CZECH METROLOGY INSTITUTE

Czech metrology institute
Notified Body No. 1383

Český metrologický institut
Oznámený subjekt č. 1383

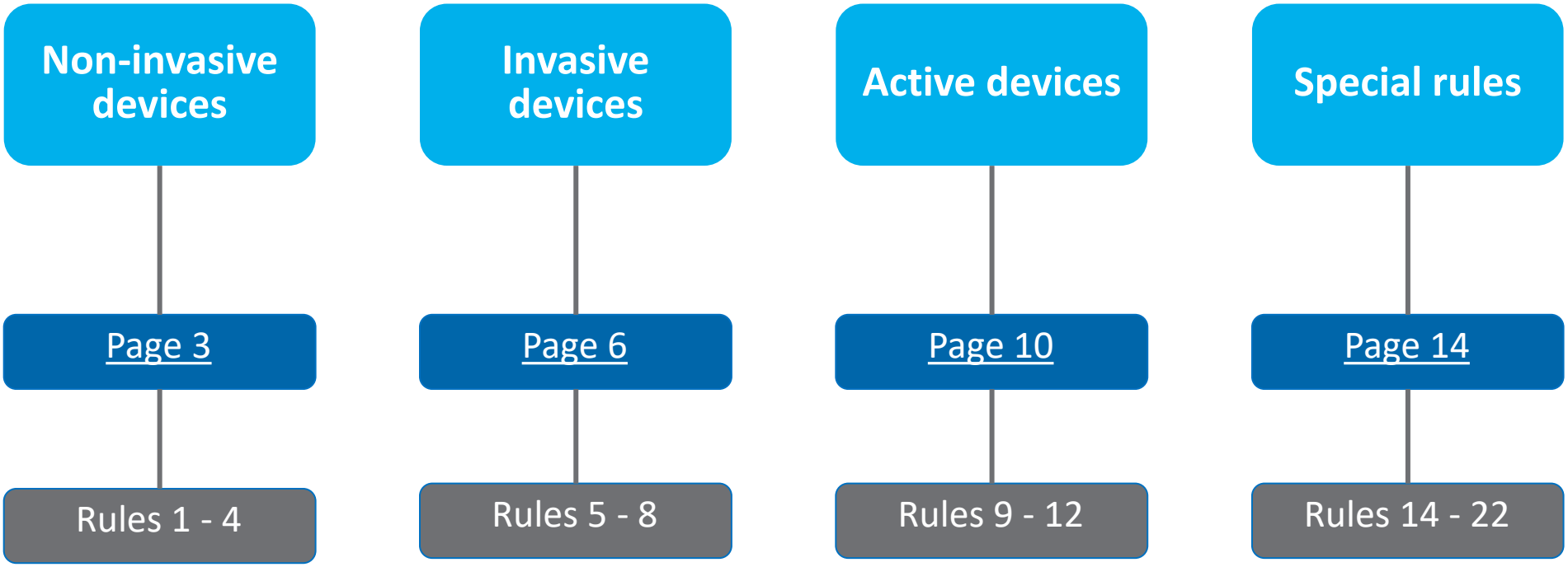
ČESKÝ METROLOGICKÝ INSTITUT

Methodological guide

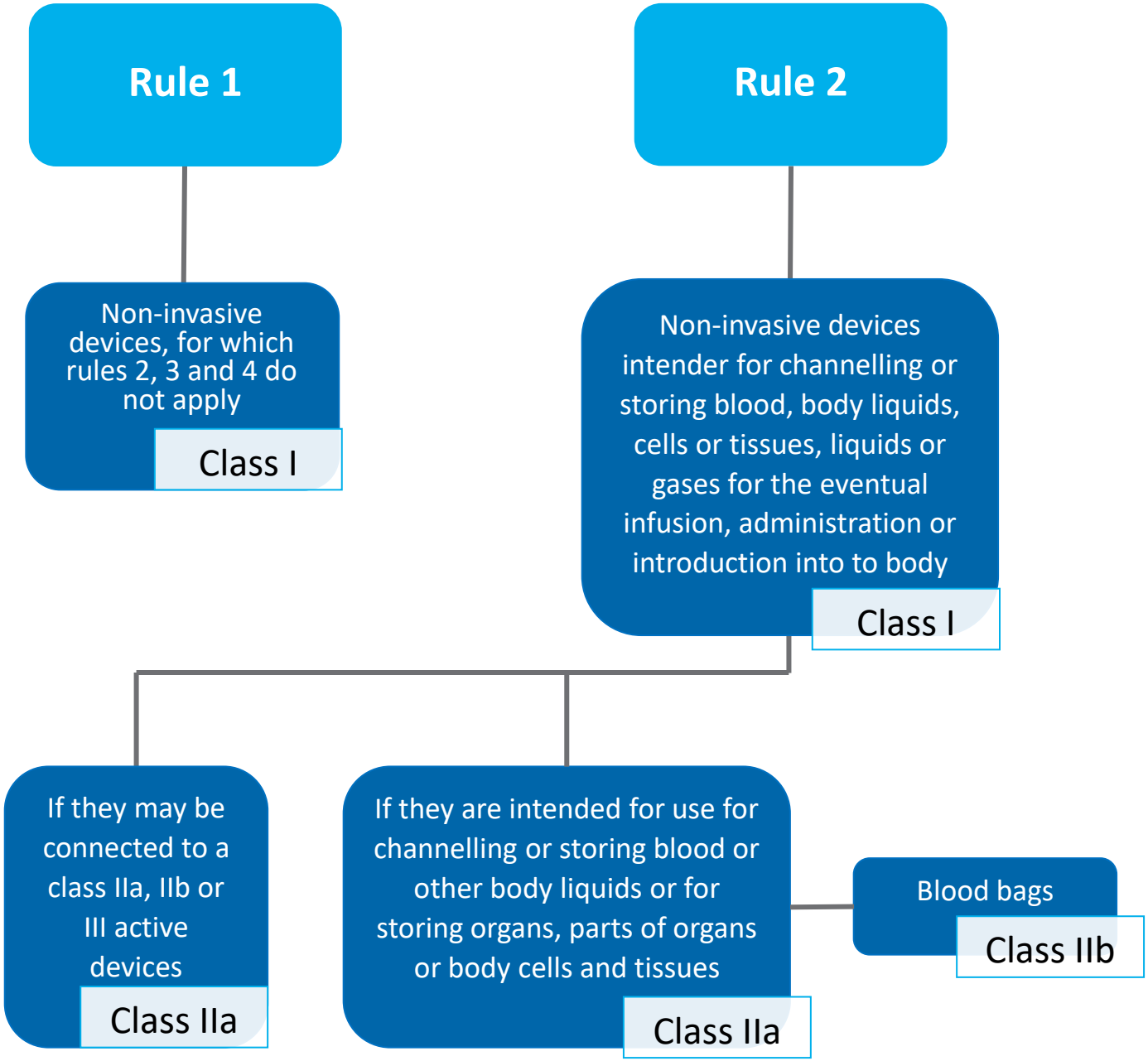
MEDICAL DEVICES CLASSIFICATION RULES

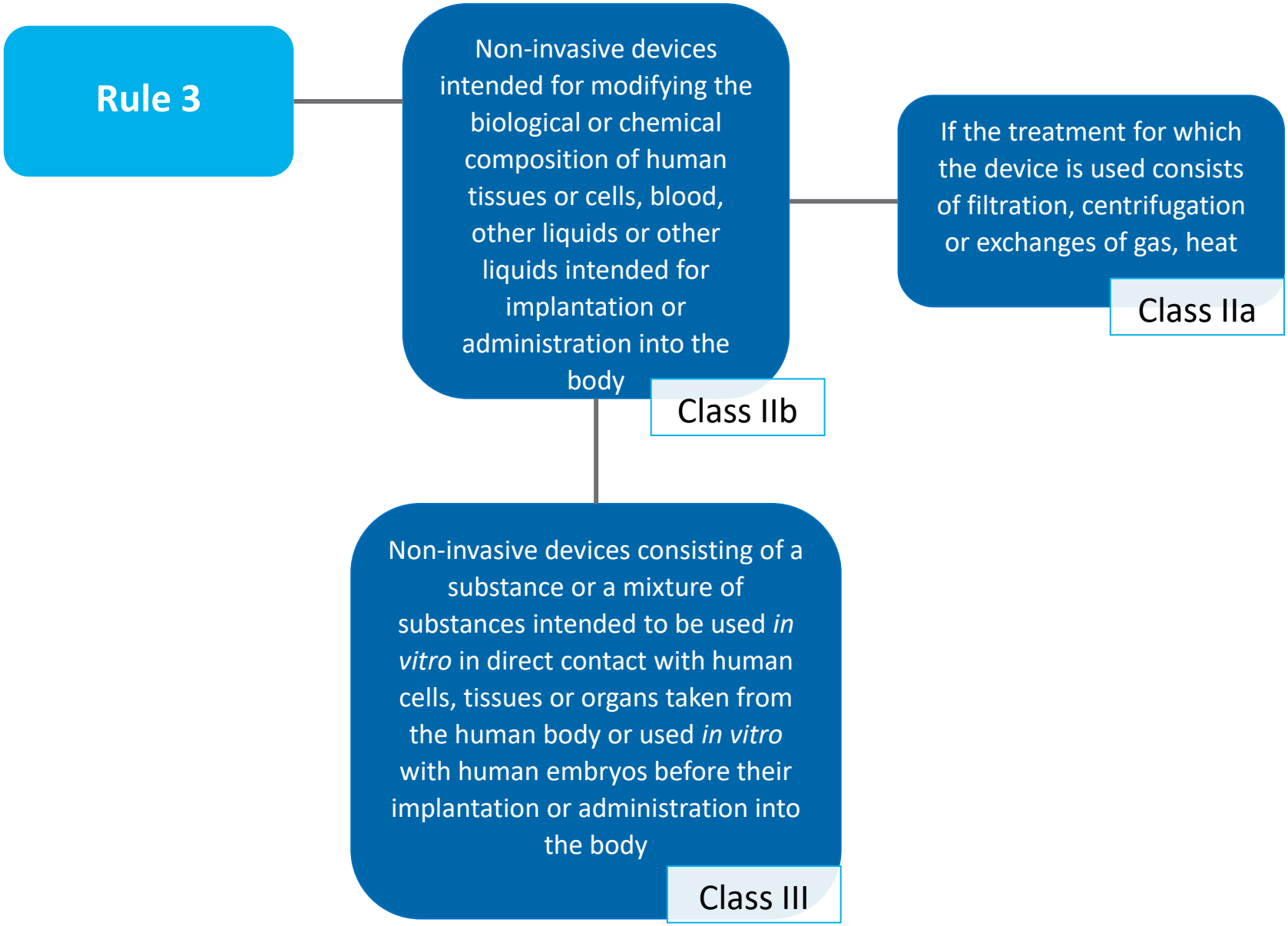
This methodological guide is only an aid for orientation in classification rules for medical devices. To determine the class of your medical device we recommend using Annex VIII of the MDR Regulation.

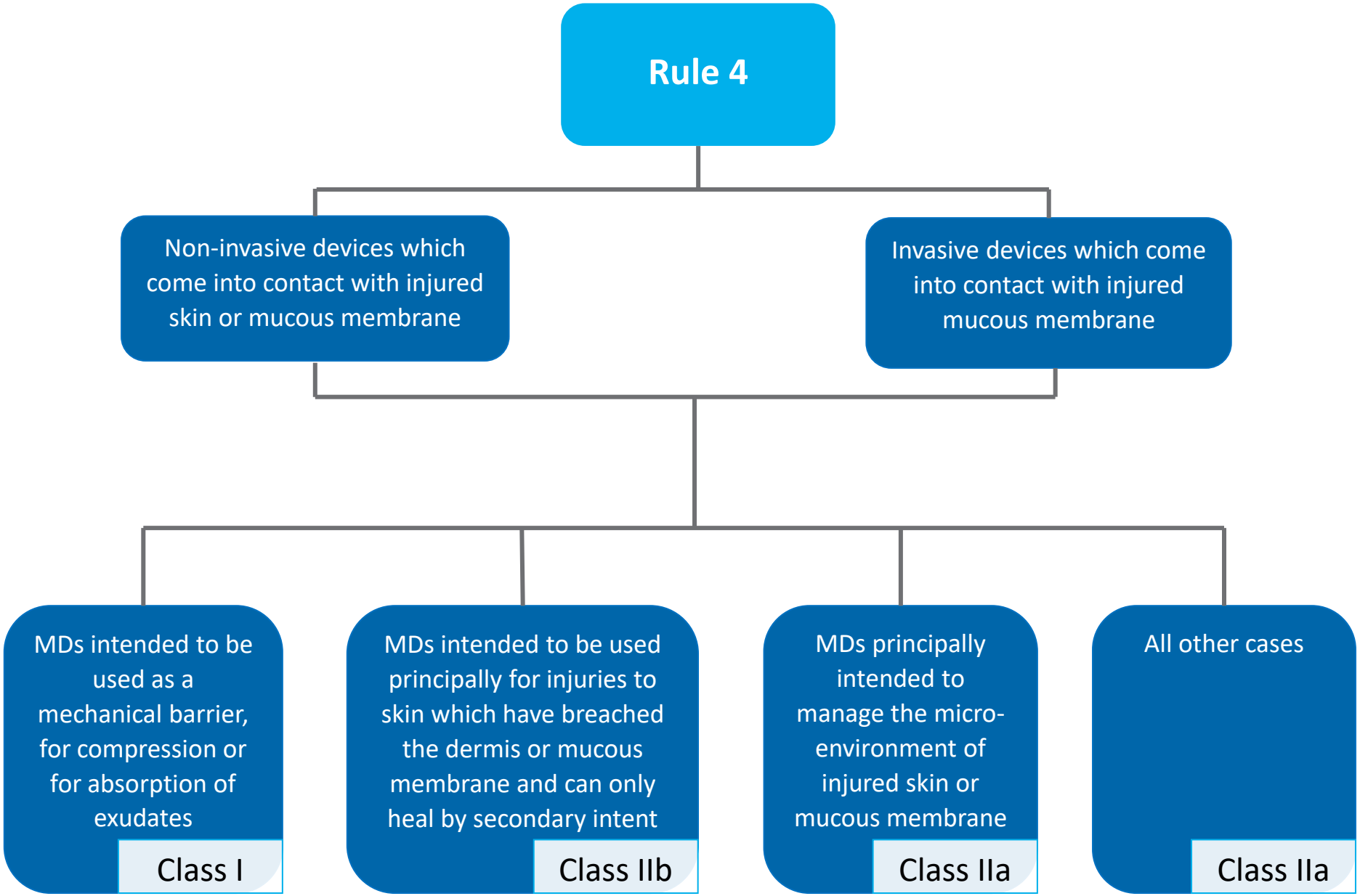
CONTENT


Non-invasive devices
Page 3
Rules 1 - 4
Invasive devices
Page 6
Rules 5 - 8
Active devices
Page 10
Rules 9 - 12
Special rules
Page 14
Rules 14 - 22

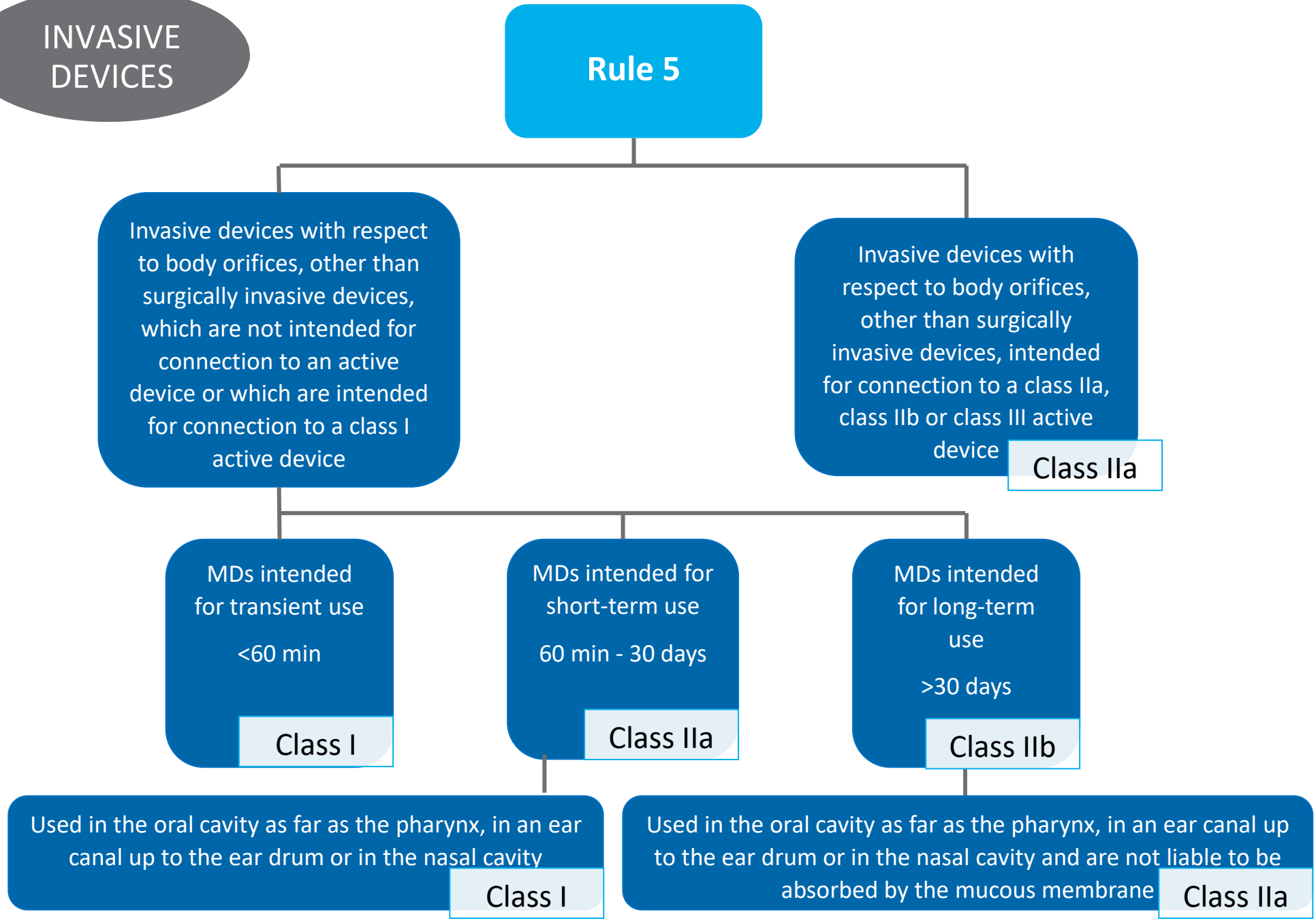
NON-INVASIVE DEVICES

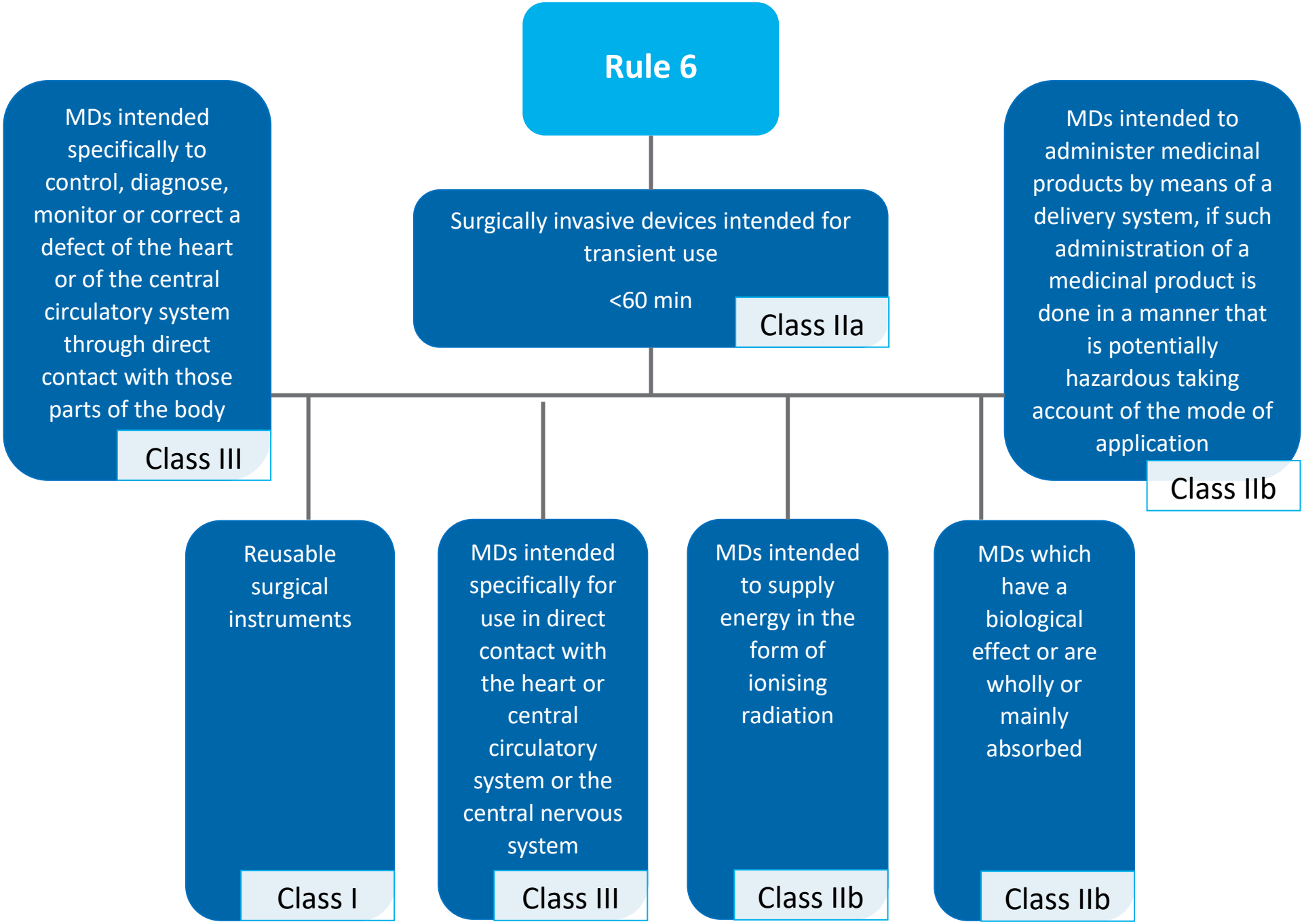


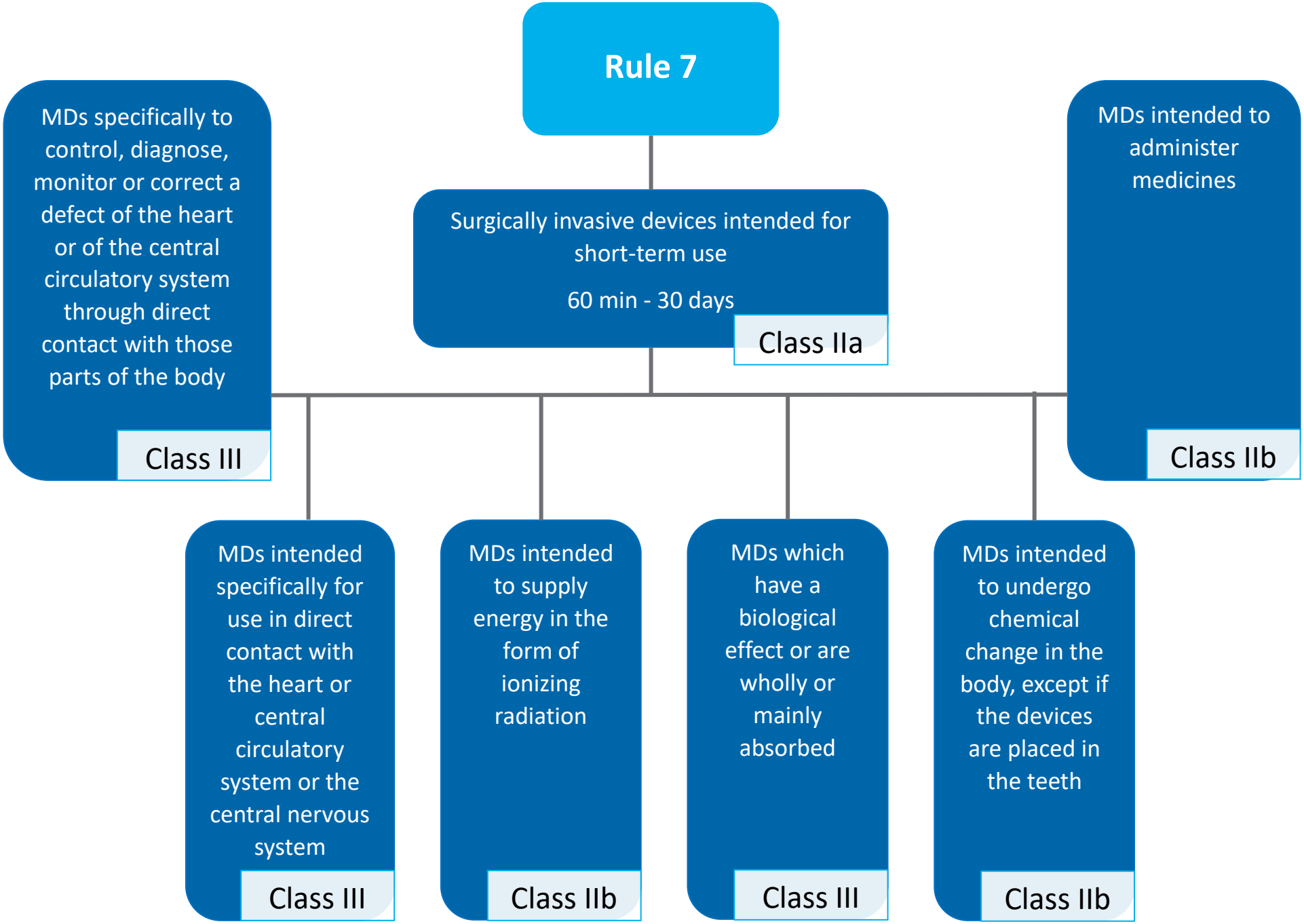

Rule 3
Non-invasive devices intended for modifying the biological or chemical composition of human tissues or cells, blood, other liquids or other liquids intended for implantation or administration into the body
Class IIb
If the treatment for which the device is used consists of filtration, centrifugation or exchanges of gas, heat
Class IIa
Non-invasive devices consisting of a substance or a mixture of substances intended to be used *in vitro* in direct contact with human cells, tissues or organs taken from the human body or used *in vitro* with human embryos before their implantation or administration into the body
Class III

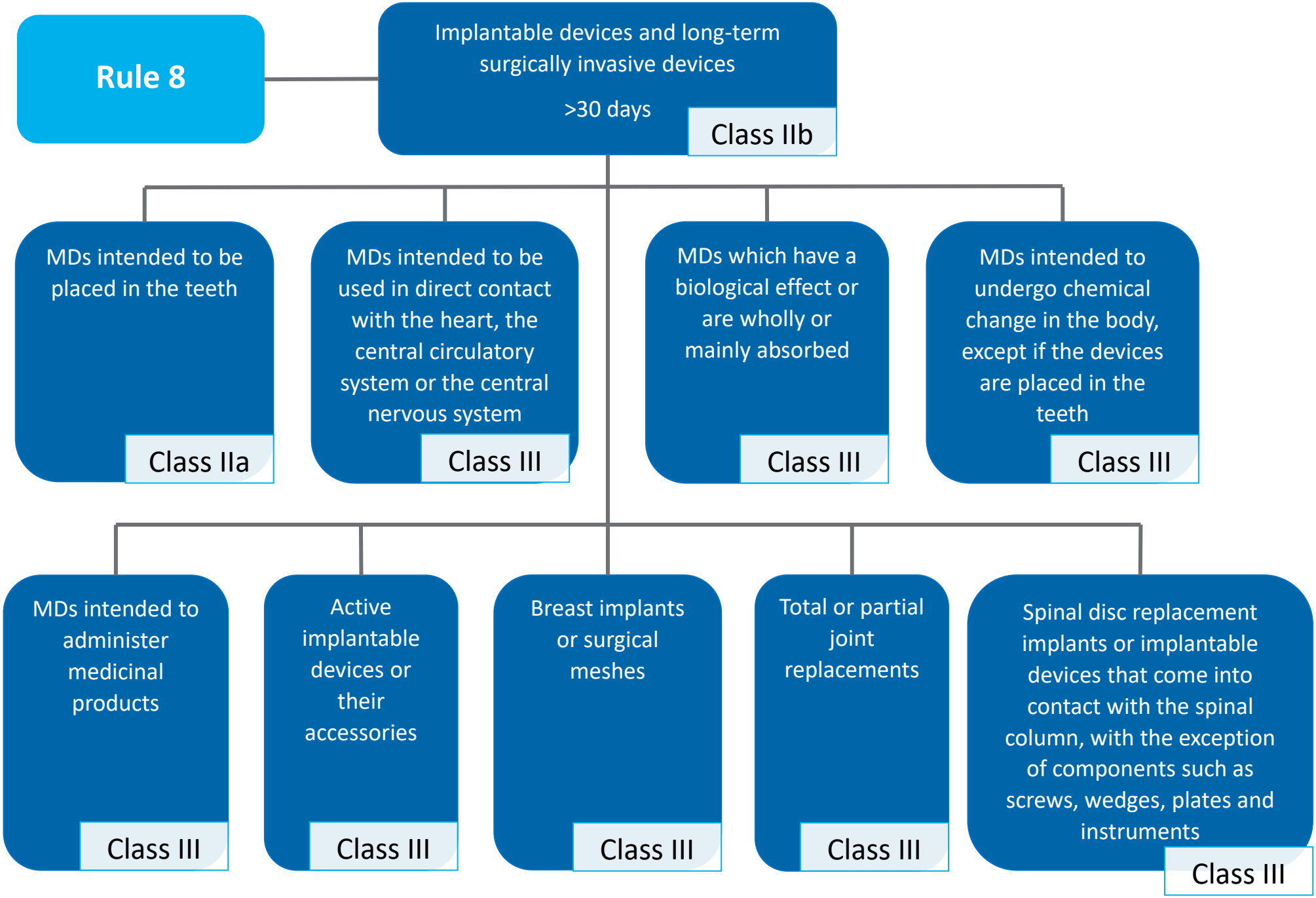

Rule 4
Non-invasive devices which come into contact with injured skin or mucous membrane
Invasive devices which come into contact with injured mucous membrane
MDs intended to be used as a mechanical barrier, for compression or for absorption of exudates
Class I
MDs intended to be used principally for injuries to skin which have breached the dermis or mucous membrane and can only heal by secondary intent
Class IIb
MDs principally intended to manage the micro-environment of injured skin or mucous membrane
Class IIa
All other cases
Class IIa

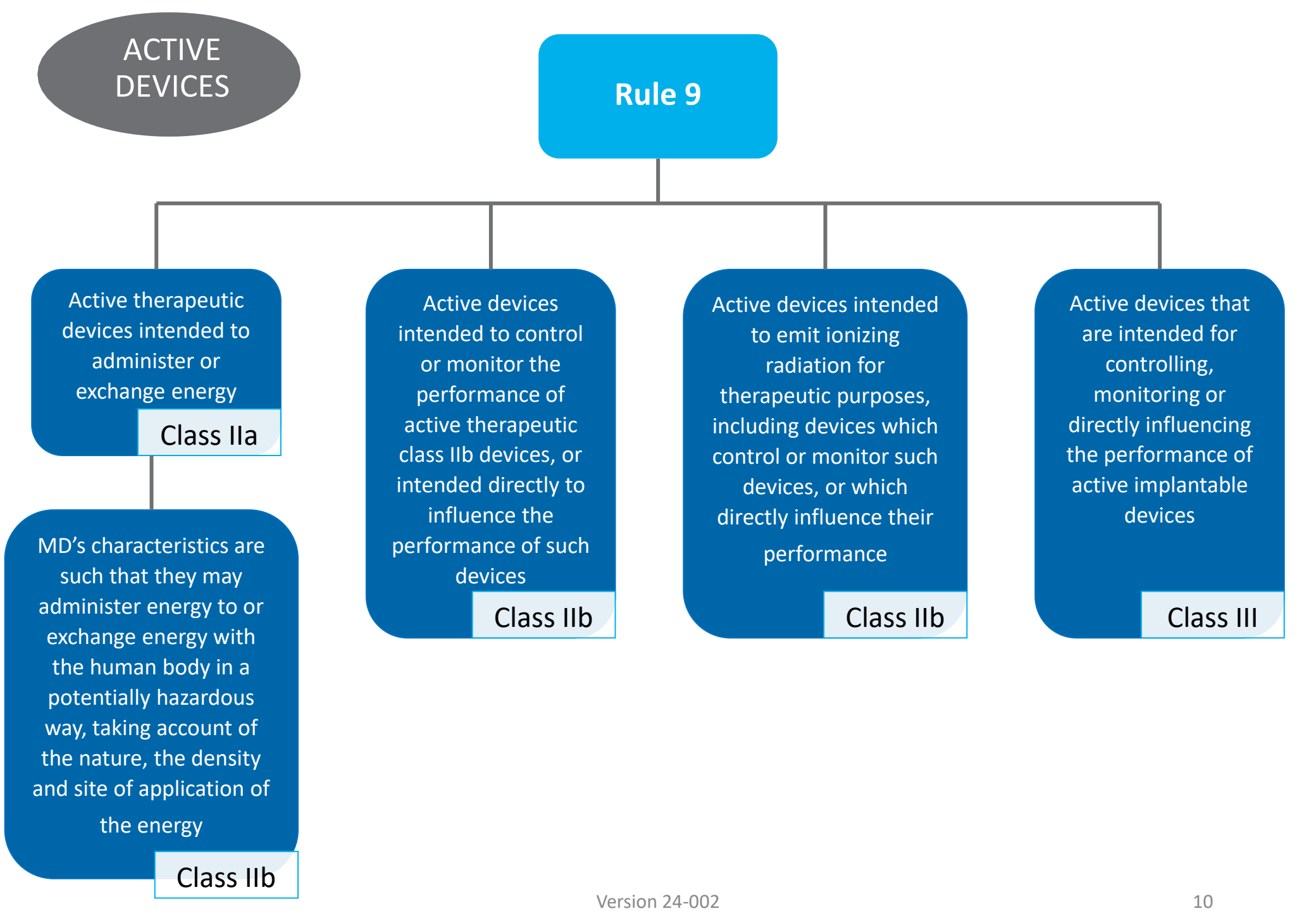
INVASIVE DEVICES

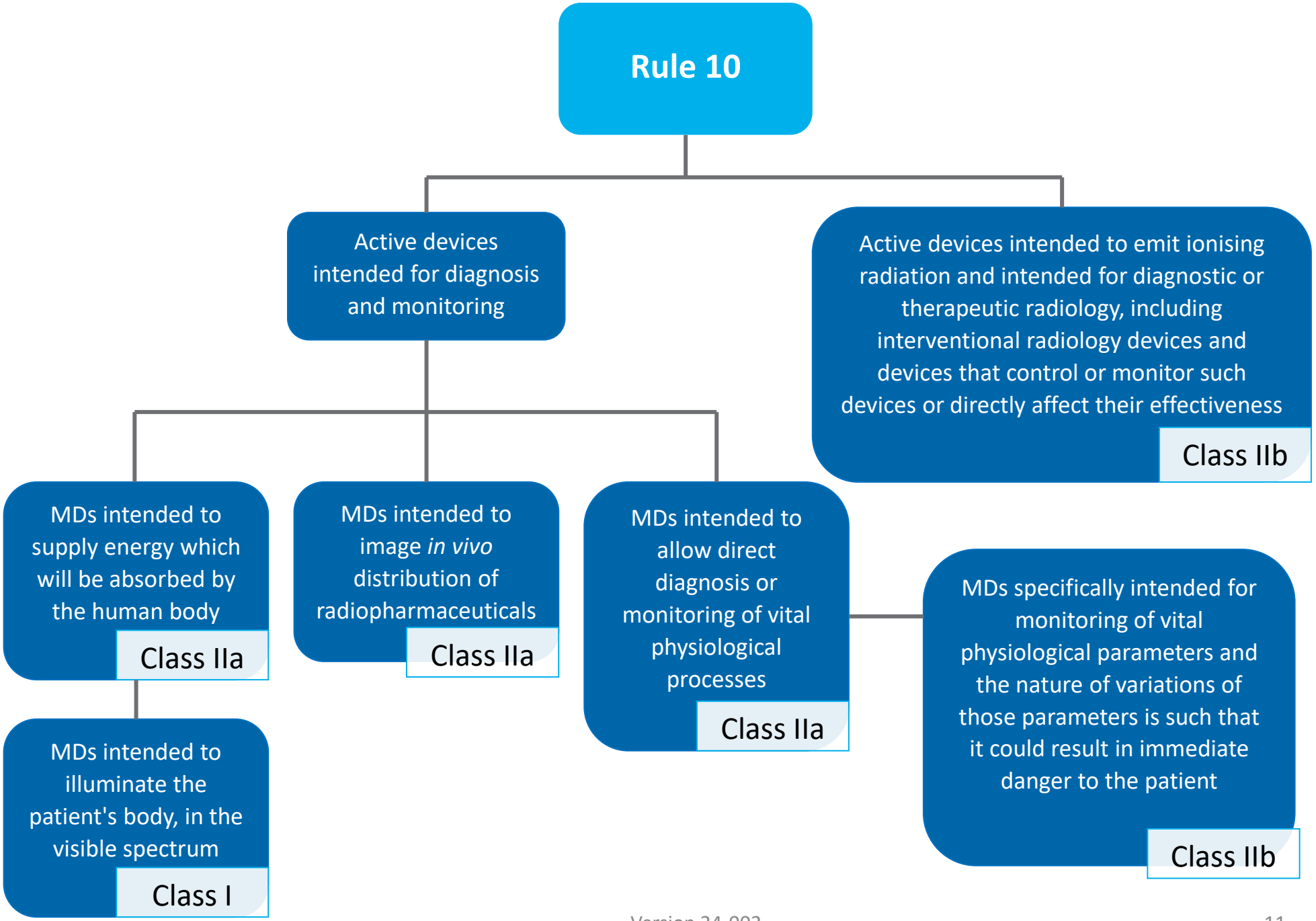


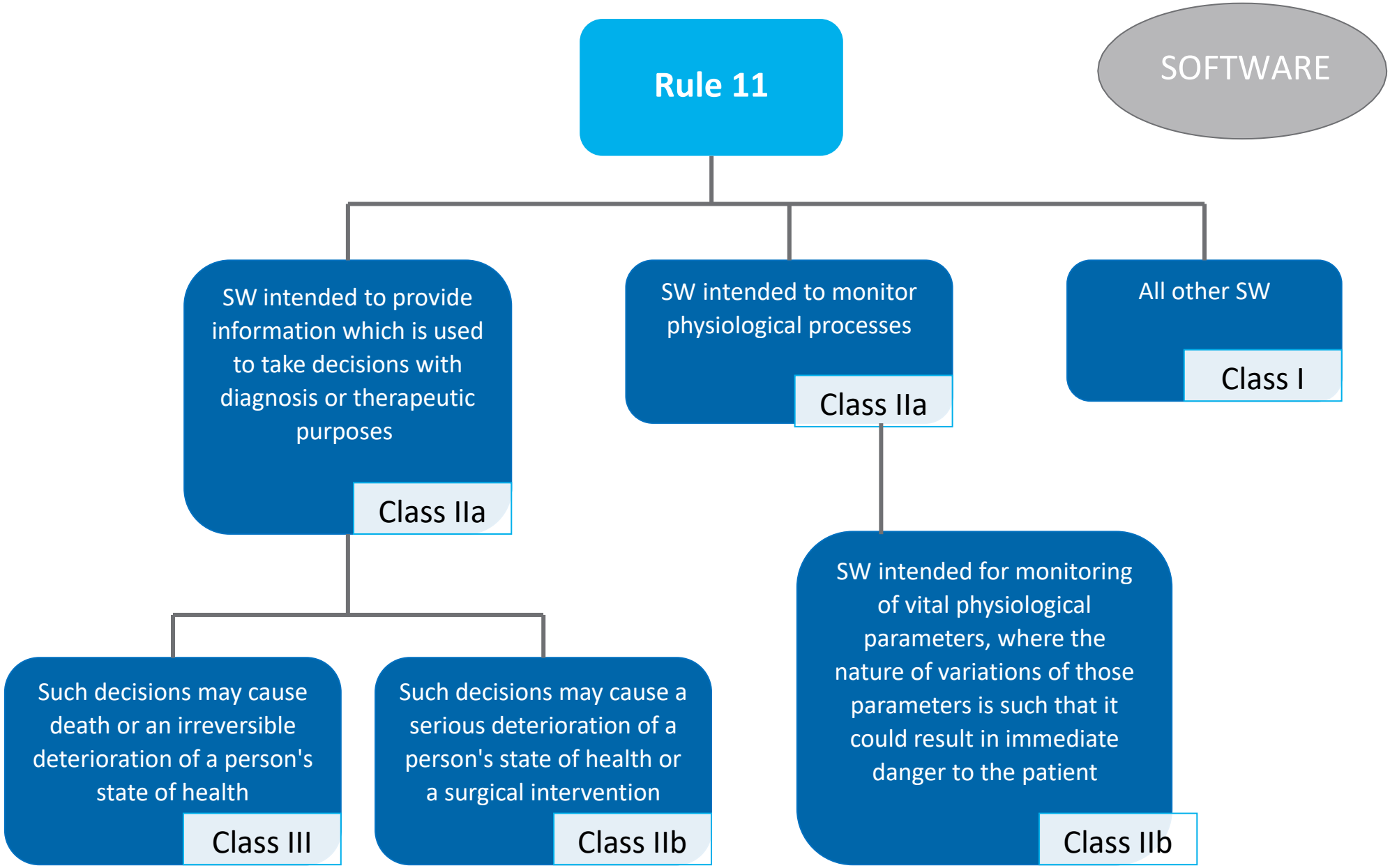

Rule 6
Surgically invasive devices intended for transient use
<60 min
Class IIa
MDs intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with those parts of the body
Class III
MDs intended to administer medicinal products by means of a delivery system, if such administration of a medicinal product is done in a manner that is potentially hazardous taking account of the mode of application
Class IIb
Reusable surgical instruments
Class I
MDs intended specifically for use in direct contact with the heart or central circulatory system or the central nervous system
Class III
MDs intended to supply energy in the form of ionising radiation
Class IIb
MDs which have a biological effect or are wholly or mainly absorbed
Class IIb

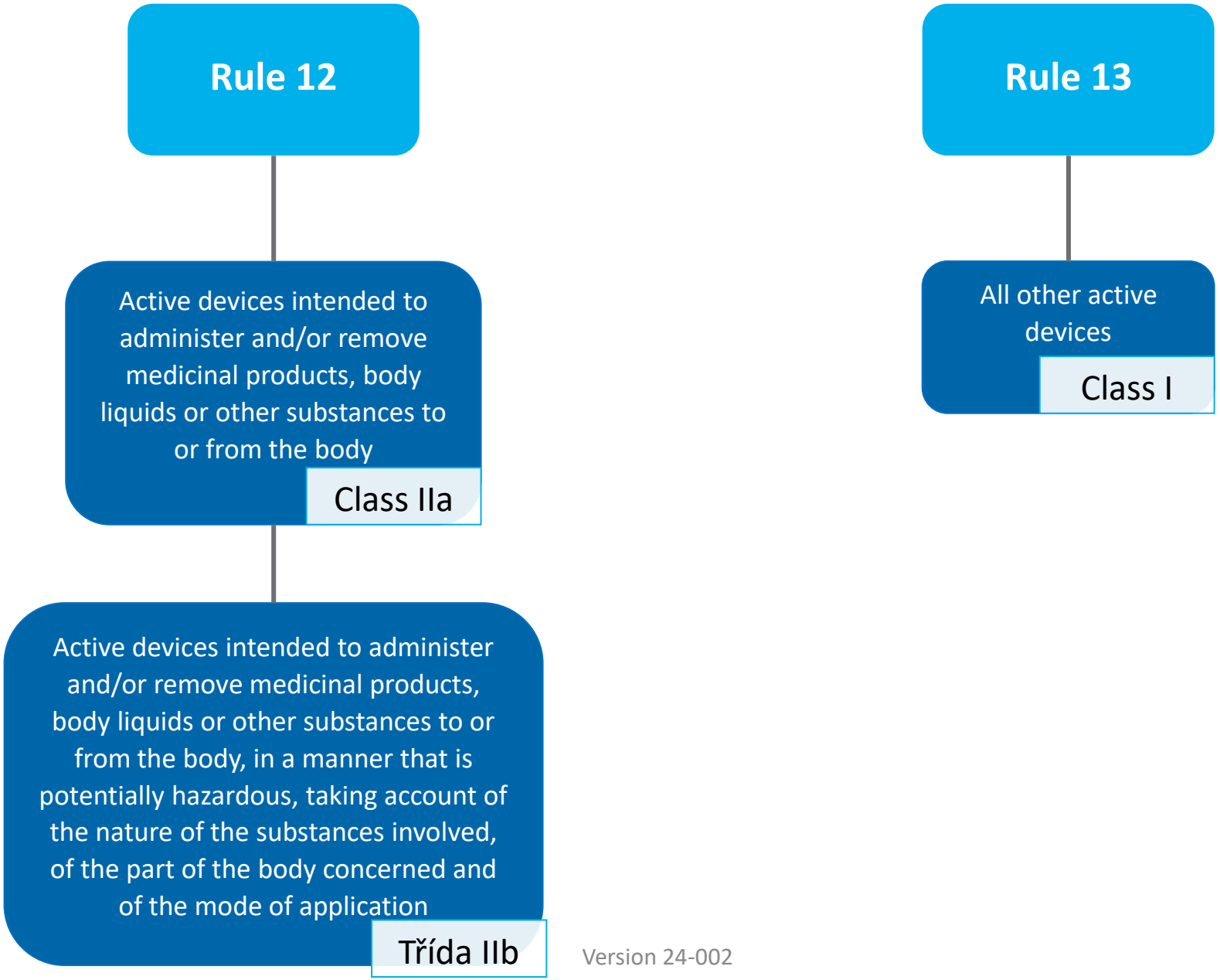

Rule 7
MDs specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with those parts of the body
Class III
Surgically invasive devices intended for short-term use
60 min - 30 days
Class IIa
MDs intended to administer medicines
Class IIb
MDs intended specifically for use in direct contact with the heart or central circulatory system or the central nervous system
Class III
MDs intended to supply energy in the form of ionizing radiation
Class IIb
MDs which have a biological effect or are wholly or mainly absorbed
Class III
MDs intended to undergo chemical change in the body, except if the devices are placed in the teeth
Class IIb


Rule 8
Implantable devices and long-term surgically invasive devices
>30 days
Class IIb
MDs intended to be placed in the teeth
Class IIa
MDs intended to be used in direct contact with the heart, the central circulatory system or the central nervous system
Class III
MDs which have a biological effect or are wholly or mainly absorbed
Class III
MDs intended to undergo chemical change in the body, except if the devices are placed in the teeth
Class III
MDs intended to administer medicinal products
Class III
Active implantable devices or their accessories
Class III
Breast implants or surgical meshes
Class III
Total or partial joint replacements
Class III
Spinal disc replacement implants or implantable devices that come into contact with the spinal column, with the exception of components such as screws, wedges, plates and instruments
Class III


ACTIVE DEVICES
Rule 9
Active therapeutic devices intended to administer or exchange energy
Class IIa
MD's characteristics are such that they may administer energy to or exchange energy with the human body in a potentially hazardous way, taking account of the nature, the density and site of application of the energy
Class IIb
Active devices intended to control or monitor the performance of active therapeutic class IIb devices, or intended directly to influence the performance of such devices
Class IIb
Active devices intended to emit ionizing radiation for therapeutic purposes, including devices which control or monitor such devices, or which directly influence their performance
Class IIb
Active devices that are intended for controlling, monitoring or directly influencing the performance of active implantable devices
Class III


Rule 10
Active devices intended for diagnosis and monitoring
Active devices intended to emit ionising radiation and intended for diagnostic or therapeutic radiology, including interventional radiology devices and devices that control or monitor such devices or directly affect their effectiveness
Class IIb
MDs intended to supply energy which will be absorbed by the human body
Class IIa
MDs intended to illuminate the patient's body, in the visible spectrum
Class I
MDs intended to image *in vivo* distribution of radiopharmaceuticals
Class IIa
MDs intended to allow direct diagnosis or monitoring of vital physiological processes
Class IIa
MDs specifically intended for monitoring of vital physiological parameters and the nature of variations of those parameters is such that it could result in immediate danger to the patient
Class IIb


SOFTWARE
Rule 11
SW intended to provide information which is used to take decisions with diagnosis or therapeutic purposes
Class IIa
SW intended to monitor physiological processes
Class IIa
All other SW
Class I
Such decisions may cause death or an irreversible deterioration of a person's state of health
Class III
Such decisions may cause a serious deterioration of a person's state of health or a surgical intervention
Class IIb
SW intended for monitoring of vital physiological parameters, where the nature of variations of those parameters is such that it could result in immediate danger to the patient
Class IIb


Rule 12
Active devices intended to administer and/or remove medicinal products, body liquids or other substances to or from the body
Class IIa
Active devices intended to administer and/or remove medicinal products, body liquids or other substances to or from the body, 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
Třída IIb
Rule 13
All other active devices
Class I

SPECIAL RULES

Rule 14

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

Class III

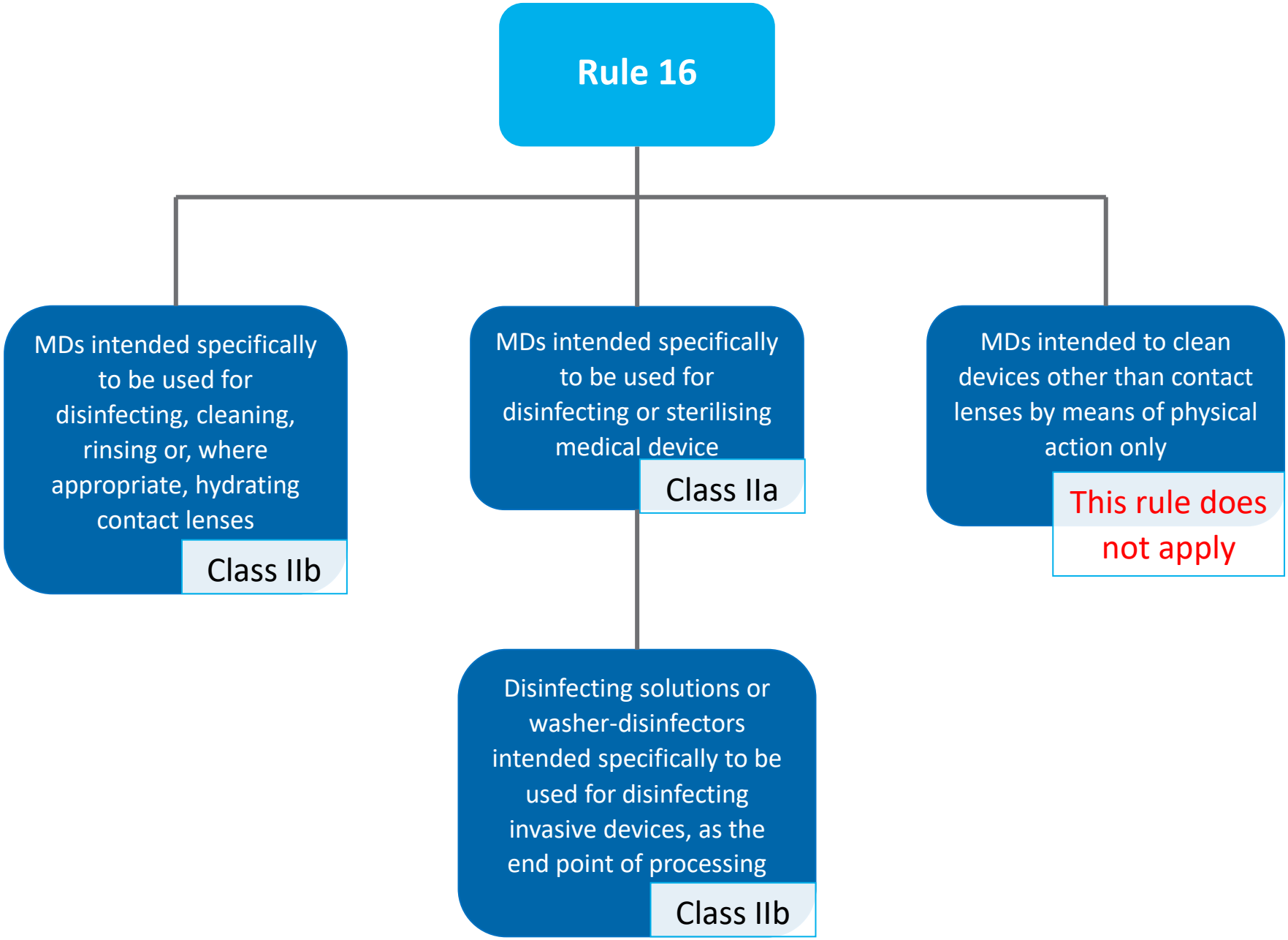
Rule 15

MDs used for contraception or prevention of the transmission of sexually transmitted diseases

Class IIb

Implantable or long term invasive devices

Class III


Rule 16
MDs intended specifically to be used for disinfecting, cleaning, rinsing or, where appropriate, hydrating contact lenses
Class IIb
MDs intended specifically to be used for disinfecting or sterilising medical device
Class IIa
MDs intended to clean devices other than contact lenses by means of physical action only
This rule does not apply
Disinfecting solutions or washer-disinfectors intended specifically to be used for disinfecting invasive devices, as the end point of processing
Class IIb

Rule 17

MDs specifically intended for recording of diagnostic images generated by X-ray radiation

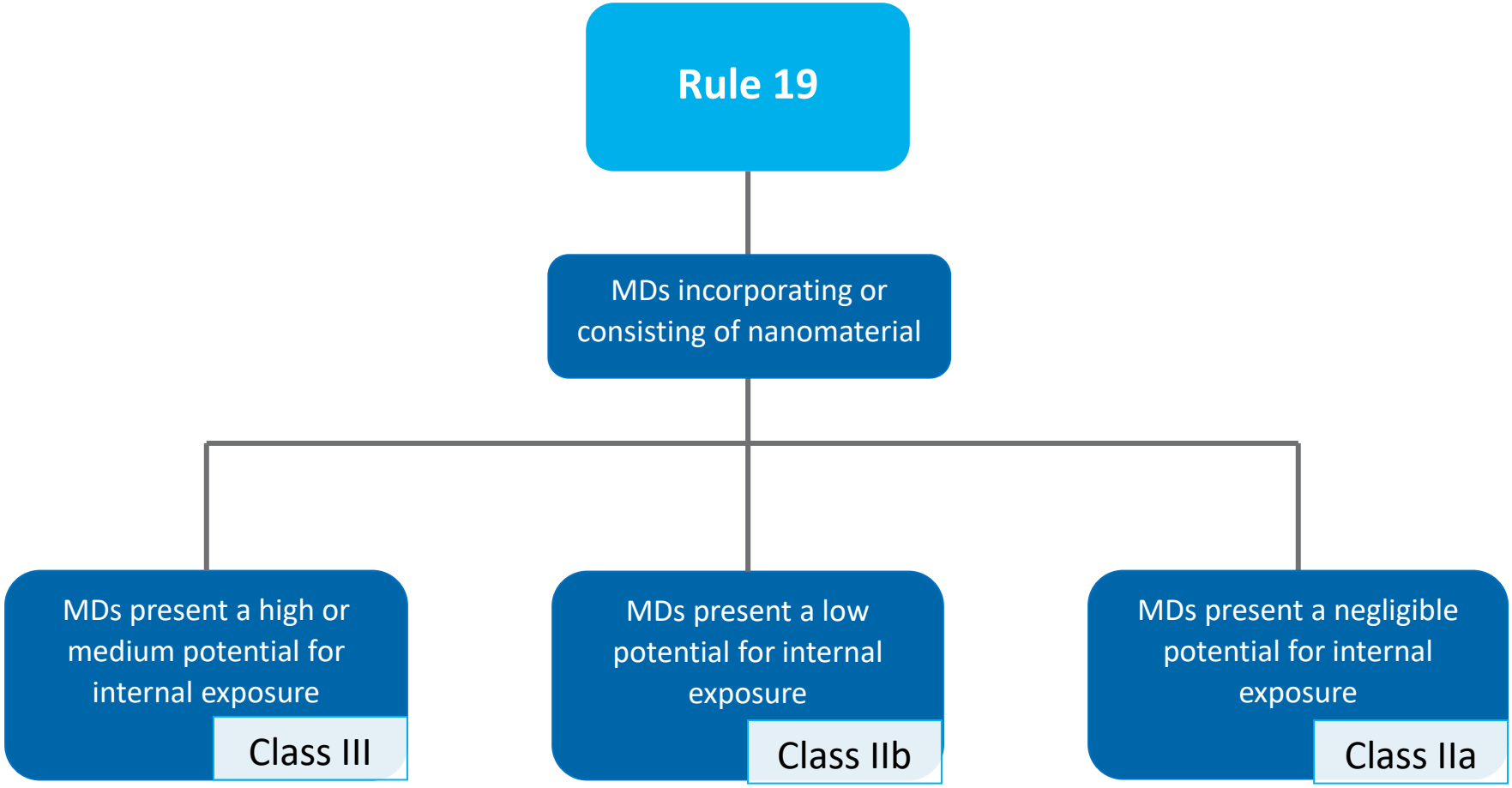
Class IIa

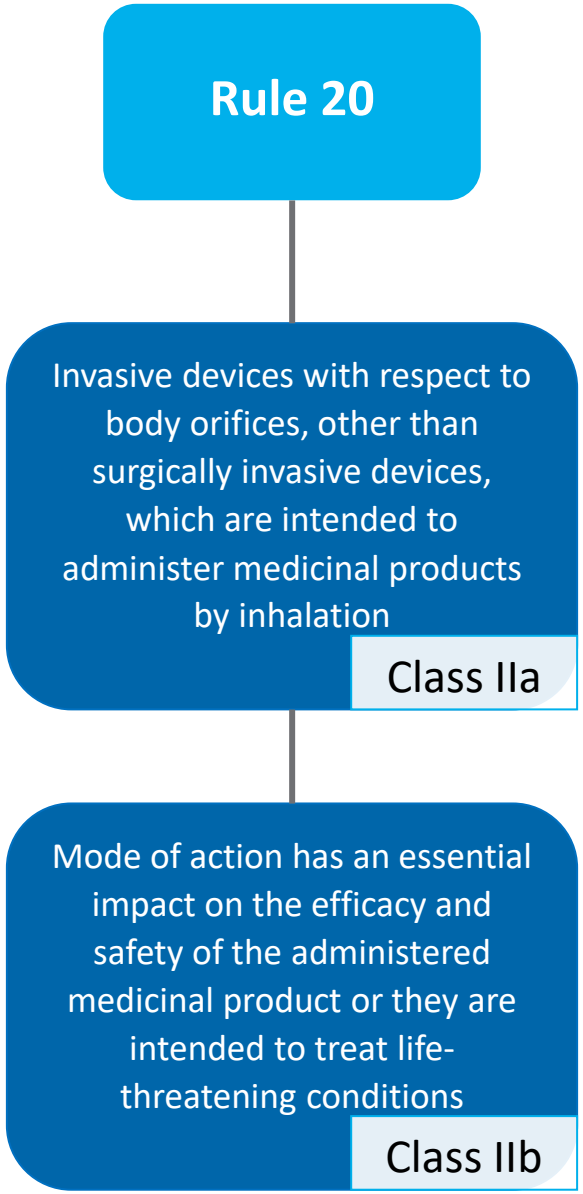
Rule 18

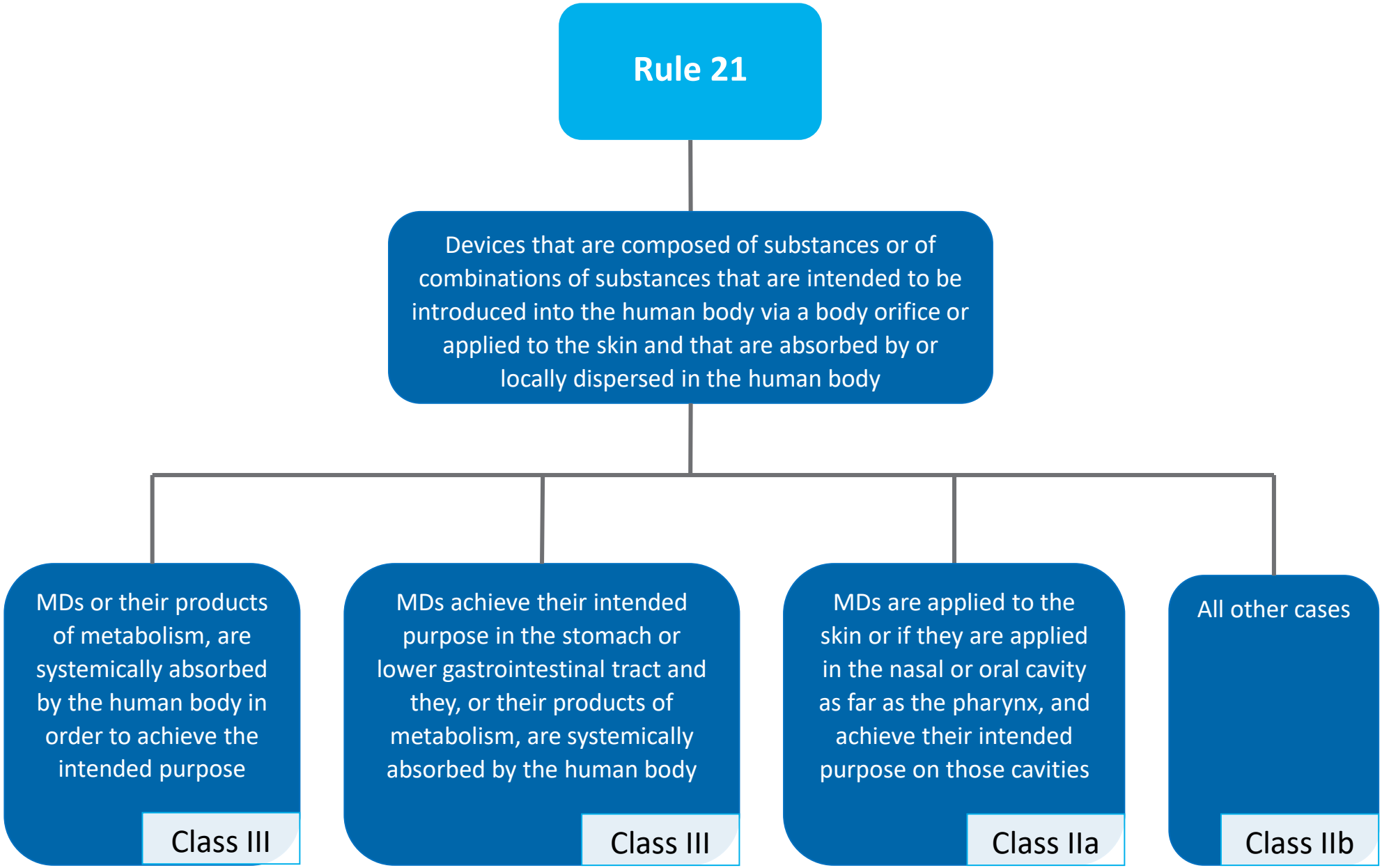
MDs manufactured utilising tissues or cells of animal origin, or their derivatives, which are non-viable or rendered non-viable and are not intended to come into contact with intact skin only, or manufactured utilising tissues or cells of human origin, or their derivatives, which are non-viable or rendered non-viable

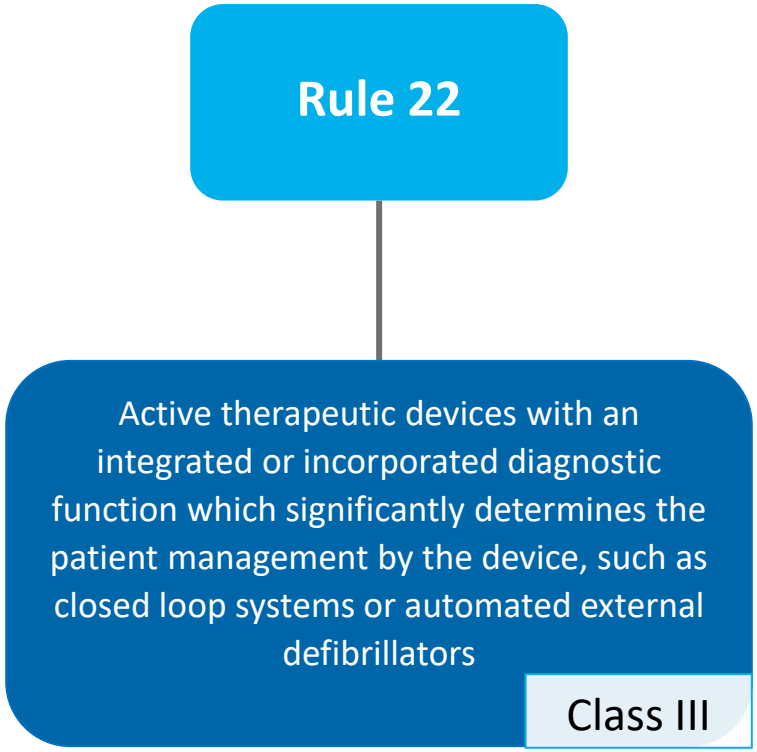
Class III

NANOMATERIAL




Rule 20
Invasive devices with respect to body orifices, other than surgically invasive devices, which are intended to administer medicinal products by inhalation
Class IIa
Mode of action has an essential impact on the efficacy and safety of the administered medicinal product or they are intended to treat life-threatening conditions
Class IIb


Rule 21
Devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body via a body orifice or applied to the skin and that are absorbed by or locally dispersed in the human body
MDs or their products of metabolism, are systemically absorbed by the human body in order to achieve the intended purpose
Class III
MDs achieve their intended purpose in the stomach or lower gastrointestinal tract and they, or their products of metabolism, are systemically absorbed by the human body
Class III
MDs are applied to the skin or if they are applied in the nasal or oral cavity as far as the pharynx, and achieve their intended purpose on those cavities
Class IIa
All other cases
Class IIb


Rule 22
Active therapeutic devices with an integrated or incorporated diagnostic function which significantly determines the patient management by the device, such as closed loop systems or automated external defibrillators
Class III