**Registration of Products – Healthcare Products**

**LIST OF PRODUCTS NOT DEEMED AS HEALTHCARE PRODUCTS**
(Updated on October 26th, 2016)

<table>
<thead>
<tr>
<th>CATEGORY 1: Products used for assessment, design, manufacture or preparation of products</th>
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<tbody>
<tr>
<td>1 Dental amalgamator</td>
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<tr>
<td>2 Equipment for making prostheses</td>
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<tr>
<td>3 Equipment for making eyeglass lenses</td>
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<tr>
<td>4 Fractionating device, doser or mixer of solutions and drugs</td>
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<td>5 Barcode scanner</td>
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<td>6 Machine for manufacturing pills</td>
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<td>7 Material for exclusive laboratory use for making prostheses that do not have contact with the patient</td>
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<tr>
<td>8 Measuring instrument for assessing eyeglass lenses (lensmeter) or eyeglass frames</td>
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<td>9 Sealer of healthcare product packaging</td>
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<tr>
<th>CATEGORY 2: Products for general laboratory activity support</th>
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<tr>
<td>1 Microtome blade sharpeners</td>
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<td>2 Solution shaker</td>
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<tr>
<td>3 Laboratory shaker/agitator, except those intended for use with blood and its derivatives</td>
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<td>4 Distilled water</td>
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<td>5 Platinum inoculation loop for microbiology</td>
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<td>6 Water analyzer</td>
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<tr>
<td>7 Dissolution analyzer for pills and capsules</td>
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<td>8 Particle size analyzer</td>
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<td>9 Karl Fischer equipment, except those intended for clinical diagnosis (IVD)</td>
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<td>10 Equipment for food analysis</td>
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<td>11 Equipment for determining friability of samples</td>
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<td>12 Electrophoresis equipment, except those intended for clinical diagnosis (IVD)</td>
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<td>13 Equipment for pyrogenic test in subjects</td>
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<td>14 Portable equipment for water treatment, except those intended for water purification in hemodialysis.</td>
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<td>15 Laboratory heater</td>
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<tr>
<td>16 Laboratory plastic or glassware without reagent, except biological sample collectors or collection containers (IVD)</td>
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<td>17 Autoclave, except those intended for sterilization of medical devices</td>
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<td>18 Laboratory scale</td>
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<td>19 Histology bath</td>
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<td>20 Bain marie, except those for implants and blood bags.</td>
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<td>21 Calorimeter, except those for health diagnosis.</td>
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<td>22 Anaerobic chamber</td>
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<tr>
<td>23 Laminar flow hood, except those intended for healthcare laboratory use (e.g.: hood for handling organs and tissues for transplantation).</td>
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<tr>
<td>23.1 Hood or cabinet intended for the preparation of supplies, drugs or chemotherapeutic substances.</td>
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<tr>
<td>24 Centrifuge, except those intended for use in clinical laboratory (IVD).</td>
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<tr>
<td>24.1 Centrifuge, except those intended for use in blood banks.</td>
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<tr>
<td>25 Emergency shower and eyewash station</td>
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<td>26 Colorimeter, except those intended for clinical diagnosis (IVD)</td>
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<td>27 Conductivity meter, except those intended for health diagnosis</td>
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<td>28 Cell or colony counter, except those intended for clinical diagnosis (IVD)</td>
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<tr>
<td>29 Atomic particle counter, except those intended for health diagnosis</td>
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<tr>
<td>30 Slide stainer for microscopy, except those intended for use in clinical laboratory (IVD)</td>
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<tr>
<td>31 Dye or solution to prepare samples or substances, except those intended for clinical diagnosis (IVD).</td>
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<td>32 Cryostat, except those intended for clinical diagnosis (IVD).</td>
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<td>33 Chromatography, except those intended for clinical diagnosis (IVD).</td>
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<tr>
<td>34 Chronometer for measuring the time of reactions.</td>
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<td>35 Densitometer, except those intended for clinical diagnosis (IVD)</td>
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<td>36 Digester</td>
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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 purifie
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.