Medical Device Regulations

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Medical Device Directive-93/42/EEC

- 27 Countries:
- Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, & United Kingdom .
- **European Free Trade Association**
- Iceland
- Switzerland
- Liechtenstein
- Norway

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Global Harmonization Task Force (GHTF) Goals

- To harmonize regulation of medical devices among members and provide a model for medical device regulations for other countries.

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Global Harmonization Task Force (GHTF)

- USA, Canada, EU, Asia Pacific (Australia & Japan), also regulatory and industry members.
- Structure:
  - Chairmanship (rotation)
  - Steering Committee (4 Regulatory and 4 Industry Members
  - Study Group (5)
  - Guidance documents
  - Conferences

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Mutual Recognition Agreement

- Is an international agreement by which two or more countries agree to recognize one another's Conformity Assessment.

Steering Committee

- Steering Committee is to provide policy and direction for the GHTF. It is responsible for the assignment and oversight of new work items, adopt and monitor GHTF guidance documents and the authorization and promotion of GHTF training events.

Study Groups

- There are 5 Study Groups in the GHTF, each with a different focus. The size of each Study Group is to be determined by the Study Group Chair. Recommended members include 1 participant from each region with Founding Member status as well as appropriate numbers from regulatory agencies and industry, technical experts.

Study Group Chair

- The Study Group Chair member is appointed for a 3 year term by the Steering Committee

Medical Device Classification

- Determination of a device – Medical
- Intended purpose, intended use
- Risk
- Classification – 16 rules

Definitions

- Is it a Medical Device?
  - Active medical device
  - Active therapeutic device
  - Active device intended for diagnosis
  - Central Circulatory system
  - Central nervous system

Medical Device

- Definition: any instrument, apparatus, appliance, software, material or other article whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:
- -diagnosis, prevention, monitoring, treatment or alleviation of disease
- -diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- -investigation, replacement or modification of the anatomy or of a physiological process
- - control of conception

Medical Device-
CONTINUED

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means but which may be assisted in its function by such means.

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.
- e.g. External feedback systems for active therapeutic devices, diagnostic ultrasound.

Active Therapeutic Device

- Any active medical device whether used alone or in combination with other medical devices, to support, modify, replace or restore biological functions or structures with a view to treatment or alleviation of an illness, injury or handicap. 93/42/EEC
- e.g. Intensive care monitoring systems, biological sensors, blood gas analyzers used in open-heart surgery, cardioscopes and apnea monitors, external defibrillators, electroconvulsive therapy equipment.

Active Device Intended for Diagnosis

- Any active medical device, whether used alone or in combination with other medical devices, to supply information for detecting, diagnosing, monitoring or to support in treating physiological conditions, states of health, illnesses or congenital deformities. 93/42/EEC
- e.g. Electrocardiographs, electroencephalographs, cardioscopes with or without pacing pulse indicators and electronic thermometers.

Central Circulatory System

- Central circulatory system means the major internal blood vessels including the following: pulmonary veins, pulmonary arteries, cardiac veins, coronary arteries, cerebral arteries, brachiocephalic artery, aorta, inferior an superior vena cava and common iliac arteries.

Central Nervous System

- For the purpose of this presentation, central system means brain, meninges and spinal cord.

GHTF 16 Rules vs. Medical Device Directive 18 Rules (Annex IX)

- Four sections
  - Non-Invasive devices
  - Invasive devices
  - Active Devices
  - Additional rules- Medicinal products, animal or human tissues, disinfectants, contraceptives

Non-Invasive Device

- Are those intended for contact with injured skin and intended as a barrier or for compression or absorption of exudates.

  e.g intestinal liner for control of diabetes, a doctor inserts it into a patient's small intestine through the mouth in a procedure known as endoscopy, bandages, cervical collar, urine collection bottles, ostomy pouches, wound drainage bottles.

Invasive device

- 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 or permanent tracheotomy. E.g. Tracheal tube, suction catheter, dental impression materials
- **Surgically invasive device:** An invasive device which penetrates inside the body through the surface of the body, with the aid or in the context of a surgical operation. e. g. drug eluting stents, heart valves. e.g. Suture needles, hypodermic needles and syringes.

Duration of the device

- Transient – Normally intended for continuous user for less than 60 minutes, e.g. Cardiovascular catheters (e.g. angioplasty balloon catheters)
- Short term - Normally intended for continuous between 60 minutes and 30 days. E.g. Clamps, infusion cannulae, skin closure devices or temporary filling materials, some surgical retractors.

Duration of the device Continued

- Long term - Normally intended for continuous use for more than 30 days. e.g. Implantable joint replacements, shunts, stents, nails, plates and screws, intra-ocular lenses, infusion ports, peripheral vascular grafts, non-absorbable sutures, bone cements and maxillo-facial implants, prosthetic heart valves.

How Medical Devices are it Classified

- Intended Purpose
- Risk
- Intended Use, duration of device in contact with the body
- Degree of Invasiveness, whether delivers medicine or energy, intended biological or systematic effect.

Intended purpose

- The purpose for which the manufacturer of the device intends it to be used, as stated in:
- (a) the information provided with the device, or
- (b) the instructions for use of the device, or (c) any advertising material applying to the device, and
- (d) the mechanism of action of the device.

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Intended Purpose

- Intended purpose: If based on the manufacturer intended purpose two or more classifications apply the device should be allocated the highest level of classification
- If the devices is intended to be used with another device (e.g.) each device should be classified separately.

Devices incorporating a medicine

- A device incorporating a substance that if used separately would be a medicine and has an ancillary action on the body.
- e.g. Antibiotic bone cements, heparin coated catheters, drug eluting stents.

Devices containing non-viable animal tissues or derivatives

- Devices containing animal tissues or derivatives that have been rendered nonviable and not intended to come into contact with intact skin only.

  e.g. Biological heart valves, porcine xenograft dressings, catgut sutures, implants and dressings made from collagen.

Continued

- Medical devices divided into two important section:
- A. Rules
- B. Risk

Risk Based: Standard ISO 14971

Risk management includes risk assessment, risk analysis,evaluation and control over the life cycle of the product.

- Harm: Physical injury or damage to the health of patient or user
- Hazard: Potential source of harm
- Immediate danger: A situation where therapy is required as soon as possible after the abnormal condition is diagnosed in order to prevent serious injury to the patient or user.

Classification

- Four classes of Medical Devices according to the risk it presents to the patient or user.

Examples of Medical Devices Classification MDD vs. GHTF

- Class I-A: devices present minimal potential for harm to the user
- These devices are subject only to general controls registration, proper branding and labeling, notification to the Authorities..
- e.g.tongue depressors, bedpans, elastic bandages, examination gloves, and hand-held surgical instruments and other similar types of common equipment

Devices in Class II-B

- Class II-B devices are also subject to special controls in addition to the general controls of Class I devices. Special controls may include special labeling requirements, mandatory performance standards typically non-invasive devices.
- e.g.include x-ray machines, powered wheelchairs, infusion pumps, surgical drapes, surgical needles and suture material, and acupuncture needles.

Class IIa-IIb
Class C

- Active medical device for therapy to administer or exchange energy – Class B

- Administer or exchange energy in a potentially hazardous way - Class C

Class III-D device

- High risk devices are life supports, critical monitoring, energy emitting and other devices whose failure or misuse is reasonably likely to seriously injure patient or staff
- e.g., heart valves, silicone gel-filled implants, implanted cerebral stimulators, implantable pacemaker pulse generators and endosseous (intra-bone) implants, anesthesia ventilators, fetal monitors, etc.

Classification of Medical Devices
vs.
GHTF Classification

93/42/EEC-Medical Devices

Class I
Low risk-
Surgical retractors / tongue depressors

Class IIa
Low Moderate risk
Hypodermic Needles / suction equipment

Class IIb
Moderate high risk
Lung ventilator / bone fixation plate

Class III
High risk
Heart valves / implantable defibrillator coronary stents, pacemakers, HIV test kits

GHTF Classification

Class A
Low risk

Class B
Low Moderate risk

Class C
Moderate high risk

Class D
High risk

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What are the Factors for Classification

- Duration and the nature of contact
- If delivery is medicinal or energy
- Biological effects
- Combination –
- Accessories
- Software

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General Principals

- Essential Principals of Safety & Performance
- “ The risk presented by a particular device depends substantially on its intended purpose and the effectiveness of the risk management techniques applied during design, manufacture and use”.

Technical Documentation

- All classification require documentation from lower to higher.
- All Essential Principals apply no matter the risk class.

Responsibility for Classification

- Manufacturer
- Final confirmation by the Regulatory Authority

Medical Device Classification

- Non-Invasive devices: Rule 1, 2, 3, 4
- Invasive devices: 5, 6, 7, 8
- Active devices: 9, 10, 11, 12
- Special rules: 13, 14, 15, 16

Drug Eluting Stent

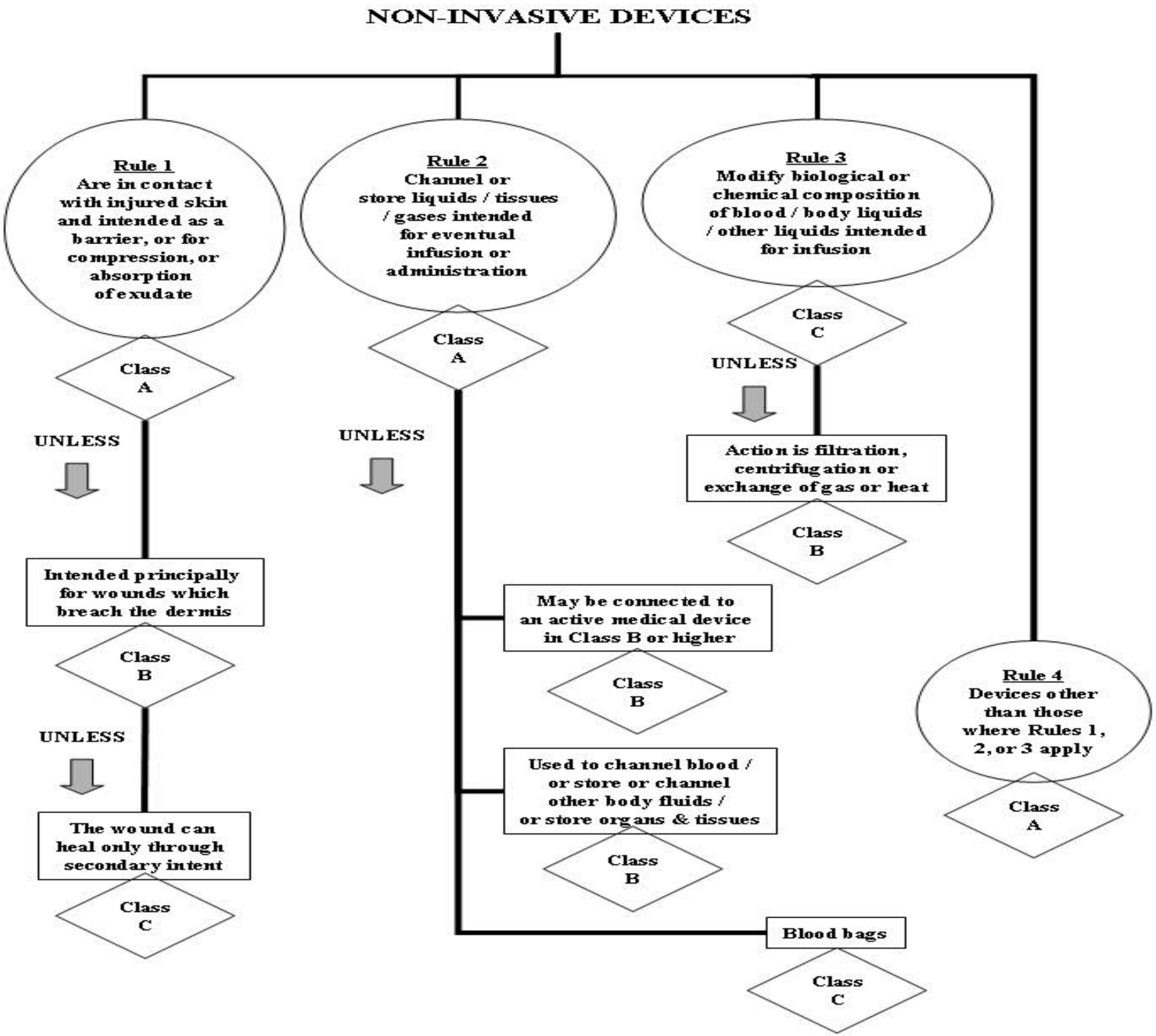
- Stent, coronary, drug-eluting -- a metal scaffold with a drug coating placed via a delivery catheter into the coronary artery or saphenous vein graft to maintain the lumen. The drug coating is intended to inhibit restenosis.
- Class D or Class III (primary purpose is the stent the secondary is the drug, thus a medical device).

Software

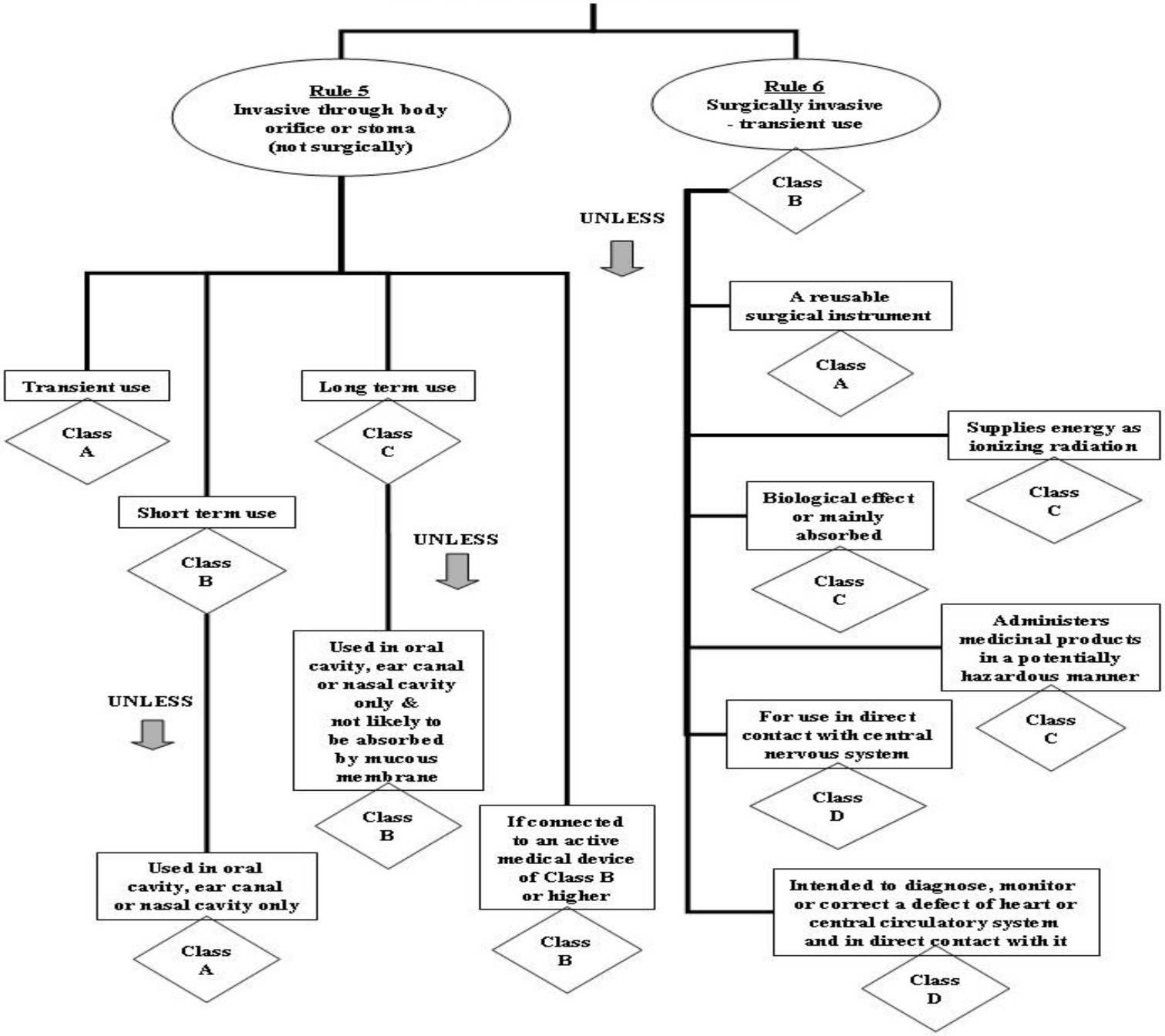
- If to drive or influence the use of a medical device falls under the same classification as the medical device.
- Based on the intended purpose, software may be a medical device in its own right.
- Stand alone software (to the extent it falls within the definition of a medical device) is deemed to be an active device.

Mistakes in classification

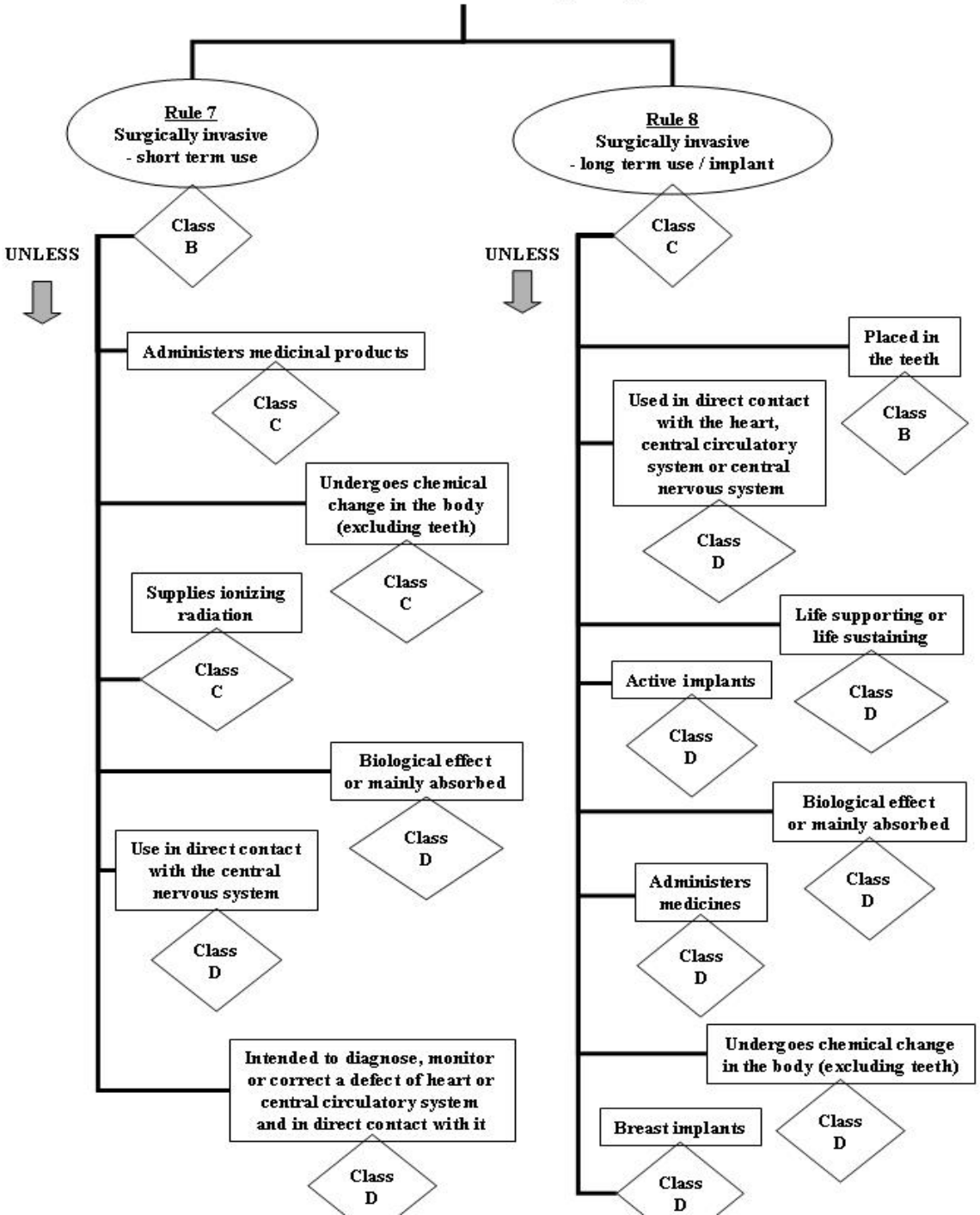
- Jurisdictions may have to adjust classification due to Post-Market experience, historical knowledge, National rules
- If several rules apply based on the performance specified for the device by the manufacturer, the strictest rules resulting in the higher classification shall apply.


NON-INVASIVE DEVICES
Rule 1
Are in contact with injured skin and intended as a barrier, or for compression, or absorption of exudate
Class A
UNLESS
Intended principally for wounds which breach the dermis
Class B
UNLESS
The wound can heal only through secondary intent
Class C
Rule 2
Channel or store liquids / tissues / gases intended for eventual infusion or administration
Class A
UNLESS
May be connected to an active medical device in Class B or higher
Class B
Used to channel blood / or store or channel other body fluids / or store organs & tissues
Class B
Blood bags
Class C
Rule 3
Modify biological or chemical composition of blood / body liquids / other liquids intended for infusion
Class C
UNLESS
Action is filtration, centrifugation or exchange of gas or heat
Class B
Rule 4
Devices other than those where Rules 1, 2, or 3 apply
Class A

INVASIVE DEVICES (1 of 2)



INVASIVE DEVICES (2 of 2)



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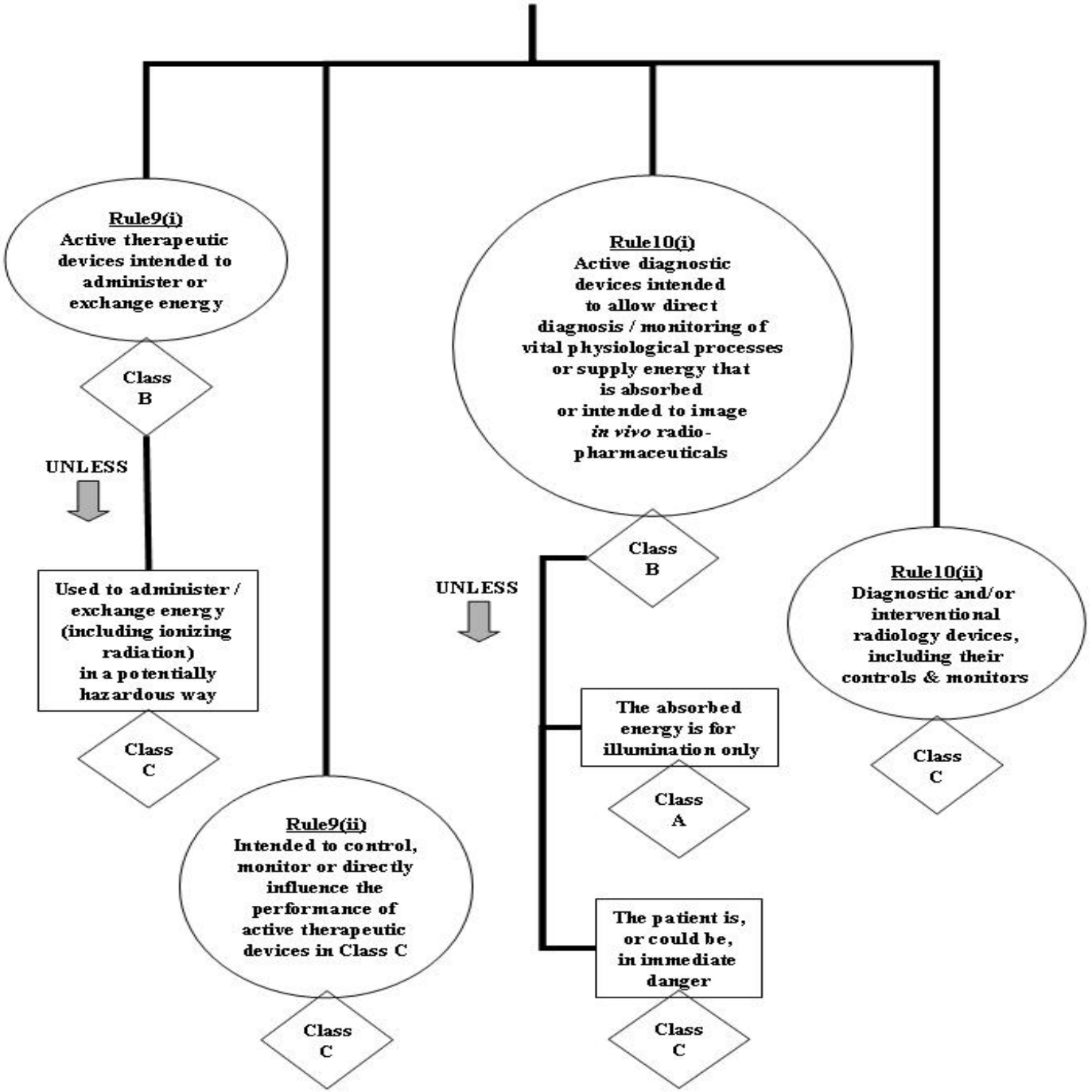
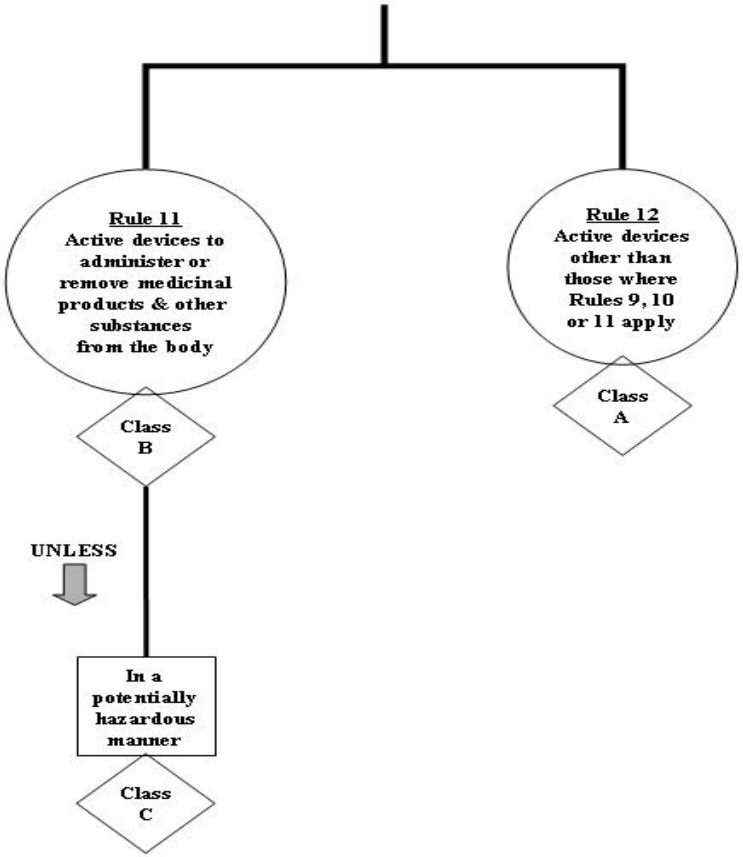
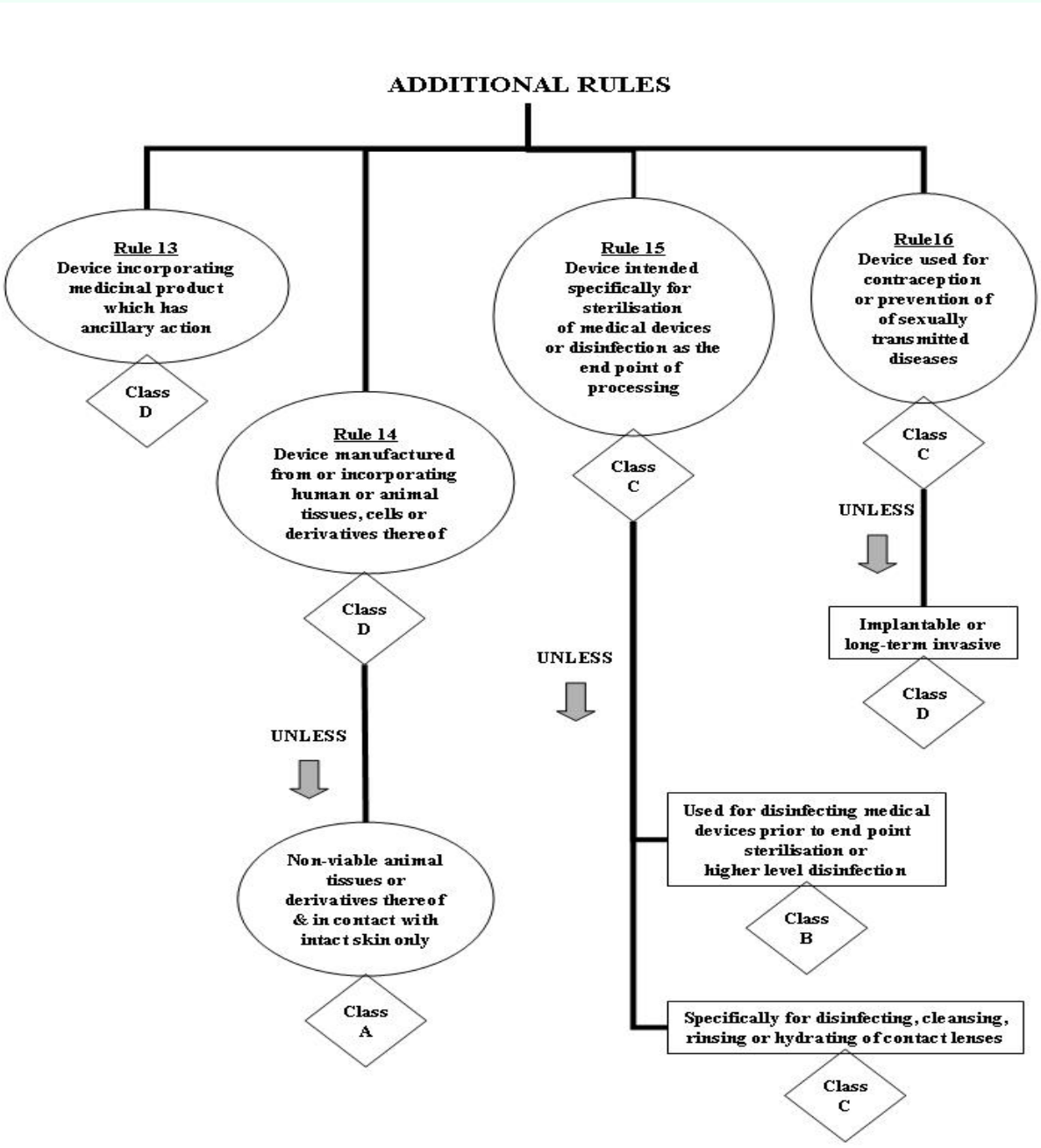
ACTIVE DEVICES (1 of 2)



ACTIVE DEVICES (2 of 2)





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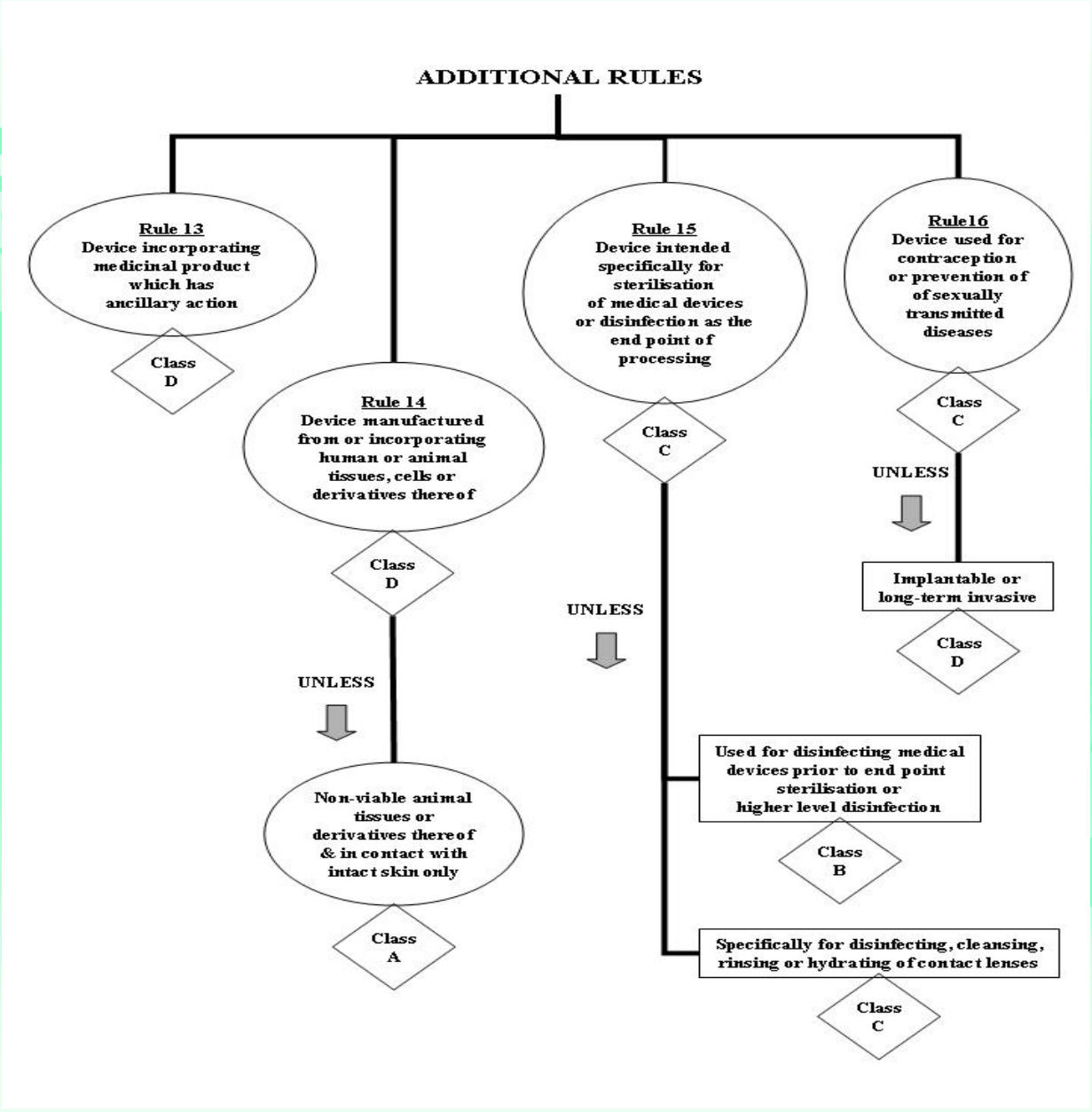
ADDITIONAL RULES
Rule 13
Device incorporating medicinal product which has ancillary action
Class D
Rule 14
Device manufactured from or incorporating human or animal tissues, cells or derivatives thereof
Class D
UNLESS
Non-viable animal tissues or derivatives thereof & in contact with intact skin only
Class A
Rule 15
Device intended specifically for sterilisation of medical devices or disinfection as the end point of processing
Class C
UNLESS
Used for disinfecting medical devices prior to end point sterilisation or higher level disinfection
Class B
Specifically for disinfecting, cleansing, rinsing or hydrating of contact lenses
Class C
Rule16
Device used for contraception or prevention of of sexually transmitted diseases
Class C
UNLESS
Implantable or long-term invasive
Class D