Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

25 February 2014

FDA Memorandum Circular
No. 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	Orthopeadic Implants (all kinds)
128	Orthopeadic 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. iral load test, other serologic markers for Hepatitis B)
2. Single or combination drug screening test kits/reagents for THC/marijuana, Shabu/MET, Cocaine, Benzodiazepine, Ecstacy/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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Acting Director-General