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NORMATIVE INSTRUCTION - IN Nº 101, OF AUGUST 30, 2021

Establishes the specific criteria for the grouping into families of materials for use in health for the purposes of registration and notification.

The Collegiate Board of the National Health Surveillance Agency, in the use of the powers conferred on it by articles 7, item III, and 15, items III and IV, of Law No. 9,782, of January 26, 1999, and considering the provisions of article 53, item VII and §§ 1 and 3, of the Internal Regulations, approved by the Resolution of the Collegiate Board of Directors - RDC No. 255, of December 10, 2018, resolves to adopt the following Normative Instruction, as resolved at a meeting held on August 30, 2021, and I, the Chief Executive Officer, determine its publication:

Art. 1 The specific criteria for the grouping in families of materials for use in health for registration and registration purposes, contained in the Annex to this Normative Instruction, are approved.

Art. 2 The families of materials for use in health with specific criteria must meet the following general rules:

I - the products must belong to the same manufacturer or manufacturing group, have the same instructions for storage, contraindications, adverse effects, precautions, restrictions, warnings and special care;

II - sterile and non-sterile products may not be grouped in the same family;

III - products whose manufacturer recommends single use and products that can be reprocessed may not be grouped in the same family;

IV - prohibited reprocessing products and reprocessed products may not be grouped into the same family;

V - Registration in the set or system family will not be allowed.

Art. 3 The products that are not contemplated in normative instruction regarding specific criteria for family grouping must follow the general criteria established in the Resolution of Collegiate Board of Directors - RDC No. 546, of August 30, 2021, or to replace it, or in specific technical regulation.

Art. 4 The examples of families set forth in the Annex to this Normative Instruction are merely indicative and do not form an exhaustive list that includes all possible families.

Article 5 The following are revoked:

I - Normative Instruction - IN No. 6, of November 18, 2011, published in the Official Gazette No. 222, of November 21, 2011; and

II - Normative Instruction - IN No. 13, of November 8, 2016, published in the Official Gazette No. 215, of November 9, 2016.

Art. 6 This Normative Instruction enters into force on October 1, 2021.

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SPECIFIC CRITERIA FOR FAMILING MATERIALS INTO FAMILIES HEALTH USE FOR REGISTRATION AND REGISTRATION PURPOSES

1. Equipment
1.1. Teams with one or more can remain in the same family.
copies, provided they are in accordance with the other criteria established below
1.2. Feedstock
1.2.1. The raw material of the main pipe must be the same for all the models.
1.2.2. Presence of latex
1.2.2.1. with latex
1.2.2.2. latex free
1.2.3. Presence of DEHP (DOP)
1.2.3.1. PVC with DEHP (DOP)
1.2.3.2. PVC without DEHP (DOP)
1.3. Mechanism of action
1.3.1. Gravitational
1.3.2. Infusion bomb
1.4. indication of use
1.4.1. Blood and blood products
1.4.2. Photosensitive solutions and drugs
1.4.3. Non-photosensitive solutions and drugs
1.4.4. enteral nutrition
1.4.5. arterial hemodialysis
1.4.6. venous hemodialysis
1.4.7. Peritoneal dialysis
1.4.8. central venous pressure
1.4.9. irrigation equipment
1.4.10. mean arterial pressure
1.5. Examples of application of the specific criteria for family of equipment:
1.5.1. Family of equipment with main PVC tube, Gravitational, for Blood, with latex
1.5.2. Family of equipment with PVC main tube with DEHP (DOP), Gravitational, for Medicines and Solutions, photosensitive, with latex
1.5.3. Family of equipment with PVC main tube without DEHP (DOP), Gravitational, for Medicines and Solutions, photosensitive, with latex
1.5.4. Family of equipment with polyurethane main tube, Gravitational, for Medicines and Solutions, photosensitive, with latex
1.5.5. Family of equipment with polyurethane main tube, Gravitational, for Medicines and Solutions, photosensitive, latex-free
1.5.6. Family of equipment with PVC main tube with DEHP (DOP), Gravitational, for Enteral Nutrition
1.5.7. Family of equipment with main PVC tube with DEHP (DOP), for infusion pump, for Medicines and Solutions, non-photosensitive, latex-free
1.5.8. Family of equipment with main PVC tube with DEHP (DOP), for infusion pump, for Enteral Nutrition, with latex
1.5.9. Family of lines for arterial hemodialysis, with main tube of DEHP-free PVC (DOP), with latex
1.5.10. Family of lines for venous hemodialysis, with main tube of DEHP-free PVC (DOP), with latex
2. Heart valves
They follow the general criteria established in the regulation, with the following remarks:
2.1.1. Biological valves with and without support can be included in the
same family. However, the raw material of the valves and supports must be the
same.

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2.1.2. The single-use and exclusive-use auxiliary instruments for heart valve implantation may be part of this family
2.2. Examples of application of the specific criteria for families of Heart valves:
2.3. Family of mechanical mitral valves with and without support
2.4. Aortic Mechanical valve family with and without support
2.5. Family of biological valves (porcine) Mitral with and without support
2.6. Family of biological valves (porcine) Aortic with and without support
2.7. Family of Biological valves (Bovine) Mitral with and without support
2.8. Biological valve family (Bovine) Aortic with and without support
3. Immobilizers
3.1. indication of use
3.1.1. orthopedic immobilization
3.1.2. Voltage
3.2. Examples of application of the specific criteria for families of immobilizers:
3.2.1. Family of Orthopedic Immobilizers (boots, rails, splints, vests, neck brace)
3.2.2. Family of Tensors (wristband, thigh pad, knee pad, elbow pad, straps, slings)
4. Male Condoms
They follow the general criteria established in the regulation, with the following remarks:
4.1. surface type
4.1.1. Lisa
4.1.2. textured
4.2. Each additive, whether lubricant, spermicide, retardant or other, must compose a distinct family. With the exception of flavor, color and aroma variations that do not characterize family and are considered commercial presentations.
4.3. Examples of application of specific criteria for families of Male condoms:
4.3.1. Family of latex condoms, with latex oil lubricant silicone, without spermicide, without retardant
4.3.2. Family of latex condoms, with latex oil lubricant silicone, with nonoxynol-9 spermicide, with Benzocaine retardant
4.3.3. Family of latex condoms, with latex oil lubricant silicone, without spermicide, with retardant Benzocaine
4.3.4. Latex condom family, no lubricant, no spermicide, without retardant
4.3.5. Family of latex condoms, with latex oil lubricant silicone, with nonoxynol-9 spermicide, without retardant
5. Instruments for medical and dental use:
5.1. connection to equipment:
5.1.1. with connection to equipment;
5.1.2. without connection to equipment.
5.2. insert presence:
5.2.1. with insert:
5.2.1.1. tungsten carbide (Video);
5.2.1.2. pottery;
5.2.1.3. Diamond.
5.2.2. without insert.
5.3. feedstock:
5.3.1. the raw material of the part that comes into contact with the patient must be the same for all models.
5.4. articulated, non-articulated, cutting and non-cutting instruments all of them may be grouped into the same family, as long as the criteria for reusable instruments for medical and dental use are observed.
5.5. Note: The specific indication for use must be mentioned for each model.
6. Trocars
6.1. Feedstock

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6.1.1. The parts may have different raw material. However, the materials raw materials for these parts cannot vary between models in the family.
6.2. presence of valve
6.2.1. with valve
6.2.2. without valve
6.3. dismountable
6.4. not collapsible
6.5. Examples of application of specific criteria for families of trocars
6.5.1. Family of removable trocars, with valve, that the manufacturer recommend single use
6.5.2. Family of detachable trocars, with valve, capable of reprocessing
6.5.3. Family of detachable trocars, without valve, capable of reprocessing
6.5.4. Family of non-removable trocars, with valve, of prohibited reprocessing
6.5.5. Family of non-removable trocars, without valve, capable of reprocessing
7. LAL
7.1. Mechanism of action:
7.1.1. Different application methods should be part of families different.
7.2. Manufacturing technology:
7.2.1. Different degrees of sensitivity can be grouped in the same family.
7.3. Examples of application of the specific criteria for LAL
7.3.1. Turbidimetric LAL family
7.3.2. Colorimetric LAL family
7.3.3. LAL gel-clot family
8. Devices for support and adaptability for use with collectors of ostomy
8.1. Protective plate, Belt, Belt holder, Rings, Clips Closing devices, Convexity devices, Ostoma occluders, Protective barriers, Filters, Filter adhesives, Sealing devices may be part of the same product family.
9. Hypodermic syringes:
They follow the general criteria established in the regulation, with the following remarks:
9.1. Safety device
9.1.1. No safety device
9.1.2. With safety device
9.1.2.1. Can syringes with different security devices;
9.2. Syringes with or without syringes can remain in the same family.anti-reuse device
9.3. Luer lock glass syringes can remain in the same family and luer slip
9.4. Insulin syringes and other hypodermic syringes
9.5. presence of needle
9.5.1. with needle
9.5.2. without needle
9.6. Insulin syringes with needle
9.6.1. with dead space
9.6.2. no dead space
9.7. Examples of application of specific criteria for families of hypodermic syringes:
9.7.1. Family of polyethylene hypodermic syringes, with safety, with needle, with or without anti-reuse device
9.7.2. Polyethylene hypodermic syringe family, without device safety, with needle, with or without anti-reuse device
9.7.3. Polyethylene hypodermic syringe family, without needle, with or without anti-reuse device
9.7.4. Family of polyethylene insulin syringes, with safety, with needle, without dead space, with or without anti-reuse device
9.7.5. Family of polyethylene insulin syringes, with safety, with dead space needle, with or without anti-reuse device

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9.7.6. Polyethylene insulin syringe family without device safety, with needle, with dead space, with or without anti-reuse device
9.7.7. Polyethylene insulin syringe family, without needle, with or without anti-reuse device
10. Hypodermic needles
They follow the general criteria established in the regulation, with the following remarks:
10.1. Safety device
10.1.1. No safety device
10.1.2. With safety device
10.1.2.1. Needles can remain in the same family with different security devices;
10.2. Needles with or without needles can remain in the same family. anti-reuse device
10.3. Examples of application of specific criteria for families of hypodermic needles:
10.3.1. Family of hypodermic needles without safety device with or without anti-reuse device
10.3.2. Family of hypodermic needles with safety device with or without anti-reuse device
11. Needles for vacuum blood collection
11.1. Presence of latex
11.1.1. with latex
11.1.2. latex free
11.2. Safety device
11.2.1. No safety device
11.2.2. With safety device
11.2.2.1. Needles can remain in the same family with different security devices;
11.3. Needles with or without needles can remain in the same family. anti-reuse device
11.4. Needles with or without needles can remain in the same family. holder
11.5. Examples of application of specific criteria for families of needles for vacuum blood collection:
11.5.1. Family of vacuum blood collection needles, without device security, with or without anti-reuse device, with or without holder
11.5.2. Family of vacuum blood collection needles with device security, with or without anti-reuse device, with or without holder
12. Needles for regional anesthesia
They follow the general criteria established in the regulation, with the following remarks:
12.1. Anesthesia needles can remain in the same family epidural and spinal
12.2. Safety device
12.2.1. No safety device
12.2.2. With safety device
12.2.2.1. Needles can remain in the same family with different security devices;
12.3. Needles with or without needles can remain in the same family. anti-reuse device
12.4. Examples of application of specific criteria for families of needles for regional anesthesia:
12.4.1. Needle family for regional epidural and spinal anaesthesia, without safety device, with or without anti-reuse device
12.4.2. Needle family for regional epidural and spinal anaesthesia, with safety device, with or without anti-reuse device
13. Catheters
They follow the general criteria established in the regulation, with the following remarks:
13.1. Catheters with one or more can remain in the same family. more ways
13.2. Safety device
13.2.1. No safety device
13.2.2. With safety device
13.2.2.1. Catheters with different security devices;
13.3. Catheters with or without catheters can remain in the same family. anti-reuse device

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13.4. Catheters with or without catheters can remain in the same family. exclusive use introducers
13.4.1. The exclusive use introducer can be considered a piece of replacement
13.5. Examples of application of specific criteria for families of catheters:
13.5.1. Family of peripheral intravenous catheters, polyurethane, without latex, with safety device, with or without anti-reuse device
13.5.2. Family of peripherally inserted central venous catheters, from polyurethane, with stainless steel guide wire, latex-free, with safety device, with or without anti-reuse device, with or without introducers
14. Scalps
They follow the general criteria established in the regulation, with the following observation:
14.1. Safety device
14.1.1. No safety device
14.1.2. With safety device
14.1.2.1. Can scalps with different security devices;
14.2. Scalps with or without anti-reuse device
14.3. Scalps for infusion and blood collection
14.4. Examples of application of specific criteria for families of scalps:
14.4.1. Family of scalps without safety device, with or without anti-reuse device, for infusion and blood collection
14.4.2. Family of scalps with safety device, with or without anti-reuse device, for infusion and blood collection
15. Lancets
15.1. Mechanism of action
15.1.1. for manual use
15.1.2. For use with lancet
15.2. Examples of application of the specific criteria for families of lancets:
15.2.1. Family of lancets for manual use
15.2.2. Family of lancets for use with a lancing device
16. External prosthesis components
16.1. anatomical position
16.1.1. Upper limbs
16.1.2. Lower members
16.2. Examples of application of specific criteria for families of external denture components
16.2.1. Family of External Limb Prosthesis Components superiors
16.2.2. Family of External Limb Prosthesis Components lower
17. Components for invasive orthodontics
They follow the general criteria established in the regulation, with the following remarks:
17.1. Bands, tubes, brackets, lingual buttons, molar distalizer.
17.2. They can be part of the family of bands, tubes, brackets, buttons lingual teeth, molar distalizers as accessories, brackets and tubes.
17.3. Wires, arcs and springs can be in the same family.
17.4. They can be part of the family of wires, bows and springs as accessories
stops for archwires, hooks, gurin, Bimler shield orthodontic tube and equiplan.
17.5. Expanders form a family following the general criteria.
17.6. Examples of application of specific criteria for Components for orthodontics:
17.6.1. Family of bands, tubes, brackets, lingual buttons, gurin, stainless steel molar distalizer;
17.6.2. Family of porcelain brackets with adhesive;
17.6.3. Adhesive-free porcelain bracket family;
17.6.4. Family of stainless steel brackets with adhesive;

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17.6.5. Family of bands, tubes, brackets, lingual buttons, distalizer Nitinol molars;
17.6.6. Family of stainless steel wires, arches and springs;
17.6.7. Family of Nitinol wires, bows and springs;
17.6.8. Family of stainless steel expanders.
18. Auxiliary components for non-invasive orthodontics
18.1. They can be part of the same family: cervical pillows, splints, cervical elastics, caps, tractors and chin cup (chin guard).
19. Acrylic resins
19.1. polymerization mode
19.1.1. thermoactivated
19.1.2. self-curing
19.1.3. photopolymerizable
19.1.4. dual: Each polymerization mode combination constitutes a family
19.2. Polymerization activation site:
19.2.1. direct
19.2.2. indirect
19.2.3. direct and indirect
19.3. Examples of application of the specific criteria for acrylic resins
19.3.1. Family of heat-activated indirect acrylic resins
19.3.2. Family of self-curing direct and indirect acrylic resins
19.3.3. Family of light-cured direct and indirect acrylic resins
19.3.4. Family of light-cured direct acrylic resins
19.3.5. Family of dual indirect acrylic resins (light-cured and self-curing)
19.3.6. Family of dual indirect acrylic resins (thermoactivated and self-curing)
20. Composite resins
20.1. polymerization mode
20.1.1. thermopolymerizable
20.1.2. self-curing
20.1.3. photopolymerizable
20.1.4. dual: Each polymerization mode combination constitutes a family
20.2. Polymerization activation site:
20.2.1. Direct
20.2.2. Indirect
20.3. Adhesives, primers and acids are not part of this family.
20.4. Examples of application of the specific criteria for acrylic resins
20.4.1. Family of thermopolymerizable indirect composite resins
20.4.2. Family of self-curing indirect composite resins
20.4.3. Family of self-curing direct composite resins
20.4.4. Family of light-cured indirect composite resins
20.4.5. Family of light cured direct composite resins
20.4.6. Family of dual indirect composite resins (light-cured and self-curing)
20.4.7. Family of dual indirect composite resins (thermopolymerizable and self-curing)
21. Molding / printing material
21.1. type of material
21.1.1. silicone based
21.1.2. Based on reversible hydrocolloid
21.1.3. Based on irreversible hydrocolloid
21.1.4. based on polyether
21.1.5. The base of godiva
21.1.6. Based on polysulfide
21.1.7. plaster base
21.1.8. Based on zinc oxide and eugenol

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21.2. Activators and catalysts belong to the pertinent family as complementary component.
21.3. Examples of application of the specific criteria for Material of molding / printing
21.3.1. Silicone-based molding / impression material family
21.3.2. Family of molding/printing material based on reversible hydrocolloid
21.3.3. Family of molding/printing material based on irreversible hydrocolloid
21.3.4. Polyether based impression/impression material family
21.3.5. Godiva-based molding/printing material family
21.3.6. Family of molding/printing material based on polysulfide
21.3.7. Gypsum-based molding / impression material family
21.3.8. Family of molding / printing material based on oxide zinc and eugenol
22. Dental alloys for casting
They follow the general criteria established in the regulation, with the following remarks:
22.1. They do not follow the general rule of composition and indication of use;
22.2. A family can have models (alloys) with a specific indication of use different for each model.
22.3. Noble metallic elements: Au, Pt, Pd, Rh, Ru, Ir and Os
22.4. Solders and fluxes for exclusive use with the alloy may be part of of this family, as an accessory.
22.5. Feedstock:
22.5.1. Highly noble alloys: with content ³ 40% by weight of gold and ³ 60% noble metallic elements
22.5.1.1. Au-based
22.5.1.2. Based on Pd
22.5.2. Noble alloys: with content ³ 25% by weight of elements noble metallics
22.5.2.1. Au-based
22.5.2.2. Based on Pd
22.5.2.3. Ag-based
22.5.3. Alloys predominantly with base metals: with content <25% by weight of noble metallic elements
22.5.3.1. Based on Co-Cr
22.5.3.2. Based on Ni-Cr
22.6. Examples of application of specific criteria for family of alloys dental for foundry:
22.6.1. Highly Noble Au-Based Alloy Family
22.6.2. Highly Noble Pd-Based Alloy Family
22.6.3. Au-based noble alloy family
22.6.4. Family of Pd-based noble alloys
22.6.5. Family of noble alloys based on Ag
22.6.6. Family of alloys predominantly with base metals based on Co-Cr
22.6.7. Family of alloys predominantly with base metals based on Ni-Cr
23. Orthodontic Implant (Screws)
They follow the general criteria established in the regulation, with the following remarks:
23.1. As for the manufacturing technology in relation to the treatment of surface can be grouped in family:
23.1.1. Without surface treatment and/or with surface treatment that does not add raw material to the implant
23.1.2. With surface treatment that adds raw material to the implant
23.1.2.1. Surface treatment that adds composition substances different from the raw material of the implant and that are different from each other cannot be grouped in the same family.
23.2. Examples of application of the specific criteria for family of Orthodontic Implant (Screws)

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23.2.1. Orthodontic Implant Family (Screws) in pure titanium or alloy titanium without surface treatment and/or with surface treatment that does not add raw material to the implant
23.2.2. Orthodontic Implant Family (Screws) in pure titanium or alloy titanium with synthetic hydroxyapatite
24. Dental Implant
They follow the general criteria established in the regulation, with the following remarks:
24.1. As for the manufacturing technology in relation to the treatment of surface can be grouped in family:
24.1.1. Without surface treatment and/or with surface treatment that does not add raw material to the implant
24.1.2. With surface treatment that adds raw material to the implant
24.1.2.1. Surface treatment that adds composition substances different from the raw material of the implant and that are different from each other cannot be grouped in the same family.
24.2. Examples of application of the specific criteria for family of Dental implant
24.2.1. Dental implant family of pure titanium or titanium alloy without surface treatment and/or surface treatment that does not add raw material to the implant
24.2.2. Dental implant family of pure titanium or titanium alloy with hydroxyapatite of bovine origin.
24.2.3. Dental implant family of pure titanium or titanium alloy with synthetic hydroxyapatite.
24.2.4. Untreated zirconia dental implant family surface and/or surface treatment that does not add raw material to the implant
25. Dental Implant Prosthetic Components
25.1. Feedstock
25.1.1. metallic
25.1.2. ceramic
25.1.3. plastic
25.1.4. Metal-plastic combination
25.1.5. Metal-ceramic combination
25.1.6. Plastic-ceramic combination
25.2. Examples of application of the specific criteria for family of Dental Implant Prosthetic Components
25.2.1. Family of Dental Implant Prosthetic Components metallic
25.2.2. Family of Dental Implant Prosthetic Components ceramic
25.2.3. Family of Plastic Dental Implant Prosthetic Components
25.2.4. Family of Dental Implant Prosthetic Components with metal-plastic combination
25.2.5. Family of Dental Implant Prosthetic Components with metal-ceramic combination
25.2.6. Family of Dental Implant Prosthetic Components with plastic-ceramic combination
26. Overdenture retention devices
26.1. They can remain in the same family: o-ring, spacer, retention capsule, capsule or housing, clip and bar.
27. Wrench for dental implant
They follow the general criteria established in the regulation, with the following remarks:
27.1. Keys with activation can remain in the same family digital manual, with ratchet or with contra-angle activation.
28. Dental ceramics
28.1. Processing technology:
28.1.1. Processed by sintering
28.1.2. processed by foundry
28.1.3. Processed by machining
28.2. Examples of application of the specific criteria for family of dental ceramics

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28.2.1. Family of dental ceramics processed by sintering
28.2.2. Family of foundry-processed dental ceramics
28.2.3. Family of dental ceramics processed by machining
29. Glass ionomer
29.1. Composition
29.1.1. glass ionomer
29.1.2. metal reinforced glass ionomer
29.1.3. resin reinforced glass ionomer
29.2. Examples of application of the specific criteria for family of glass ionomer
29.2.1. Glass ionomer family
29.2.2. Glass-metal ionomer family
29.2.3. Resin-containing glass ionomer family