

What classification is your Medical Device?

Non-Invasive Devices

Rule 1 Either do not touch the patient or contact only intact skin

- Rule 2 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
- For use with blood, other body fluids, organs, tissues, cells
- Connected to an active device in Class IIa or higher
- Bloodbags

Rule 3 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

- Only filtration, centrifugation or exchange of gas or heat
- 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

Rule 4 In contact with injured skin or mucous membrane (Also for invasive devices into contact with injured mucous membrane)

- As mechanical barrier, compression or absorbation exudates
- Intended to manage microenvironment of injured skin or mucous membrane
- Intended for wounds which breach dermis and heal only by secondary intent

Invasive Devices

Rule 8 Surgically invasive - Long term use and implantable devices

- Intended to be placed in teeth
- Intended to be used in direct conatct with heart or central circulatoiry/ nervous system; biological effect or are wholly or mainly absorbed; intended to undergo Chemical change in body (NOT in teeth); intended to administer medicinal products; active implantable devices or their accessories; breast implants, surgical meshes; total or partial joint replacement,; OR Spinal disc replacement or implants in contact with spinal column
- except components such as screws, wedges, plates and instruments

Rule 7 Surgically invasive- Short term use

- Intended to undergo chemical change in body- (NOT in teeth); intended to administer medicines (NOT in teeth); OR intended to supply energy / ionizing radiation
- Biological effectmainly or wholly absorbed; intended specifically to monitor/ control/ diagnose/correct defect of heart or central circulatory system – by direct contact; OR intended for use in direct contact with the central nervous system or the heart or the central circulatory system

Rule 6 Surgically invasive - Transient use

- Reusable surgical instrument
- Intended to administer medicines in a potentially hazardous manner; intended to supply energy/ ionizing radiation; OR biological effect mainly or wholly absorbed
- Intended specifically for use in direct contact with the heart or central circulatory system or central nervous system; OR intended specifically to control/ diagnose/ monitor/ correct a defect or heart or central circulatory system through direct contact

Rule 5 Invasive in body orifice or stoma (not surgically)

- Transient use or short term use if only oral cavity in ear canal or in nasal cavity
- Short term use or long term use If only in oral cavity, in ear canal or in nasal cavity and not liable to be absorbed by the mucous membrane
- Long term use:
- Connected to an active medical device in Class IIa or higher

Active Devices

Rule 9 Active therapeutic devices intended to administer or exchange energy

- Intended to control or monitor or influence directly the performance of a Class IIb active therapeutic device,
- Administer or exchange energy in a potentially hazardous way
- Intended to emit ionizing radiation for therapeutic purposes, and devices which control or monitor such devices, or which directly influence their performance
- Intended for controlling, monitoring or directly influencing the performance of active implantable devices

Rule 10 Active devices for diagnosis and monitoring or suppling energy to be absorbed by the body or to image in vivo distribution of radiopharmaceuticals or allowing direct diagnosis or monitoring of vital physiological processes

- Except for devices intended to illuminate the patient's body, in the visible spectrum
- all Devices emitting ionizing radiation for diagnostic or therapeutic radiology. Including interventional radiology devices and devices which control or monitor such devices
- Specifically intended to monitor vital physiological parameters where variations could result in immediate danger to the patient
- Are intended for diagnosis in clinical situations where the patient is in immediate danger

Rule 11 Software

- Intended to provide information used to take decisions with diagnosis or therapeutic purposes
- Decision impact can cause serious deterioration in health or surgical intervention
- Decision impact can cause death or irreversible deterioration of health
- Monitor physiological processes
- For monitoring of vital physiological parameters, where the nature of parameter variations could result in immediate danger to the patient

Rule 12 Active devices to administer and/or remove medicines & other substances from the

If this is a potentialy hazardous way

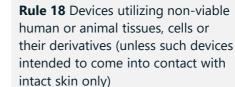
Rule 13 All other active devices

Special Rules

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Rule 19 Devices incorperating or consisting Nanomaterials

- Negligible potential for internal
- Low potential for internal exposure
- High or medium potential for internal



Rule 17 Devices intended for recording of X-Ray diagnostic images

Rule 16 Devices intended specifically to be used for disinfecting or sterilising medical

- Specifically Intended For Disinfecting, Cleaning, Rinsing or Hydrating Contact Lenses
- Disinfecting Solutions or Washer Solutions specifically to be used for disinfecting invasive devices, as the end point of processing

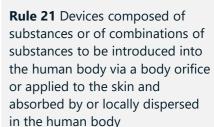
Rule 15 Devices used for contraception or prevention of sexually transmitted diseases

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- Implantable or long-term invasive
- Rule 14 Devices incorporating integral medicinal substance and that has an action ancillary to that of the devices

Rule 20 Devices invasive in respect to body orifices (not surgical) to administer medicinal products by inhalation

- Mode of action has an essential impact on the efficacy and safety of the administered medicinal product
- Intended to treat life-threatening conditions,



- If they applied to the skin or in the nasal or oral cavity as far as the pharynx and achieve their intended purpose on those cavities
- 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
- 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

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