# INCLUSION OF HEPATITIS C TESTING KITS IN LIST I-B OF DIAGNOSTIC REAGENTS REQUIRED TO BE REGISTERED

*BFAD MEMORANDUM CIRCULAR NO. 7, April 24, 1992*

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In the interest of safety and protection of the users, Hepatitis C testing kits is hereby included as No. 5 in List I-B of Memorandum Circular No. 9 s. 1991, Diagnostic Reagents Required to be Registered.

Attached hereto (see below) are the updated List I-A, List I-B and List II of Medical devices.

This Circular supersedes Memo Circular No. 9 s. 1991.

Adopted: 24 Apr. 1992

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LIST I-A Medical Devices Required to be Registered

1. Absorbable Collagen Hemostatic Felt
2. Absorbent Cotton, sterile, and non-sterile
3. Arterial Venous Fistula Needle Set
4. Bandages with Plaster of Paris
5. Elastic Bandage
6. Band-Aid Plastic Strip Plain Pad
7. Bone Wax
8. Blood Transfusion Set
9. Catheters
10. Cervical Collar
11. Collagen
12. Condom
13. Contact Lenses (hard and soft and disposable)
14. Corset Cast
15. Cosmetic Puffs Cotton
16. Cotton Buds
17. Cotton Swabs
18. Dental Filling Alloy
19. Disposable Needles
20. Disposable Skin Stapler and Staples
21. Disposable Tissue Measuring Device
22. Drainage Pouches
23. Duodenal Tube
24. Earpiercing Device
25. Endotracheal Tube
26. Exchange Transfusion Set
27. Feeding Tube

28. Filter Set
29. Fluor Alloy Amalgam
30. Gauze Pads, sterile and non-sterile
31. Humidifier Mask
32. Hypo-Allergenic Paper Tape
33. Implantable Staple
34. Infusion Administration Set
35. Intraocular Lenses
36. Intrauterine Device (IUD)
37. I.V. Catheter Needles
38. Ligating Clip Device
39. Lubricating Jelly
40. Lumbar Puncture Tray
41. Nasal Oxygen Cannula
42. Nebulizer with Aerosol Mask
43. Orthoplast Cervical Collar
44. Ostotomy set
45. Oxygen Catheter
46. Oxygen Mask
47. Peridontal Bone Grafting Implant
48. Peritoneal Dialysis Administration Set
49. Plaster
50. Porcine Heart Valve
51. Implantable Prostheses
52. Rectal Catheter
53. Rectal Tube

LIST I-A Medical Devices Required to be Registered

54. Removable Skin Staple
55. Rotahalers
56. Scalp Vein Infusion Set
57. Scissors Skin Retractors
58. Skin Traction Kit
59. Spinal Anesthesia Tray
60. Stoma Bag
61. Stomach Tube
62. Suction Catheter
63. Surgical Blades, disposable
64. Surgical Gloves (Sterile and Unsterile
65. Sutures
66. Suturing Needles
67. Synthetic Cast Padding
68. Syringes
69. Thermometers
70. Transfusion Set
71. Urethal Catheter
72. Urinary Drainage Tube
73. Urine Collecting Bag
74. Abdominal Pads


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LIST I-B Diagnostic Reagents Required to be Registered

1. HIV Testing Kits
2. Hepatitis B Testing Kits
3. Blood Typing Seva
4. Pregnancy Test Kits
5. Hepatitis C Testing Kits

LIST II Products that are not Required to be Registered

1. Plastic Bags for Blood Transfusion
2. Non-sterile Surgical Facemasks
3. Surgical Caps (non-sterile)
4. Tounge Depressors
5. Non-sterile Applicator Sticks
6. Gauze (in bolts)
7. Anti Embolism Stocking
8. Undercast Padding
9. Sputum Caps
10. Rubber Stoppers
11. Aluminum Seals
12. Vials (50, 10, 5 cc)
13. Ampules (5, 10 mL amber/white)
14. Laboratory Glasswares
15. Surgical Instruments (e.g. scissors, forceps, blade-holder, needle-holder, clamps, biopsy, punches, retractors, scopes, etc.)
16. Toothbrushes
17. Dental Floss
18. Heat Solution
19. Mortuary Refrigerator
20. Abdominal Binder
21. Weighing Scale
22. Ice Bags
23. Urinal/Receptables
24. Splints
25. Plaster of Paris
26. [Abdominal Pads] - deleted by M.C. No. 9 s. 1991
27. Centrifuges and equipment
28. Anaerobic Generating System
29. X-ray Films and Chemicals
30. Surgical Face Mask


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