Medical Device Regulation
Classification

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- Devices shall be divided into classes I, IIa, IIb and III, taking into account the purpose intended by the manufacturer and inherent risks
- Any dispute between manufacturer and NB arising from the application of classification criteria
  - referred for a decision to CA. CA shall notify MDCG and Commission of its decision.
  - decision shall be made available upon request.
- At a request of a MS, the Commission shall after consulting the MDCG, decide, by means of implementing acts, on the following
  - application of the classification criteria to a given device, or category or group of devices, with a view to determining their classification
  - that a device, or category or group of devices shall be reclassified
    - for reasons of public health based on new scientific evidence
    - based on any information which becomes available in the course of vigilance and market surveillance activities
- Commission may also, on its own initiative and after consulting the MDCG, decide, by means of implementing acts
  - on the issues referred to above
  - In order to ensure the uniform application of the classification criteria

Duration of use

- Transient
  - normally intended for continuous use for less than 60 minutes
- Short term
  - normally intended for continuous use for between 60 minutes and 30 days
- Long term
  - normally intended for continuous use for more than 30 days

Invasive devices

- 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 means
  - an invasive device which penetrates inside the body through the surface of the body, including through mucus membranes of body orifices with the aid or in the context of a surgical operation
  - a device which produces penetration other than through a body orifice
- Reusable surgical instrument
  - intended for surgical use by cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar procedures, without connection to any active device
  - intended by the manufacturer to be reused after appropriate procedures such as cleaning, disinfection and sterilisation have been carried out

Active devices

- Active therapeutic device
  - any active device, whether used alone or in combination with other devices
  - support, modify, replace or restore biological functions or structures
  - with a view to treatment or alleviation of an illness, injury or disability
- Active device intended for diagnosis and monitoring
  - any active device, whether used alone or in combination with other devices
  - to supply information for detecting, diagnosing, monitoring or treating physiological conditions, states of health, illnesses or congenital deformities

Central circulatory and nervous system

- Central circulatory system
  - arteriae pulmonales, aorta ascendens, arcus aortae, aorta descendens to the bifurcatio aortae, arteriae coronariae, arteria carotis communis, arteria carotis externa, arteria carotis interna, arteriae cerebrales, truncus brachiocephalicus
  - venae cordis, venae pulmonales, vena cava superior, vena cava inferior
- Central nervous system
  - brain, meninges and spinal cord
- Injured skin or mucus membrane
  - area of skin or a mucus membrane presenting a pathological change or change following disease or a wound

Implementing rules for classification rules

- Application of classification rules shall be governed by intended purpose of the devices
- If device is intended to be used in combination with another device
  - classification rules shall apply separately to each of the devices
  - accessories to a medical device are classified in their own right separately from the device with which they are used
- Software, which drives a device or influences the use of a device, falls automatically in the same class as the device
  - If the software is independent of any other device, it is classified in its own right
- If the device is not intended to be used solely or principally in a specific part of the body
  - considered and classified on the basis of the most critical specified use
- If several rules, or within the same rule several sub-rules, apply to the same device based on the device's intended purpose
  - strictest rule and sub-rule resulting in the higher classification shall apply

Continuous use

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

Non-invasive devices

- **Rule 1**
  - All non-invasive devices are in class I, unless one of the rules set out hereinafter applies
- **Rule 2**
  - class IIa
    - All non-invasive devices intended for channelling or storing blood, body liquids, cells or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the body
    - if they may be connected to an active medical device in class IIa or a higher class
  - class IIb
    - if they are intended for use for storing or channelling blood or other body liquids or for **storing organs, parts of organs** or **body cells and tissues**, except for blood bags
  - in class I
    - In all other cases

Non-invasive devices

- **Rule 3**
  - class IIb
    - intended for modifying the biological or chemical composition of human tissues or cells, blood, other body liquids or other liquids intended for implantation or administration into the body
  - class IIa
    - treatment consists of filtration, centrifugation or exchanges of gas, heat
  - class III
    - 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 off from the human body or with human embryos before their implantation or administration into the body

Non-invasive devices

- **Rule 4**
- All non-invasive devices which come into contact with injured skin or mucous membrane
  - class I
    - intended to be used as a mechanical barrier, for compression or for absorption of exudates
  - class IIb
    - 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 IIa
    - in all other cases, including devices principally intended to manage the micro-environment of injured skin or mucous membrane
    - all other cases
- This rule applies also to the invasive devices that come into contact with injured mucous membrane

Invasive devices

- **Rule 5**
- All invasive devices with respect to body orifices, other than surgically invasive devices
  - **not intended for connection to an active medical device**
  - **intended for connection to a class I active medical device**
- class I
  - intended for transient use
  - intended for short-term use, used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in the nasal cavity
- class IIa
  - intended for short-term use
  - intended for long-term use
    - are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in the nasal cavity and are not liable to be absorbed by the mucous membrane
  - 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
- class IIb
  - intended for long-term use

Invasive devices

- **Rule 6**
- IIa
  - All surgically invasive devices intended for transient use unless
- class III
  - intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body
  - intended specifically for use in direct contact with the heart or central circulatory system or the central nervous system
- class I
  - reusable surgical instruments
- class IIb
  - intended to supply energy in the form of ionising radiation
  - have a biological effect or are wholly or mainly absorbed
  - intended to administer medicinal products by means of a delivery system, if this is done in a manner that is potentially hazardous taking account of the mode of application

Invasive devices

- **Rule 7**
- class IIa
  - All surgically invasive devices intended for short-term use unless
- class III
  - intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body
  - intended specifically for use in direct contact with the heart or central circulatory system or the central nervous system
  - have a biological effect or are wholly or mainly absorbed
- class IIb
  - intended to supply energy in the form of ionizing
  - intended to undergo chemical change in the body, except if the devices are placed in the teeth,
  - administer medicines

Invasive devices

- **Rule 8**
- class IIb
  - All implantable devices and long-term surgically invasive devices unless
- class IIa
  - intended to be placed in the teeth
- class III
  - intended to be used in direct contact with the heart, the central circulatory system or the central nervous system
  - have a biological effect or are wholly or mainly absorbed
  - intended to undergo chemical change in the body, except if the devices are placed in the teeth
  - administer medicinal products
  - active implantable devices or their accessories
  - breast implants or surgical meshes
  - total and partial joint replacements
    - with the exception of ancillary components such as screws, wedges, plates and instruments
  - spinal disc replacement implants and implantable devices that come into contact with the spinal column
    - with the exception of components such as screws, wedges, plates and instruments

Active devices

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

Active devices

- **Rule 10**
- class IIa
  - active devices intended for diagnosis and monitoring
  - intended to supply energy which will be absorbed by the human body
  - intended to image *in vivo* distribution of radiopharmaceuticals
  - intended to allow direct diagnosis or monitoring of vital physiological processes
- class I
  - intended to illuminate the patient's body, in the visible spectrum
- class IIb
  - specifically intended for monitoring of vital physiological parameters, where variations could result in immediate danger to patient
    - cardiac performance, respiration, activity of the central nervous system
  - intended to emit ionizing radiation and for diagnostic or therapeutic radiology, including interventional radiology devices and devices which control or monitor such devices, or which directly influence their performance

Active devices -- software

- **Rule 11**
- class IIa
  - Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes, except if such decisions have an impact that may directly or indirectly cause
- class III
  - the death or an irreversible deterioration of the state of health
- class IIb
  - a serious deterioration of the state of health or a surgical intervention
- class IIa
  - Software intended to monitor physiological processes
- class IIb
  - intended for monitoring of vital physiological parameters, where the nature of variations is such that it could result in immediate danger to the patient
- class I
  - All other software

Active devices

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

Special rules

- **Rule 14**
- class III
  - all devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product
    - including a medicinal product derived from human blood or human plasma, with action ancillary to that of the devices

- **Rule 15**
- class IIb
  - all devices used for contraception or the prevention of the transmission of sexually transmitted diseases
- class III
  - implantable or long term invasive devices

Special rules

- **Rule 16**
- class IIb
  - all devices intended specifically to be used for disinfecting, cleaning, rinsing or, when appropriate, hydrating contact lenses
  - are disinfecting solutions or washer-disinfectors intended specifically to be used for disinfecting invasive devices, as the end point of processing
- class IIa
  - all devices intended specifically to be used for disinfecting or sterilising medical devices
- This rule does not apply to devices that are intended to clean devices other than contact lenses by means of physical action only
- **Rule 17**
- class IIa
  - Devices specifically intended for recording of diagnostic images generated by X-ray

Special rules

- **Rule 18**
- class III
  - All devices manufactured utilising tissues or cells of human or animal origin, or their derivatives, which are non-viable or rendered non-viable
  - unless such devices are manufactured utilising tissues or cells of animal origin, or their derivatives, which are non-viable or rendered non-viable that are intended to come into contact with intact skin only
- **Rule 19**
- All devices incorporating or consisting of nanomaterial are:
- class III
  - if they present a high or medium potential for internal exposure;
- class IIb
  - if they present a low potential for internal exposure
- class IIa
  - if they present a negligible potential for internal exposure

Special rules

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

Special rules

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

Special rules

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