



25 February 2014

FDA Memorandum Circular
No. 2014- **2014-005**

TO: ALL DIRECTORS OF FDA CENTERS AND OFFICES, DOH CENTERS, BUREAUS, REGIONAL OFFICES, SERVICES, AND SPECIALTY HOSPITALS, MEDICAL CENTERS AND HOSPITALS, IMPORTERS/DISTRIBUTORS/WHOLESALERS/ RETAILERS/ MANUFACTURERS/RE-PACKERS OF MEDICAL DEVICES INCLUDING IN-VITRO DIAGNOSTIC MEDICAL DEVICES, AND OTHERS CONCERNED

Subject: Updated List of Medical Devices required to be registered prior to sale, distribution and use

In pursuit of attaining systematic regulation of medical devices, including in-vitro diagnostic medical devices, the Center of Device Regulation, Radiation Health, and Research (CDRRHR) of the Food and Drug Administration, Department of Health is providing the updated list of medical devices and in-vitro diagnostic medical devices that are required for mandatory registration pending the implementation of the full regulation of all medical devices.

The list is based on the BFAD Memorandum No. 7 s. 1992 that identifies the list of registrable medical devices and from the consolidated database of registered medical devices.

The following is the initial list of medical devices and in-vitro diagnostic medical devices that are required for mandatory registration:

A. Medical Devices:

- 1 Abdominal Pad
- 2 Absorbable Hemostatic Agents
- 3 Abutment
- 4 Access/injection port
- 5 Acetabular
- 6 Adhesive, all types
- 7 Administration Set, all types
- 8 Adoptor/Connector (all types)
- 9 Alcohol Swab
- 10 Anchor, Preformed
- 11 Anesthesia Set
- 12 Apheresis Kit



13	Artificial Saliva
14	Atopiclair Cream/Non-steroidal Cream
15	Bandage
16	Base Paste
17	Biopsy Needle/instrument
18	Blade, all types
19	Blood Bag
20	Blood Collection Tube/Kit; Blood Sampling Tube/Kit
21	Blood Transfusion Set
22	Blunt
23	Bone Marrow Collection/transfusion Kit
24	Bone Wax
25	Breathing Circuit
26	Burette
27	Burr, Dental/Surgical/Orthopeadic
28	Cannula, all types
29	Cap (disinfection, seal, taper, dead-end)
30	Cardiotomy Reservoir
31	Catheter, all types
32	Cavity Liner
33	Cell Regeneration Kit
34	Cell Separation Kit
35	Cement, Dental/Bone
36	Central Venous Blood Pressure Kit
37	Cervical Collar
38	Cervix Set
39	Chest Drainage Kit
40	Clave
41	Clinical Thermometer, all types except mercurial
42	Clip/Clip Applier
43	Closure Device; Skin Stapler (including remover)
44	Collagen
45	Condom
46	Conical Ring Segment
47	Contact lens solution
48	Contact Lens, including cosmetic contact lenses
49	Corset Cast
50	Cotton
51	Cytology Brush
52	Delivery System
53	Dental Bone
54	Dental Restorative Material/Filler/Agent/Tooth Bonding/Etching/Varnish
55	Dental Suspension
56	Dialysate Concentrate for Hemodialysis
57	Dialyzer
58	Diamond Disc
59	Dilatation Device
60	Disinfectant of Medical Devices
61	Dissector
62	Drainage Pouche

63	Drape, Sterile
64	Dressing
65	Drill, Bone/Surgical
66	Drug Delivery Embolization System
67	Duodenal Tube
68	Ear Wax Remover
69	Earpiercing Device
70	Ecodrop - Inject
71	Electrode needle/pencil (electrosurgical)
72	Embolic Protective Device/System
73	Endoscopic Harvesting System
74	Endotracheal Tube
75	Epidural Probe
76	Evacuator
77	Extention Set/Kit
78	Feeding Set
79	Filler
80	Filter
81	Filtration Device
82	Flowmeter, blood, cardiovascular
83	Former Compact
84	Gastric Band
85	Gauze
86	Gingiva Former
87	Gloves (surgical, examining, sterile, non-sterile)
88	Graft, bone/skin/vascular/biological
89	Guidewire, guide catheter
90	Heart Valve
91	Heart Valve/Annuloplasty Ring
92	Hemoconcentrator
93	Implantable Defibrillator
94	Implantable hearing device
95	Implantable Lead
96	Implantable Pacemakers
97	Implantable Prosthesis
98	Impression Material
99	Inflation Device
100	Infusion Fluid Thermal Warmer
101	Infusion System
102	Injectors
103	Intraocular Lens
104	Introducer Kit
105	IUD
106	IV Container
107	Knife, all types, sterile
108	Knot Pusher
109	Lancet
110	Laryngeal mask
111	Ligating Clip
112	Light Shield

113	Lubricating Gel/Jelly
114	Luer lock
115	Lumbar Puncture Tray
116	Manual Resuscitator with Mask
117	Mask (facemask, full mask, anesthesia, oxygen)
118	Moisture/Lubricating Eyedrop
119	Nasal Spray
120	Nasopharyngeal Airway
121	Nebulizing Kit with mask
122	Needle (all types) except for tattoo and acupuncture
123	Neurovascular Remodelling Device
124	Neurovascular/Endovascular Coil
125	Ophthalmic Drop/Solution
126	Ophthalmic Viscoelastic Device
127	Orthopaedic Implants (all kinds)
128	Orthopaedic Wire
129	Peak Flowmeter
130	Percutaneous Retrieval Device
131	Plaster of Paris
132	Plaster, all types
133	Plastic Strip
134	Plumset
135	Reconstruction Kit/Device; Fixation Device
136	Renal Dilatation Set
137	Revascularization Device
138	Root Canal Sealing Material
139	Rotahaler
140	Scalp Vein Infusion Set
141	Skin Retractor
142	Scrub, w/o drugs
143	Sealant
144	Self Adhering Wrap
145	Shunt System
146	Silicon Oil in Vial for Ophthalmic Use
147	Skin Barrier for Ostomy Use
148	Skin Traction Set
149	Sodium Hyaluronate
150	Spinal Anaesthesia Tray
151	Spine System
152	Stent
153	Sterilant for medical device
154	Stoma Adhesive Protective Powder/wafer
155	Stoma Bag
156	Stop-cock
157	Suction, Airway Kit
158	Surgical Mesh
159	Surgical Milk
160	Surgical Pack/Surgical Kit
161	Suture (with or without needle)
162	Suture Anchor

- 163 Synthetic Cast Padding
- 164 Syringe (with or without needle)
- 165 Tape, surgical/medical
- 166 Thrombectomy Set
- 167 Tissue Expander
- 168 Tissue Measuring Device
- 169 Tracheostomy Kit
- 170 Transfer Pack
- 171 Trocar System
- 172 Tube, all kinds that are connected to the patient or will be used to pass any type of fluids going into or from the patient's body)
- 173 Tulle Dressing (without drugs/medicine)
- 174 Umbilical Clamp
- 175 Urine Collecting Bag
- 176 Varnish, Cavity
- 177 Vascular Access System
- 178 Ventricular Probe
- 179 Wound Drainage Kit
- 180 All other implantable medical devices (in parts or in system)

B. In-Vitro Diagnostic (IVD) Medical Devices:

1. HIV (antibody and/or antigen), HBV (HBsAg and other markers), HCV (antibody and/or antigen) and syphilis (Treponemal and non-treponemal) kits for:
 - Screening Test
 - Confirmatory Test
 - Other marks for nucleic application systems for in-vitro diagnostic use and test to monitor disease activity (e.g. viral load test, other serologic markers for Hepatitis B)
2. Single or combination drug screening test kits/reagents for THC/marijuana, Shabu/MET, Cocaine, Benzodiazepine, Ecstasy/MDMA and Opiates/Morphine
3. Blood Typing Sera for Anti-A, Anti-B, Anti-D, Anti-AB
4. Anti-human Globulin Reagents
5. Potentiators such as enzyme, LISS and albumin
6. Column Agglutination test for crossmatching & blood typing
7. Pregnancy test kits/reagents
8. Leptospirosis test kits/reagents

All medical devices that have any of the abovementioned devices in part or in whole shall be considered registrable.

Application shall be made separately per specific medical device. In case of the following conditions, only one application can be filed, however, separate product certification/s shall be issued:

- medical device with accessories that are intended to be sold separately;
- medical device manufactured in multiple manufacturing sites and shall co-exist in the market;
- medical device system where the use of one part of the system is needed to be used together with all or any part of the system;
- medical devices with the same intended use and the same manufacturing process but differ in one or more raw materials;
- medical devices with the same intended use and the same manufacturing process but differ in the design;
- medical devices with the same raw materials but differ in types or shapes resulting in different specific intended uses.

The registration fee for this type of application shall be equivalent to the total registration fee for all the individual products that will be registered.

All unregistered medical devices included in this Memorandum Circular that are not listed in BFAD Memorandum Circular No. 7 s. 1992 shall be given one year from the time this Circular is approved to file the application for registration; otherwise, all unregistered medical devices included in this list shall not be allowed to be sold and distributed and corresponding sanctions based on Republic Act 9711 shall be imposed.

All devices indicated in the list are used in medical application. Other devices that are similar in terminology but are NOT for medical use shall not be considered as medical devices.

Medical devices that were issued with a CPR that are not included in this list will remain as registrable devices and should inform the CDRRHR-FDA.

This FDA Memorandum Circular shall supersede BFAD Memorandum Circular No. 7 s. 1992.

This Memorandum Circular shall take effect immediately.


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