Rules	Description	Class	Examples
Non-Invasive Devices			
Rule 1	All non-invasive devices	I	• Wheelchairs, stretchers • Urine collection bottles, incontinence pads • Non-sterile dressings, and Plaster of Paris (PoP) • Spectacle frames and lenses • Stethoscopes
Rule 2	All non-invasive devices intended for channelling or storing blood, body liquids, cells or tissues, liquids or gases for eventual infusion, administration, or introduction into the body are classified as class IIa (except blood bags) if they can be connected to a Class IIa, Class IIb, or Class III active device; or if they are intended to store organs, parts of organs, or body cells and tissues.	IIa	• Tubing intended for use with an infusion pump • Anaesthesia breathing circuits • Syringes for infusion pumps • Bags and containers are used to store and transport sperm, human embryos, etc., temporarily. • Fridges/freezers specifically intended for storing blood, tissues etc.
	Blood bags	IIb	• Blood bags
	Rest other cases	I	• Cups and spoons for administering medicines • Empty syringes without needles
Rule 3	All non-invasive devices are used to change the biological or chemical composition of human tissues or cells, blood, other bodily fluids, or liquids intended for implantation or administration into the body	IIb	• Hemodialysers used to remove undesirable substances out of the blood • Concentrates used in Haemodialysis

	If the therapy provided by the device includes filtration, centrifugation, or gas exchanges	IIa	• Blood centrifuge • Heart-lung machine
	All non-invasive devices are made up 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 implantation or administration into the body	III	• Static cold storage (SCS) • Hypothermic machine perfusion (HMP) • In Vitro Fertilization (IVF) products
Rule 4	Non-invasive devices that come into contact with wounded skin or mucous membranes:		
	meant to serve as a physical barrier, compression, or absorption of secretions	I	• Cotton wool • Dressings such as absorbent pads, wound strips • Gauze dressings • Ostomy bags
	intended to be used primarily for skin injuries that have broken the dermis or mucous membrane, and may only be healed through secondary purpose.	IIb	• Dressings used in: o Ulcerated wounds o Burns when the wounds have damaged the dermis • Dressings providing a temporary skin substitute
	• if their primary purpose is to control the injured skin's or mucous membrane's microenvironment • rest other cases	IIa	• Hydrogel dressings • Polymer film dressings
	Rule 4 applies to invasive devices that come into contact with injured mucous membrane		• Dressings for nose bleeds • Dental wound dressings without animal products
	Invasive Devices		
Rule 5	Other than surgically invasive devices, all invasive devices concerning body orifices that are not intended for connection to an active device or are intended for reference to a class I active device are:		
	• intended for transient use	I	• Handheld mirrors used in dentistry

	• used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in the nasal cavity		• Examination gloves • Embryo transfer and insemination catheter • Dental prostheses • Dental impressions materials
	• intended for short-term use • used in the oral cavity up to the throat, an ear canal up to the ear drum, or the nasal cavity, and are not absorbed by the mucosal membrane	IIa	• Tracheal tubes • Short term corrective contact lenses • Orthodontic wires • Fixed dental prostheses
	intended for long-term use	IIb	• Long term corrective contact lenses • Urinary catheters for long term use • Urethral stents
	All invasive devices concerning body orifices, other than surgically invasive devices, intended for connection to a Class IIa, Class IIb or Class III active device	IIa	• Tracheostomy or tracheal tubes connected to a ventilator • Endoscopes • Suction catheters or tubes for stomach drainage
Rule 6	All surgically invasive devices are intended for:		
	transient use	IIa	• Needles used for suturing • Lancets • Surgical gloves and swabs • Single use scalpels and blades
	• controlling, diagnosing, monitoring, or repairing a defect of the heart or central circulatory system by direct contact with those parts of the body	III	• Cardiovascular catheters, guidewires, and introducers • Neuro-endoscopes

	• use in direct contact with the heart of the central circulatory system or the central nervous system		• Spinal needles • Cranium guide for use in craniotomy • Heart valve occluders, sizers and holders
	reuse of surgical instruments	I	• Scalpels and scalpel handles • Saws (not intended for connection to an active device)
	• supplying energy in the form of ionising radiation • have a biological effect or are wholly or mainly absorbed • administering medicinal products through a delivery system, considering the mode of application	IIb	• Catheters containing sealed radioisotopes • The viscoelastic solution used in ophthalmic surgery • Refillable insulin pens • Analgesia pumps
Rule 7	All surgically invasive devices intended for:		
	short-term use	IIa	• Clamps • Skin closure devices
	• controlling, diagnosing, monitoring or correcting a defect of the heart of the central circulatory system through direct contact with those parts of the body • use in direct contact with the heart of central circulatory system or the central nervous system • having a biological effect or are wholly or mainly absorbed	III	• Cardiovascular catheters • Cardiac output probes • Heart bypass cannula • Neurological catheters • Cortical electrodes • Central venous/vascular catheters • Absorbable sutures
	• supplying energy in the form of ionizing radiation • undergo chemical change in the body (except if the devices are placed in the teeth) • administer medicines	IIb	• Brachytherapy devices • Vascular closure devices • Temporal dialysis catheter
Rule 8	All implantable devices and long-term surgically invasive devices	IIb	• Intra-ocular lenses

			• Non-absorbable sutures • Non-biodegradable bone cement • Maxillo-facial implants
	All implantable devices and long-term surgically invasive devices are intended:		
	to be placed in the teeth	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 • to have a biological effect or are wholly or mainly absorbed • to undergo chemical change (except if the devices are placed in the teeth) • to administer medicinal products	III	• Prosthetic heart valves • Biodegradable Bone Cements • Peritoneal dialysis
	• active implantable devices or their accessories • breast implants or surgical meshes • total or partial joint replacements (except ancillary components such as screws, wedges, plates and instruments) • spinal disc replacement implants or are implantable devices that come into contact with the spinal column (except components such as screws, wedges, plates and instruments)	III	• Cochlear implants and accessories • Implantable cardiac pacemakers • Breast tissue expanders • Surgical meshes for hernia repair • Spinal disc replacement implants
Active Devices			
Rule 9	All active therapeutic devices are intended to:		
	administer or exchange energy	IIa	• Muscle stimulators • Electrical acupuncture • Phototherapy for skin treatment and neonatal care • External hearing aids

			• Sleep apnoea ventilators without monitoring function
	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	IIb	• Lung ventilators • Surgical lasers • External pacemakers and defibrillators
	All active devices intended to:		
	• control or monitor the performance of active therapeutic class • emit ionizing radiation for therapeutic purposes, including devices which control or monitor such devices, or which directly influence their performance	IIb	• Brachytherapy therapy devices • Therapeutic X-ray sources
	control, monitor or directly influence the performance of active implantable devices	III	• Cardioscopes with pacing pulse indicators • Remote monitoring devices
Rule 10	Active devices intended for:		
	• diagnosis and monitoring • supplying energy that the human body will absorb • picturing in-vivo distribution of radiopharmaceuticals • allowing direct diagnosis or monitoring of vital physiological processes	IIa	• Gamma cameras • Tomography • ECG and EEG • Electronic thermometers, stethoscopes, and blood pressure measuring equipment
	• monitoring of vital physiological parameters and the nature of variations of those parameters • emitting ionising radiation • diagnostic or therapeutic radiology, including interventional radiology devices and devices that control or monitor such devices or which directly influence their performance	IIb	• Patient monitors • Apnoea monitors, • Blood gas analysers used in open-heart surgery • Diagnostic X-Ray machine • Computed Tomography Devices
	illuminating the patient's body in the visible spectrum	I	• Examination lamps • Dermatoscopes

Rule 11	• Software intended to provide information that is used to make decisions with diagnosis or therapeutic purposes • Software designed to monitor physiological processes	IIa	• Software that lists and ranks all available chemotherapy options for individuals • BMI and body fat calculators
	If the decisions may cause death or an irreversible deterioration of a person's state of health	III	• Software that regulates an installed medical device like a pacemaker
	• If the decisions may cause severe deterioration of a person's state of health or a surgical intervention • If the software is intended for monitoring vital physiological parameters, where the nature of variations of those parameters is such that it could result in immediate danger to the patient	IIb	• Apps that send alarms to patients or doctors when they detect cardiac arrhythmia in the form of irregular heartbeats • Software used for continuous surveillance of vital physiological processes in anaesthesia, intensive care or emergency care.
	Rest of the software	I	• Software that displays MRI and other types of medical images on mobile devices
Rule 12	All active devices intended to administer and/or remove medicinal products, body liquids or other substances to or from the body	IIa	• Suction pump • Feeding pumps
	If the approach of doing is potentially hazardous, taking into account of the nature of the substances involved, of the part of the body concerned and of the mode of application	IIb	• Infusion pumps • Ventilators • Anesthesia machines
Rule 13	Rest of the active devices falling under Rules 9 to 12	I	• Electric wheelchairs, and hospital beds

			• Dental curing lights, and patient chairs
	Special Rules		
Rule 14	All devices that include material as an integral part, if used separately, can be considered a medicinal product, including a medicinal product generated from human blood or human plasma, and that has an additional effect on that of the devices	III	• Bone cement with antibiotics • Condoms with spermicide • Catheters coated with anticoagulants (e. G. Heparin) • Drug-eluting stents (e.g. Coronary, pulmonary) • Intra-Uterine Devices (IUD) containing medicinal substances, including copper or silver
Rule 15	All devices used for contraception or prevention of the transmission of sexually transmitted diseases	IIb	• Condoms and femidoms • Fertility monitors and medical device software intended to be used in contraception
	If they are implantable or long-term invasive devices	III	• Non-hormonal intrauterine contraceptive devices (IUCD or ICD)
Rule 16	All devices intended specifically to be used for disinfecting, cleaning, rinsing or, where appropriate, hydrating contact lenses	IIb	• Solutions for storing contact lenses
	All devices intended specifically to be used for disinfecting or sterilising medical instruments	IIa	• Washer-disinfectors, and disinfecting solutions for non-invasive medical devices • Sterilisers
	If disinfecting solutions or washer-disinfectors are explicitly intended for	IIb	• Washer-disinfector equipment

	disinfecting invasive devices as the endpoint of processing		specifically for disinfecting endoscopes or other invasive devices • Disinfectants for the fluid pathways of haemodialysis equipment
	Rule 16 does not apply to devices specifically intended to clean devices other than contact lenses by physical action.		• Brushes specifically intended to clean medical devices by mechanical action • Ultrasonic devices
Rule 17	Devices intended explicitly for the recording of diagnostic images generated by X-ray radiation	IIa	• X-ray films • Digital x-ray detectors
Rule 18	All devices made with human or animal tissues or cells, or their derivatives, that are non-practical or have been declared non-practical	III	• Animal-derived biological heart valves • Devices made from animal-sourced collagen/gelatine
	If such devices are made from animal tissues or cells, or their derivatives, and are non-viable or declared non-viable, and are exclusively meant to come in contact with intact skin	I	• Leather components of orthopaedic appliances
Rule 19	All devices incorporating or consisting of nanomaterial:		
	demonstrating a high or medium potential for internal exposure	III	• Bone fillers with nanomaterials in their composition
	presenting a low potential for internal exposure	IIb	• Bone fixation screws/plates
	presenting a negligible potential for internal exposure	IIa	• Solution administration set made of a non-degradable polymer • Dental filling materials
Rule 20	All invasive devices concerning body orifices, other than surgically invasive devices		
	intended to administer medicinal products by inhalation	IIb	• Inhalers • Oxygen delivery system with a nasal

			cannula unless treating life-threatening conditions
	Intended to treat life-threatening illnesses and their mode of action significantly influencing the efficacy and safety of the supplied medicinal product		• Nebulisers • Spacer attached to the inhaler for metered dosage inhalers.
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 and:		
	if absorbed systematically by the human body to achieve the intended purpose in the stomach or lower gastrointestinal tract	III	• Fat absorbers
	if they are applied to the skin or if they are used in the nasal or oral cavity as far as the pharynx	IIa	• Skincare products based on substances
	Rest other cases	IIb	• Gel for vaginal lubricants • Eye drops for hydration • Ear drops
Rule 22	Active therapeutic devices having an integrated or included a diagnostic function that has a substantial impact on the patient care by the device, such as closed-loop systems or automated external defibrillators	III	• Automated external defibrillators (AED), semi-automatic defibrillators including their pads/electrodes • Automated closed-loop insulin delivery system