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CRITERIA FOR THE CLASSIFICATION OF MEDICAL DEVICES BASED ON THEIR LEVEL OF HEALTH RISK

OBJECTIVE:

This document has been prepared by the Technical Committee for Health Products in order to develop a standard applicable criteria for the wide range of products included in the Medical Devices sector in Mexico, which are an important part of the health system in Mexico for their role and participation in diagnosis, prevention, treatment and rehabilitation of illness and disease in humans.

The purpose of this document is to establish the criteria under which Medical Devices in Mexico are classified based on their level of health risk. The established criteria are presented as rules, signaling the product characteristics as related to its use, activity, contact and level of permanency inside of the body, as well as the class to which they belong, including a number of examples in a descriptive and declarative way, but not limited to those, published to help people who are interested in registering a medical device in Mexico, as much for domestic manufacturers as for foreigners, in classifying their products properly, and thus identifying the registration requirements pertaining to them.

In support of the harmonization and technological advances in the sphere of globalization, the contents of this document is partially consistent with international guidelines applicable to the classification of medical devices.

DEFINITIONS:



For purposes of this document and the correct classification of medical devices the following definitions are provided:

1. Medical Device Categories. These are the six main groups which divide the medical device sector in Mexico, based on their function and intended use. These categories are defined as:

- I. **Medical device:** The devices, accessories and equipment for specific use intended for medical or surgical use or examination procedures, diagnosis, treatment and rehabilitation of patients as well as for conducting biomedical research.
- II. **Prosthetics, orthotics and functional supports:** Those devices to replace or complement a bodily function, an organ or a tissue of the human body.
- III. **Diagnostic agents:** All inputs including antigens, antibodies, calibrators, verifiers and controls, reagents, equipment, reagents, culture media and contrast any other similar to be used as auxiliary or other clinical procedures paraclinical.
- IV. **Dental supplies:** All substances or materials used in the care Dental Health.
- V. **Surgical and healing materials:** Devices or materials added or not antiseptics or germicides used in surgical practice or treatment of solutions continuity, skin lesions or its attachments.
- VI. **Hygiene products:** The materials and substances that are applied on the surface of the skin or body cavities and having drug or preventive action.

2. Classification of Medical Devices. Medical devices are classified for registration purposes according to the risk involved in their use, as follows:

- **Class I:** Those products that are well-known to medical practice; their safety and effectiveness are proven; and, generally, they are not introduced into the body.
- **Class II:** Those products that are well-known to medical practice; they may have variations in material with which they are made or in their concentrations; and, generally, they are introduced into the body to remain there for a period of less than thirty days.
- **Class III:** Those products that have only recently been accepted in medical practice; or else when they are introduced into the body, they remain there for more than thirty days.

3. Medical Devices. Substance, mixture of substances, material, device or instrument (including computer program necessary for proper use or application); used alone or in combination with



others in the diagnosis, monitoring or prevention of disease in humans; or aids in the treatment of the same and of disabilities, such as those employed in the replacement, correction, restoration or modification of the anatomy or human physiological processes. For the correct application of the criteria for the classification of medical devices based on their level of risk, these products are divided as follows:

- a. Implantable Medical Device.
- b. Active Medical Device.
- c. Active Medical Device for Diagnosis.
- d. Active Therapeutic Medical Device.
- e. Invasive Medical Device.
- f. Surgically Invasive Medical Device.

4. Implantable Medical Device. Medical device designed to be totally implanted into the human body to replace an epithelial surface or an ocular surface through surgical intervention, intended to remain there after its introduction. Any medical device is also considered to be an implantable medical device if it is designed to be partially introduced into the human body through surgical intervention and to remain there after the procedure for a period of at least thirty days.

5. Active Medical Device. Medical device whose operation depends on an electrical energy source or other power source other than that directly generated by the human body or by gravity, and which acts via the conversion of this energy.

6. Active Medical Device for Diagnosis. Active medical device used alone or in combination with other medical devices, designed to provide information for the detection, diagnosis, control or treatment of physiological conditions, health conditions, diseases or congenital malformations in humans.

7. Active Therapeutic Medical Device. Active medical device used alone or in combination with other medical devices, designed to support, modify, replace or restore biological functions or structures in the context of prevention, treatment, relief or rehabilitation of an illness, injury or deficiency in humans.

8. Invasive medical devices. Medical device that partly or wholly penetrates inside the body



through a body orifice or else through the body surface, meaning a body orifice or any other natural body opening, the outer surface of the eyeball, or an artificially created permanent opening, such as a stoma.

9. Surgically Invasive Medical Device. Invasive medical device that penetrates inside the body through the body surface, through or in the context of surgery. Medical devices are also considered surgically invasive products if their method of penetration into the human body does not occur through one of the recognized bodily orifices.

10. Duration. Refers to the medical device's length of stay within or contact with the human body.

10.1 Temporary Use. Normally intended to be used continuously for a period of less than sixty minutes.

10.2 Short-term Use. Meant to be used for a period not exceeding thirty days.

10.3 Long-term use. Designed for continuous use for longer than 30 days.

11. Reusable surgical instrument. Instrument intended for surgical purposes, for cutting, drilling, sawing, ripping, scraping, clamping, retracting, clipping or similar procedures, without being connected to any active medical device, and can be reused after completion of all pertinent procedures.

12. Central Circulatory System (SCC). Refers to the following vessels: pulmonary arteries, ascending aorta, coronary arteries, primary carotid artery, external carotid artery, internal carotid artery, cerebral arteries, brachiocephalic trunk, coronary veins, pulmonary veins, superior vena cava, inferior vena cava.

13. Central Nervous System (CNS). Refers to the brain, meninges and spinal cord.

APPLICATION CRITERIA:

For the correct application of the rules defining the classification of medical devices the following general guidelines should be taken into account:



1. The application of the classification criteria is governed by the intended use of the products.
2. If a medical device is intended to be used in combination with another product, the criteria for classification is applied to each of the individual products separately. Accessories should be classified on their own independently of the product with which they are used.
3. The software that drives a device or influences its utilization is automatically included in the same category.
4. If a product is not intended to be used solely or mainly on a specific part of the body, it is considered and classified according to its most critical specified use.
5. If for the same product several rules apply, taking into account the different purposes of use or functions attributed to it by the manufacturer, the rules that lead to the highest classification shall be applied.

Rule 1 Products that do not touch the patient or only have contact with intact skin.

- All non-invasive and in vitro products which enter into contact only with intact skin or that do not touch the patient, except when specific rules are applied, are classified as **Class I**.

These products include but are not limited to:

- Products for the collection of bodily fluids, in which a reflux liquid is unlikely to occur (urine bags, ostomy, incontinence diapers)
- Products used to immobilize part of the body or apply force or compression (bandages, cervical collars, elastic stockings)
- Products for external support of the patient (hospital beds, wheelchairs, dental chairs)
- Diagnostic agents for use in vitro, except those listed in Rule 19.
- Others: corrective lenses, frames, stethoscopes for diagnosis, ocular occlusion patches, incise drapes, conductive gel, non-invasive electrodes, and amplifying image screens.

Rule 2 Products for channeling or storage for its eventual administration

- The following products are classified as **Class II**:
 - a. All non-invasive products, for channeling or storing blood, body fluids or tissues, liquids or gases for eventual infusion, administration or introduction into the body.



These include but are not limited to:

- Products used as conduits in active systems of administration (tubes to be used in infusion pumps)
 - Products used for channeling, antistatic tubes for anesthesia, circuits for the inhalation of anesthesia, pressure gauges, pressure relief products.
- b. Products that can be connected to an Active Medical Device Class II or higher, such as syringes for infusion pumps.
- c. Products that are used for storing or channeling of blood or other fluids or for the storage of organs or parts of organs or body tissues, including products for storage and transport of infectious hazardous biological waste.

These products include but are not limited to:

- Products for channeling blood in transfusions and extracorporeal circulation.
 - Products intended for temporary storage and transportation of organs for transplants.
 - Products intended for the prolonged storage of biological substances and tissues such as corneas, sperm and human embryos.
 - Bags or containers for the collection and disposal of infectious hazardous biological waste
- All other products are classified as **Class I**.

These include but are not limited to:

- Products that act using gravity as the driving force for liquid transport to carry out simple channeling functions (tubes used in gravity droppers for saline solution and drugs)
- Syringes without needles.

Rule 3 Products that modify the biological or chemical composition of blood, bodily fluids or of other liquids.



- All non-invasive devices intended to modify the biological or chemical composition of blood, body fluids or other liquids that are intended for introduction into the body are classified as **Class III**.

These include but are not limited to:

- Devices intended to remove undesirable substances from the blood via the exchange of dissolved substances, such as hemodialyzers.
- Products intended to separate cells.

Rule 4 Products that make contact with broken skin.

- Products that are intended primarily for use in wounds that have produced a dermal rupture and that will only heal by secondary intention are classified as **Class III**.

These include but are not limited to:

- Products intended for use in serious injuries involving a substantial and wide break of the dermis, where the healing process can only be achieved by secondary intention (dressings for very large chronic ulcers, dressings for severe burns with a disappearance of the dermis that affect a large area, dressings for bedsores)
- All non-invasive devices which come into contact with injured skin that are intended to be used as a mechanical barrier for compression or absorption of exudates are classified as **Class I**.

These include but are not limited to:

- Wound dressings, such as absorbent pads, insulating dressings, cotton wool, bandages and dressings designed to act as a barrier or maintain the position of the wound or its exudates.
- All other products, including those intended primarily to treat the microenvironment of a wound, are classified as **Class II**.

These include but are not limited to:



- Dressings that have the means to augment tissues, and that constitute a temporary skin substitute
- Products with specific properties that are intended to promote healing by controlling the wound moisture, temperature, oxygen levels, pH values or influencing the process through other physical means.
- Products that may have additional healing properties but are not intended for extensive wounds that require healing by secondary intention.
- Adhesives for topical use.
- Polymer film dressings, hydrogel dressings and gauze dressings impregnated without medicine.

Rule 5 Devices that are invasive with respect to the body orifices.

All products that are invasive with respect to the body orifices, other than surgically invasive devices, and that are not intended to be connected to an active product are classified as:

- **Class III**, if used for prolonged lengths of time, such as in the case of urethral stents.

- **Class II**:

- a. If the devices are used in the oral cavity up to the pharynx, the external ear canal to the eardrum or the nasal cavity, they cannot be absorbed by the mucous membrane and they are intended for short term use

These include but are not limited to:

- Tracheal tubes.
- Orthodontic wire, fixed dentures, fissure sealants.

- b. All devices that are invasive with respect to the body orifices, including those that are intended for connection to an Active Device of Class II or higher, except for invasive surgical products.

These include but are not limited to:

- Tracheostomy tubes, tracheal tubes connected to a respirator, blood oxygen analyzers located underneath the eyelid, electric nasal irrigators,



nasopharyngeal airways, heat and moisture exchangers, some enteral feeding tubes, optical fibers for surgical endoscopes that are connected to surgical lasers, suction catheters or tubes for gastric drainage.
- Contact lenses, urological catheters, stents.

- **Class I**

a. If they are used in the oral cavity up to the pharynx, the external ear canal to the eardrum or nasal cavity, and are intended for temporary use.

These include but are not limited to:

- Manual mirrors used in stomatology to aid diagnosis and dental surgery, dental impression material, gavage, enema products, examination gloves and balloon dilating prostatic catheters.
- Nosebleeds dressings, dentures that are removable by the patient.

Rule 6 Surgically invasive devices for temporary use.

- The following products are classified as **Class III**:

a. Products specifically intended to diagnose, monitor or correct a heart defect or defect of the Central Circulatory System, through direct contact with these body parts.

These include but are not limited to:

- Cardiovascular catheters, angioplasty, including related guides disposable cardiovascular surgical instruments for angioplasty.

b. Products intended to supply energy in the form of ionizing radiation.

These include but are not limited to:

- Tomography machines (CT scan)

c. Products intended to have a biological effect or to be largely or completely absorbed.



These include but are not limited to:

- Synthetic absorbable sutures and implants

d. Products intended to administer medicines by means of a delivery system if the way it is used is potentially hazardous, taking into account the mode of application

These include but are not limited to:

- Repeated self-application devices where dosage levels and the nature of the drug is critical, for example implantable insulin pumps.

- The following devices are classified as **Class II**: all surgically invasive devices intended for temporary use, except for reusable surgical instruments, which are classified as Class I.

These include but are not limited to:

- Suture needles, syringes, lancets, suction, single-use scalpels, aids in eye surgery, staplers, drills connected to active devices, surgical gloves.
- Scalpels, drills, saws that are not intended to be connected to an active product and forceps, retracting excavators and chisels.

Rule 7 Surgically invasive devices for short term use.

- Surgically invasive products for short-term use are classified as **Class III** if they are intended to:
 - a. Be used specifically in direct contact with the CNS, such as neurological catheters and cortical electrodes.
 - b. Supply energy in the form of ionizing radiation, such as brachytherapy products.
 - c. Have a biological effect or be absorbed entirely or largely on the body, such as absorbable sutures or implants and biological adhesives.
 - d. Undergo chemical change in the body or to administer medicines, except those products that are placed on the teeth.



e. Specifically to diagnose, monitor or correct a cardiac or central circulatory system defect through direct contact with these body parts, such as cardiovascular catheters, cardiac catheters and temporary pacemaker electrodes.

- All other surgically invasive devices intended for short term use are classified as **Class II**.

These include but are not limited to:

- Clamps, infusion cannulae, products for skin closure, temporary filling materials.

Rule 8 Surgically invasive devices for prolonged use and implantable products.

- Surgically invasive devices for prolonged use and implantable products are classified as **Class III** if they are intended to:

a. Have a biological effect or be absorbed entirely or largely on the body.

These include but are not limited to:

- Prosthetic joints, ligaments, anastomosis, stents, nails, plates, intraocular lenses, internal closure products, tissue augmentation implants, infusion pathways, peripheral vascular grafts, penile implants, non absorbable sutures, bone cements and maxillofacial implants, visco-elastic surgical products intended specifically for eye surgery.
- Absorbable Sutures
- Adhesive and implantable products presented as bioactive through the addition of surface coatings such as phosphocholine

b. Undergo chemical change inside the body or in the administration of drugs, except those products that are placed in the teeth, such as rechargeable systems for the release of non-active drugs.

c. Are used in direct contact with the heart, the SCC (central circulatory system) or the CNS, such as heart valves, clips or staples for aneurysms, vascular prostheses, spinal stents, vascular stents, CNS electrodes and cardiovascular sutures.



- Surgically invasive devices for prolonged use and implantable products are classified as **Class II** if they are intended to be placed in the teeth, such as bridges, crowns, dental filling and pin materials, dental alloys, ceramics and polymers.

Rule 9 Active therapeutic products intended to administer or exchange energy.

- The following active therapeutic products intended to administer or exchange energy are classified as **Class III**:
 - a. If their characteristics are such that they can administer or exchange energy in the human body in a potentially hazardous way, taking into account the nature, intensity and point of application of the energy.

These include but are not limited to:

- Products that administer or exchange kinetic energy, such as fans (respirators).
- Products that administer or exchange thermal energy, such as incubators for newborns, electric blankets for unconscious patients and blood warmers.
- Products that administer or exchange electric energy, such as high-frequency surgical electric generators, electro cauteries, external pacemakers, external defibrillators, electroconvulsive therapy equipment.
- Products that administer or exchange coherent energy, such as surgical lasers.
- Products that administer or exchange ionizing radiation, such as radioactive sources for afterload therapy, therapeutic cyclotrons, linear accelerators, therapeutic X-ray sources.
- Lithotripters.

- b. All active products intended to control the operation of Class III active therapeutic products or intended to directly influence the operation of these products.

These include but are not limited to:

- External feedback systems for active therapeutic devices, afterload control products.



- All other therapeutic products intended to administer or exchange energy are classified as **Class II**.

These include but are not limited to:

- Products intended to administer or exchange electrical, magnetic and electromagnetic energy, such as muscle stimulators and external bone growth stimulators, ocular magnets and hyperbaric chambers.
- Products intended to administer or exchange thermal energy, such as electric blankets, except for unconscious patients; cryosurgery equipment.
- Products intended to administer or exchange mechanical energy, such as electrical dermatomes, electric drills and dental hand pieces.
- Products intended to administer or exchange light, such as light therapy for the treatment of skin or for neonatal care.
- Products intended to administer or exchange sound, such as ultrasound therapeutic machines, hearing aids.

Rule 10 Active products for diagnosis.

- Active devices for diagnosis are classified as **Class III** if they are intended:
 - a. Specifically for the monitoring of vital physiological parameters, when the variations of those parameters may pose an immediate danger to the patient's life, such as variations in cardiac function, respiration and activity of the CNS.

These include but are not limited to:

- Monitoring systems for intensive care, biosensors, gas blood analyzers used in open heart surgery, cardioscopes and apnea monitors, including for home care.
- b. To emit ionizing radiation and that are intended for use in radiology for diagnostic purposes, including those which control or monitor such devices, or which directly influence the functioning of the same, such as X-ray sources for diagnosis or hearing aids.



- Active devices intended for diagnostic purposes are classified as **Class II** if they are intended:
 - a. To supply energy that will be absorbed by the human body, except for devices whose function is the illumination of the patient's body in the visible spectrum.

These include but are not limited to:

- MRI equipment
- Dental pulp examiners
- Stimulators for recalled response
- Diagnostic equipment for ultrasound.

- b. Create a live picture of the distribution of radiopharmaceuticals.

These include but are not limited to:

- Gamma cameras, tomography for positron emission and computed tomography with single photon emission.

- c. To allow direct diagnosis or monitoring of vital physiological processes.

These include but are not limited to:

- Electrocardiographs, EEG, cardioscopes with or without heart rate indicators.

Rule 11 Active products to deliver drugs and other substances to the body, or to eliminate them from it.

- Active products are **Class III** if they are intended to administer medicines and other substances to the body or to eliminate them in a potentially hazardous way, taking into account the nature of the substances, the body part in question and the mode of application.

These include but are not limited to:



- Infusion pumps, respirators (ventilators), anesthesia machines, anesthesia vaporizers, dialysis equipment, blood pumps for cardiopulmonary machines, pressure regulators for medical gases.
- All other active devices intended to administer medicines, body fluids or other substances into the body or eliminate them from the system are classified as **Class II**.

These include but are not limited to:

- Suction equipment, food pumps, micro infusers and insulin pens.

Rule 12 All other active products

- All other active devices are classified as **Class I**, such as:
 - a. Active diagnostic products intended to illuminate the patient's body within the visible spectrum.

These include but are not limited to:

- Lights used for recognition or to optimally display the body such as: surgical microscopes.

- b. Products that are generally intended for the external support of the patient.

These include but are not limited to:

- Hospital beds, patient lifts, walkers, wheelchairs, stretchers, dental chairs.

- c. Active diagnostic products intended for thermography
- d. Active products intended to record, process or display diagnostic images
- e. Dental lights

Rule 13 Products incorporating a drug (medication)



- All devices that include as an integral part a substance that if it is used separately can be considered a drug, and that can exercise on the human body an action that is secondary or additional to that of the medical device, are classified as **Class III**.

These include but are not limited to:

- Antibiotic bone cement, medicated dressings, catheters coated with heparin, endodontic materials with antibiotics, medicated stents.

Rule 14 Products used for contraception or prevention of sexually transmitted diseases.

- All products used for contraception that are implantable or are invasive devices for prolonged use, such as intrauterine devices (IUDs), are classified as **Class III**.
- All devices used for contraception or for the prevention of sexually transmitted diseases, such as condoms and diaphragms, are classified as **Class II**

Rule 15 Products specifically for disinfection, cleaning and rinsing.

- All products for disinfection, cleaning, rinsing or for moisturizing contact lenses, such as contact lens solutions and conditioning solutions, and sterilizers specifically intended to sterilize medical devices in a medical environment, are classified as **Class II**.
- All products intended specifically for disinfecting medical instruments are classified as **Class I**.

These include but are not limited to:

- Specifically targeted disinfectants, for example endoscopes

This rule does not apply to products that are intended to clean through physical action any medical devices other than contact lenses.

Rule 16 Non-active products for recording diagnostic X-Ray images.

- Non-active products that are specifically intended for recording radiographic diagnostic images.



These include but are not limited to:

- X-ray films and photo stimulating phosphate plates

Rule 17 Products that use animal tissues or their derivatives.

- All devices manufactured utilizing animal tissues or derivatives thereof which have been rendered non-viable and that may come into contact with the human body for prolonged time periods, are included in **Class III**, except in the case that the products are intended to come in contact only with intact skin.

These include but are not limited to:

- Biological heart valves
- Dressings with porcine xenografts
- Catgut sutures
- Collagen implants and dressings

Rule 18 Blood Bags.

- Notwithstanding other rules, blood bags, including those with an anticoagulant, are included in **Class III**.

In the event that the blood bags have a function that goes beyond the simple purpose of storage and includes systems of preservation distinct from that of the anticoagulants, other rules may apply.

Rule 19 Diagnostic agents for the diagnosis of HIV-AIDS, Hepatitis C and superficial antigens of Hepatitis B.

- Notwithstanding other rules, diagnostic agents for the diagnosis of HIV-AIDS hepatitis C and Hepatitis B surface antigens are included in **Class II**.

Rule 20 Hygienic Products.

- Notwithstanding other rules, the following sanitary products are classified as **Class I** if they are:



- a. Used in the oral cavity up to the pharynx, in the external ear canal up to the eardrum, in the nasal or vaginal cavity and are not absorbed by the mucous membrane, and which are considered non-invasive

These include but are not limited to:

- Toothpaste
- Mouthwash
- Whitening Solutions

- b. For external use or if they only enter into contact with intact skin, such as dandruff shampoos, dandruff rinses, anti-wrinkle creams, antibacterial soaps.