oxygen saturation) - Biological sensors - Blood gas analysers used in open heart surgery - Cardioscopes - Apnoea monitors, including apnoea monitors 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 IIb.	- Diagnostic X-ray sources

Examples of special concepts:

Note 1: 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 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 intended to administer and/or remove medicines, body liquids or other substances to or from the body

General explanation of the rule

This rule is intended to primarily cover drug delivery systems and anaesthesia 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 - Nebulisers to be used on conscious and spontaneously breathing patients where failure to deliver the appropriate dosage characteristics is not potentially hazardous
unless this is done in a manner: - that is potentially hazardous, taking account of the nature of the substances involved, of the part of the body concerned and of the mode of application, in which case they are in Class IIb.	- 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 - Nebulisers where the failure to deliver the appropriate dosage characteristics 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, wheelchairs, dental patient chairs) - Active diagnostic devices intended for thermography - Dental curing lights

4. Special rules

Rule 13 - Devices incorporating, as an integral part, a medicinal product or a human blood derivative (See MEDDEV. 2.1/3 for further guidance)

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. 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 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 2001/83/EC, 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 - Condoms with spermicide - Heparin coated catheters - Endodontic materials with antibiotics - Ophthalmic irrigation solutions principally intended for irrigation, which contain components which 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 - Contraceptive intrauterine devices (IUDs) containing copper or silver - Drug eluting stents, *e.g.* coronary, pulmonary
All devices incorporating as an integral part, a human blood derivative are in Class III	- Surgical sealants containing human serum albumin

Note 1: "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.

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 not medical devices (see Article 1.3 2nd paragraph of this Directive).

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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 and other equipment 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 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
unless they are specifically to be used for disinfecting invasive devices in which case they are in Class IIb.	- 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
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 - Devices to record X-ray diagnostic images

RULE 16	**EXAMPLES**
Devices specifically intended for recording of X-ray diagnostic images are in Class IIa.	- 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 utilising 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 viable animal tissues and/or any human tissues or derivatives are excluded from the scope of this Directive.

Further information on this issue can be found in MEDDEV 2.11/1 rev.2[13].

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.

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[2] only.	- Biological heart valves - Porcine xenograft dressings - Implants and dressings made from collagen - Devices utilising hyaluronic acid of animal origin

Practical classification issues

- 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 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

Note 2: Intact skin includes the skin around an established stoma unless the skin is breached.

[13] http://ec.europa.eu/enterprise/sectors/medical-devices/files/meddev/2_11_1_rev2_bsetse_january2008_en.pdf

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".