FDA Memorandum Circular
No. 2014-005

25 February 2014

TO: ALL DIRECTORS OF FDA CENTERS AND OFFICES, DOH CENTERS, BUREAUS, REGIONAL OFFICES, SERVICES, AND SPECIALTY HOSPITALS, MEDICAL CENTERS AND HOSPITALS, IMPORTERS/DISTRIBUTORS/WHOLESALE/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
Artificial Saliva
Atopiclair Cream/Non-steroidal Cream
Bandage
Base Paste
Biopsy Needle/instrument
Blade, all types
Blood Bag
Blood Collection Tube/Kit; Blood Sampling Tube/Kit
Blood Transfusion Set
Blunt
Bone Marrow Collection/transfusion Kit
Bone Wax
Breathing Circuit
Burette
Burr, Dental/Surgical/Orthopeadic
Cannula, all types
Cap (disinfection, seal, taper, dead-end)
Cardiotomy Reservoir
Catheter, all types
Cavity Liner
Cell Regeneration Kit
Cell Separation Kit
Cement, Dental/Bone
Central Venous Blood Pressure Kit
Cervical Collar
Cervix Set
Chest Drainage Kit
Clave
Clinical Thermometer, all types except mercurial
Clip/Clip Applier
Closure Device; Skin Stapler (including remover)
Collagen
Condom
Conical Ring Segment
Contact lens solution
Contact Lens, including cosmetic contact lenses
Corset Cast
Cotton
Cytology Brush
Delivery System
Dental Bone
Dental Restorative Material/Filler/Agent/Tooth Bonding/Etching/Varnish
Dental Suspension
Dialysate Concentrate for Hemodialysis
Dialyzer
Diamond Disc
Dilatation Device
Disinfectant of Medical Devices
Dissector
Drainage Pouche
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<th>Item</th>
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<td>63</td>
<td>Drape, Sterile</td>
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<td>65</td>
<td>Drill, Bone/Surgical</td>
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<td>66</td>
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<td>67</td>
<td>Duodenal Tube</td>
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<td>68</td>
<td>Ear Wax Remover</td>
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<td>Ear piercing Device</td>
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<td>Ecodrop - Inject</td>
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<td>71</td>
<td>Electrode needle/pencil (electrosurgical)</td>
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<td>72</td>
<td>Embolic Protective Device/System</td>
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<td>73</td>
<td>Endoscopic Harvesting System</td>
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<td>74</td>
<td>Endotracheal Tube</td>
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<td>75</td>
<td>Epidural Probe</td>
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<td>76</td>
<td>Evacuator</td>
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<td>77</td>
<td>Extention Set/Kit</td>
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<td>Feeding Set</td>
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<td>79</td>
<td>Filler</td>
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<td>Filter</td>
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<td>81</td>
<td>Filtration Device</td>
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<td>82</td>
<td>Flowmeter, blood, cardiovascular</td>
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<td>83</td>
<td>Former Compact</td>
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<td>84</td>
<td>Gastric Band</td>
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<td>Gauze</td>
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<td>86</td>
<td>Gingiva Former</td>
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<td>87</td>
<td>Gloves (surgical, examining, sterile, non-sterile)</td>
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<td>88</td>
<td>Graft, bone/skin/vascular/biological</td>
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<td>89</td>
<td>Guidewire, guide catheter</td>
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<td>90</td>
<td>Heart Valve</td>
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<td>91</td>
<td>Heart Valve/Annuloplasty Ring</td>
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<td>92</td>
<td>Hemoconcentrator</td>
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<td>93</td>
<td>Implantable Defibrillator</td>
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<td>94</td>
<td>Implantable hearing device</td>
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<td>Implantable Lead</td>
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<td>Implantable Pacemakers</td>
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<td>Implantable Prosthesis</td>
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<td>Impression Material</td>
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<td>99</td>
<td>Inflation Device</td>
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<td>Infusion Fluid Thermal Warmer</td>
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<td>Infusion System</td>
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<td>102</td>
<td>Injectors</td>
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<td>103</td>
<td>Intraocular Lens</td>
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<td>104</td>
<td>Introducer Kit</td>
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<td>105</td>
<td>IUD</td>
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<td>106</td>
<td>IV Container</td>
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<td>107</td>
<td>Knife, all types, sterile</td>
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<td>108</td>
<td>Knot Pusher</td>
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<tr>
<td>109</td>
<td>Lancet</td>
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<tr>
<td>110</td>
<td>Laryngeal mask</td>
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<td>111</td>
<td>Ligating Clip</td>
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<td>112</td>
<td>Light Shield</td>
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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 Orthopedic Implants (all kinds)
128 Orthopedic 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 Sterillant 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, Ecstasy/MDMA and Opiates/Morphine
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.

KENNETH HARTIGAN-GO, MD
Acting Director-General