

Registration of Products – Healthcare Products

LIST OF PRODUCTS NOT DEEMED AS HEALTHCARE PRODUCTS

(Updated on October 26th. 2016)

CATEGORY 1: Products used for assessment, design, manufacture or preparation of products

- 1 Dental amalgamator
- 2 Equipment for making prostheses
- 3 Equipment for making eyeglass lenses
- 4 Fractionating device, doser or mixer of solutions and drugs
- 5 Barcode scanner
- 6 Machine for manufacturing pills
- 7 Material for exclusive laboratory use for making prostheses that do not have contact with the patient
- 8 Measuring instrument for assessing eyeglass lenses (lensmeter) or eyeglass frames
- 9 Sealer of healthcare product packaging

CATEGORY 2: Products for general laboratory activity support

- 1 Microtome blade sharpener
- 2 Solution shaker
- 3 Laboratory shaker/agitator, except those intended for use with blood and its derivatives
- 4 Distilled water
- 5 Platinum inoculation loop for microbiology
- 6 Water analyzer
- 7 Dissolution analyzer for pills and capsules
- 8 Particle size analyzer
- 9 Karl Fischer equipment, except those intended for clinical diagnosis (IVD)
- 10 Equipment for food analysis
- 11 Equipment for determining friability of samples
- 12 Electrophoresis equipment, except those intended for clinical diagnosis (IVD)
- 13 Equipment for pyrogenic test in subjects
- 14 Portable equipment for water treatment, except those intended for water purification in hemodialysis.
- 15 Laboratory heater
- 16 Laboratory plastic or glassware without reagent, except biological sample collectors or collection containers (IVD)
- 17 Autoclave, except those intended for sterilization of medical devices
- 18 Laboratory scale
- 19 Histology bath
- 20 Bain marie, except those for implants and blood bags.
- 21 Calorimeter, except those for health diagnosis.
- 22 Anaerobic chamber
- 23 Laminar flow hood, except those intended for healthcare laboratory use (e.g.: hood for handling organs and tissues for transplantation).
- 23.1 Hood or cabinet intended for the preparation of supplies, drugs or chemotherapeutic substances.
- 24 Centrifuge, except those intended for use in clinical laboratory (IVD).
- 24.1 Centrifuge, except those intended for use in blood banks.
- 25 Emergency shower and eyewash station
- 26 Colorimeter, except those intended for clinical diagnosis (IVD)
- 27 Conductivity meter, except those intended for health diagnosis
- 28 Cell or colony counter, except those intended for clinical diagnosis (IVD)
- 29 Atomic particle counter, except those intended for health diagnosis
- 30 Slide stainer for microscopy, except those intended for use in clinical laboratory (IVD)
- 31 Dye or solution to prepare samples or substances, except those intended for clinical diagnosis (IVD).
- 32 Cryostat, except those intended for clinical diagnosis (IVD).
- 33 Chromatography, except those intended for clinical diagnosis (IVD).
- 34 Chronometer for measuring the time of reactions.
- 35 Densitometer, except those intended for clinical diagnosis (IVD)
- 36 Digester

- 37 Sample diluter
- 38 Automatic dispenser (to fill flasks and tubes)
- 39 Paraffin wax dispenser/remover for histology
- 40 Device for opening or sealing objects
- 41 Equipment for management of samples
- 42 Personal protective equipment for exclusive laboratory use.
- 43 Spectrophotometer, except those intended for clinical diagnosis (IVD).
- 44 Spectrometer, except those intended for clinical diagnosis (IVD).
- 45 Stove, except those for sterilization of medical devices and products intended for beautification or aesthetic purposes
- 46 Centrifugal vacuum evaporator
- 47 Culture fermenter
- 48 Filter for solutions
- 49 Muffle furnace
- 50 Flame photometer
- 51 Solution homogenizer, except those intended for blood and its derivatives
- 52 Glass slide and cassette printer.
- 53 Incubator, except those intended for clinical diagnosis (IVD)
- 54 Indicator of sedimentation rate of solutions
- 55 Physical, chemical or biological indicator.
- 56 Labware washer, except the washers that disinfect medical devices.
- 56.1 Labware washer, except microplate washers and washers intended for immunological tests (IVD).
- 57 Fluorescence reader, except those intended for clinical diagnosis (IVD).
- 58 Tissue for skin asepsis
- 59 Freeze dryer
- 60 Lux meter
- 61 Instrument for measuring dissolved oxygen in samples
- 62 pH meter, except those intended for clinical diagnosis (IVD)
- 63 Melting point meter
- 64 Microscope, except those intended for medical or dental procedures
- 65 Microtome for histology, except those intended for clinical diagnosis (IVD)
- 66 Laboratory furniture
- 67 Solid sample mill
- 68 Bacterial growth monitor, except those intended for clinical diagnosis (IVD)
- 69 Automated glass coverslipper.
- 70 Knives for microtomes and cryostats
- 71 Osmometer, except those intended for clinical diagnosis (IVD)
- 72 Automatic pipette
- 73 Manual micropipette or pipette
- 74 Heated/Freeze plate for histology
- 75 Cotton holder
- 76 Paper holder
- 77 DNA processing equipment, except those intended for clinical diagnosis (IVD)
- 78 Tissue processor for histology, except those intended for use in clinical laboratory (IVD)
- 79 Product for testing solutions of non-diagnostic application
- 80 Radiometer, except those intended for use in phototherapy equipment
- 81 Container for disposal of organic waste (trash)
- 82 Refractometer, except those intended for health diagnosis
- 83 Sealing machine for the packaging of laboratory items
- 84 Support for laboratory items
- 85 Timer
- 86 Titration system
- 87 Viscometer, except those intended for clinical diagnosis (IVD)

CATEGORY 3: Products used for hospital support or infrastructure

- 1 Equipment for environmental treatment or air conditioning
 - 1.1 – Air conditioners
 - 1.2 – Air purifier

- 1.3 – Air sterilizer
- 1.4 – Air humidifier
- 2 Bucket
- 3 Tray, except those for sterilization
- 4 Room divider
- 4.1 Folding screen
- 5 Vacuum pump
- 6 Boiler
- 7 Compressed air system
- 8 Medical gas system
- 9 Vacuum system
- 10 Air compressor
- 11 Oxygen concentrator, except those for personal use
- 12 Foam cutter for making molds
- 13 Device for opening medical devices
- 14 Equipment for packaging or transportation of products
- 14.1 - Emergency cart (transportation of drugs, equipment and instruments for medical procedures), except those that have a panel with electrical, hydraulic, or gas connections for medical devices.
- 15 Laundry equipment
- 16 Stepladder for patients, except those intended for therapy
- 17 Brush for cleaning products in general
- 18 Brush for surgical cleaning and asepsis without antimicrobial agents.
- 19 Medical waste sterilizer, except those intended for use in the place of health procedure
- 20 Oven for cooking food
- 21 Gel for absorption of organic waste
- 22 Fridge and freezer for general use (except those intended for storage of vaccines, blood bags, tissues and organs)
- 23 Steam generator
- 24 Incinerator for medical waste
- 25 Physical, chemical or biological indicator.
- 26 Table, chair or another support with no indication, intended for the assistance in medical or dental procedures
- 26.1 – Dental or surgical saddle chair
- 26.2 – Waiting chairs
- 26.3 – Furniture for office/clinics (tables, chairs, cabinets, and others).
- 26.4 – Mayo table (support for surgical instruments)
- 26.5 – Nightstand
- 26.6 – Necropsy table
- 27 X-ray view box
- 28 Toilet paper
- 29 Hospital sink
- 30 Earplug
- 31 Portable water purifier, except those intended for water purification to be used in hemodialysis
- 32 Container non-affixed to the body for collection of organic waste
- 33 Container for collection or packaging of products in general
- 34 Temperature and humidity recorder (thermo-hygrograph)
- 35 Bed sheets, except those intended for disposable hospital use
- 36 Medical air dryer
- 37 Sealing machine for the packaging of medical devices
- 38 Hospital communication system
- 39 Hospital signage system

CATEGORY 4: Products for medical teaching or training

- 1 Medical training manikin
- 2 Anatomical model for teaching purposes

3 Simulator of physiological functions for teaching purposes

CATEGORY 5: Products for collective health prevention

- 1 Pest control trap
- 2 Pesticide sprayer
- 3 Instrument for the elimination of parasites and insects
- 4 Container for the storage of corpses

CATEGORY 6: Products for physical conditioning or sporting activities

- 1 Exercise bar
- 2 Ball
- 3 Wheelchair and bicycle for handicapped people for use in sporting activities and competitions.
- 4 Chronometer
- 4.1 Training watch
- 5 Darts
- 6 Adhesive nasal dilator
- 7 Disc
- 8 Equipment intended for physical conditioning
- 8.1 – Ergometric bicycle (except those intended for medical diagnosis)
- 8.2 – Dumbbells
- 8.3 – Workout stations
- 8.4 – Rowing machine
- 8.5 – Ab workout machine
- 8.6 – Ergometric treadmill (except those intended for medical diagnosis)
- 9 Massage table or chair
- 10 Exclusive equipment for gyms or home use. (Except electrical muscle stimulators and tanning beds)
- 11 Pedometer (step/distance counter)
- 12 Non-orthopedic protector of body parts
- 13 Exercise platform (except those intended for physiotherapy)
- 14 Pole for pole vaulting

CATEGORY 7: Products for personal or home use

- 1 Sanitary napkin
- 2 Nail clipper
- 3 Equipment for environmental treatment or air conditioning
- 3.1 – Air conditioners
- 3.2 – Air purifier
- 3.3 – Air sterilizer
- 3.4 – Air humidifier
- 4 Scales
- 5 Shaver
- 6 Walking stick or other support of non-orthopedic use
- 7 Pacifier
- 8 Toothbrush
- 9 Hairbrush
- 10 Skin cleansing sponge
- 11 Dental floss
- 12 Disposable blade, except those intended for health procedures
- 13 Zoom lens
- 14 Tongue cleaner
- 15 Baby bottle and nipple
- 16 Covers and blankets without therapeutic indications
- 17 Gum massager
- 18 Muscle massager (pillows, chairs, seats, mattresses, etc) without therapeutic indications
- 19 Teether for breastfeeding babies
- 20 Presbyopic glasses
- 21 Dental floss threader
- 22 Product for sexual arousal
- 23 Erotic products not intended for health use
- 24 Water purifier
- 25 Sauna
- 26 Hair dryer and hairbrush

CATEGORY 8: Products for general use used as parts or accessories of healthcare products

- 1 Camera for general use
- 2 IT equipment for general use
- 3 Common photographic film for general use
- 4 Film fixer or film developer
- 5 Image recorder
- 6 Printer
- 7 Monitor
- 8 Lubricant oil
- 9 Thermosensitive paper, except those intended for medical image or signal recording

CATEGORY 9: Parts and accessories of products not deemed as healthcare products

CATEGORY 10: Products used in laboratories

- 1 Laboratory glassware, material and instruments for general use (pipettes, pipette tips, graduated cylinders, test tubes, coverslips, slides, cell counting chambers, petri dishes, etc.)
- 2 Isolated chemical reagents that have no specific purpose for *in vitro* diagnostic (acid/alkaline solutions, alcohols, pH indicators) and other reagents that are not directly related or comprise an IVD kit.
- 3 Culture medium and products not intended for human diagnosis (scientific research, veterinary use, water control, environmental control, drug or food control, industrial analysis, among others)
- 4 Culture medium in form of dried powders and supplements to enrich media and other unfinished products that require processing and controls performed by the user.
- 5 Biological indicators.
- 6 Reagents and reference materials specifically intended for quality assessment in proficiency tests or interlaboratory comparison.
- 7 Reagents or set of reagents assembled in clinical analysis laboratories to be exclusively used in the same institution, according to the defined work-related protocols, for which commercialization or donation is prohibited.
- 8 Laboratory reagents not intended for the diagnosis in human sample.
- 9 Products exclusively intended for sports doping control tests, the result of which will not be used for the purpose of health treatment.
- 10 Products intended for research use only, including those imported and labeled as RUO – Research Use Only.
- 11 Gas generators and anaerobic indicators
- 12 Reagents commercialized as supplies for the manufacturing of *in vitro* diagnostic products and in intermediate production stage;
- 13 Products intended for exclusive use in legal medicine (report and police investigation);
- 14 Products used exclusively by technicians of the manufacturer of IVD instruments in cleaning and maintenance procedures that are not commercialized or made available to the market, such as calibration plates, calibration standard for a specific test, cleaning and maintenance solutions, etc.