November 04, 2020

NO. 264 - 2020

To:

All Deputy Commissioners

All Service Directors
All District/Port Collectors
All Others Concerned

SUBJECT:

LETTER DATED 29 SEPTEMBER 2020 FROM THE FOOD AND DRUG

ADMINISTRATION (FDA) REGARDING THEIR NEW GUIDELINES AND ISSUANCES, INCLUDING THE REQUIRED AUTHORIZATION

PRIOR TO THE IMPORTATION OF MEDICAL DEVICES

Attached hereto is the letter dated 29 September 2020 from ROLANDO ENRIQUE D. DOMINGO, MD, DPBO, Director General, FDA regarding the issuance of FDA Circular No. 2020-001, "Processing of Initial Implementation of Administrative Order No. 2018-2002: Guidelines Governing the Issuance of an Authorization for a Medical Device Based on the ASEAN Harmonized Technical Requirements" signed on 23 January 2020, including the required authorization prior to the importation of medical devices.

The said letter mentions, among others, that the issuance of Certificate of Exemption (COE) for Medical Device and In-Vitro Diagnostic Devices (IVD) that are non-registrable **shall cease**. In lieu of the COE, the License to Operate (LTO) as Medical Device Importer/Distributor of the establishment shall be required during importation.

For your information and guidance.

For records purposes, please confirm the dissemination of this Circular throughout your offices within fifteen (15) days from receipt.

Commissioner NOV 17 2020

BOC-09-1642

MEMORANDUM

MASTER COPY

TO

.

GLADYS C. CABUGAWAN

Chief, Central Records Management Service

FROM

ATTY. YASSER ISMAIL A. ABBAS, CESE

Director III, Imports and Assessment Service

SUBJECT

CUSTOMS MEMORANDUM CIRCULAR DATED 4 NOVEMBER

2020

DATE

20 November 2020

Respectfully forwarded the herein 4 November 2020 memorandum RE: LETTER DATED 29 SEPTEMBER 2020 FROM THE FOOD AND DRUG ADMINISTRATION (FDA) REGARDING THEIR NEW GUIDELINES AND ISSUANCES, INCLUDING THE REQUIRED AUTHORIZATION PRIOR TO THE IMPORTATION OF MEDICAL DEVICES signed by the Commissioner of Customs dated 17 November 2020, for numbering and dissemination.





Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



OCT 28



29 September 2020

COMMISIONER REY LEONARDO GUERRERO

Bureau of Customs G/F, OCOM Bldg., 16th Street South Harbor, Port Area, Manila

Dear Commisioner Guerrero:

This refers to the new guidelines and Drug Administration specifically in Medical Devices.

BUREAU OF

With the issuance of FDA Circular No. 2020-001, "Processing of Initial Implementation of Administrative Order No, 2018-0002: Guidelines Governing the Issuance of an Authorization for a Medical Device Based on the ASEAN Harmonized Technical Requirements" signed on 23 January 2020, Issuance of Certificate of Exemption (COE) for Medical Device and In-Vitro Diagnostic Devices (IVD) that are non-registrable shall cease. In lieu of the COE, the License to Operate (LTO) as Medical Device Importer/Distributor of the establishment shall be required during importation.

To summarize, the following are the authorization needed or to be required during importation of medical devices:

A. LTO

- a. Importers of Medical Devices and In Vitro Medical Devices, Registrable and Non-Registrable Products
 - The list of Non-Registrable Products is hereby attached.

B. Certificate of Product Registration - ONLY for Registrable Products

- a. For Registrable Medical Device Products classified as Class B, Class C and Class D – Refer to Annex of the List of Medical Devices in the FDA Circular No. 2020-001, "Processing of Initial Implementation of Administrative Order No, 2018-0002: Guidelines Governing the Issuance of an Authorization for a Medical Device Based on the ASEAN Harmonized Technical Requirements"
- b. For Registrable IVD products Refer to FDA Memorandum Circular No. 2014-005, "Updated List of Medical Devices Required to be Registered Prior to Sale, Distribution and Use".

C. Certificate of Medical Device Notification (CMDN) – For Class A Medical Devices

CMDN is the certification issued for Class A medical devices. COEs issued from 25 February 2014 shall remain valid only until 03

10:m)



Management System ISO 9001:201





November 2021. After this date, all Class A should present a CMDN. Attached is the list for Class A medical devices.

D. Special Certification

Special Certification is being issued for new technologies or new test kits brought about by emerging disease or global outbreak of international and national concern. Please see FDA Memorandum No. 2020-006, "Issuance of Special Certification for Imported Test Kits of COVID -19" for reference.

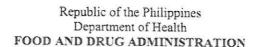
Thank you for your usual support in ensuring the quality, safety and effectiveness of medical devices.

Very truly yours,

ROLANDO ENRIQUE D. DOMINGO, MD, DPBO Director General

OFFICE OF THE DIRECTOR









2 3 JAN 2020

FDA CIRCULAR No. 2020-001

TO:

ALL MEDICAL DEVICE MANUFACTURERS,

TRADERS, DISTRIBUTORS AND OTHER

CONCERNED PARTIES

SUBJECT:

Initial Implementation of Administrative Order No. 2018-

0002 "Guidelines Governing the Issuance of an Authorization for a Medical Device Based on the ASEAN

Harmonized Technical Requirements"

I. BACKGROUND AND RATIONALE

On 25 February 2014 and on 3 June 2015, FDA Memorandum Circular No. 2014-005 and FDA Memorandum Circular No. 2014-005-A were issued respectively, to attain systematic regulation for medical devices. The said FDA issuances provide list of medical devices that are required to be registered prior to sale, distribution and use.

On 21 November 2014, the Philippines, represented by the Secretary of Trade and Industry, together with 9 other ASEAN countries, agreed on a harmonized medical device regulations and common technical documents. Only medical devices which conform to the provisions of the ASEAN Agreement on Medical Device Directive (AMDD) and its Annexes may be placed on the markets of the Member State.

On 26 January 2018, DOH Administrative Order No. 2018-0002 entitled "Guideline Governing the Issuance of an Authorization for a Medical Device based on the ASEAN Harmonized Technical Requirements" was issued to provide guidelines on the documentary requirements for the registration of medical devices and to align the registration requirements to the CSDT (Common Submission Dossier Template) based on the provisions of AMDD.

With the implementation of AO 2018-0002, the FDA through the Center for Device Regulation, Radiation Health and Research (CDRRHR) is also mandated to release list of medical devices per classification based on the classification set forth in the ASEAN AMDD.

In compliance with Section IX of AO 2018-0002 and to implement the initial phase of the implementation of the said policy which covers all registrable products listed in FDA Memorandum Circular No. 2014-005 and FDA Memorandum Circular No. 2014-005-A, this issuance is hereby issued.







This Circular includes modifications in the list of medical devices in FDA Memorandum Circular No. 2014-005 and FDA Memorandum Circular No. 2014-005-A (see Annex A).

II. OBJECTIVE

This issuance aims to provide information regarding the acceptance of applications based on AO 2018-0002, validity of issued Certificate of Exemption (COE), and application fees for identified marketing authorizations. This shall guide establishments engaged in the manufacture, importation, exportation, sale, offer for sale, distribution, donation, transfer, and where applicable, the use, testing, promotion, advertising, or sponsorship of medical devices.

This Circular also aims to provide guidance for the medical device industry and all concerned regarding the classification of medical devices listed in FDA Memorandum Circular No. 2014-005 and FDA Memorandum Circular No. 2014-005-A according to the level of risk as specified below:

Class	Risk Level
A	Low
В	Low-moderate
C	Moderate-high
D	High

III. POLICIES AND GUIDELINES

- The Center for Device Regulation, Radiation Health, and Research (CDRRHR) shall be accepting applications for the following marketing authorizations
 - a. Certificate of Medical Device Registration (CMDR) for medical devices with risk classification of B, C, and D which are included in FDA Memorandum Circular 2014-005 and 2014-005-A (see annex A).
 - Certificate of Medical Device Notification (CMDN) for all medical devices with risk classification A whether or not included in FDA Memorandum Circular No. 2014-005 and FDA Memorandum Circular No. 2014-005-A.
 - Certificate of Medical Device Listing (CMDL) for research, clinical trial, exhibit, personal use and/or donated, brand new medical devices.
- Classification of medical devices that are not included in Annex A shall follow the classification rules of AMDD as stated in item 2 of Section V. General Guidelines of AO 2018-0002.





- 3. All Certificate of Exemption for Class A medical devices issued from 25 February 2014 shall remain valid only until 03 November 2021 or within 2 years from date of effectivity of this Circular whichever is earlier. This is to give ample time for the industry to apply for CMDN.
- 4. All Certificates of Product Registration (CPR) that were issued for Class A medical devices shall be deemed equivalent to CMDN only until the validity of the CPR. CMDN shall be issued upon renewal of the issued CPR.
- 5. The list of in-vitro diagnostic (IVD) medical devices that are registrable in Section B of FDA Memorandum Circular No. 2014-005 remains the same; however, the blood collection tube listed in Section A of the said FDA Memorandum Circular shall be added under the list of IVD since it has been re-classified as in-vitro diagnostic (IVD) medical devices based on the definition of IVD in the ASEAN AMDD.
- 6. Issuance of COE shall cease. All Class B, C and D medical devices that are not included in item 1.a of this Circular and in-vitro diagnostic (IVD) devices that are not included in FDA Memorandum Circular No. 2014-005 shall be considered non-registrable products. The License to Operate (LTO) of the establishment shall be provided in lieu of the COE at the point of entry and/or as part of bidding requirements.
- 7. The fees for the following issuances shall be in accordance with Administrative Order No. 50 s. 2001, until such time of modification, supersession, and/or revocation, with the following clarification:
 - a. Payment for initial application of CMDN and CMDR is ₱7,500.00 + Legal Research Fee (LRF) based on the current fee for initial registration of ₱1,500.00 + LRF x 5 years validity.
 - Payments for renewal applications of CMDN and CMDR are ₱5,000.00 + LRF.
 - c. Payment for application of CMDL is ₱500.00 + LRF.
 - d. LRF is 1% of the filing fee imposed but in no case lower than Ten Pesos (₱10.00), based on FDA Circular No. 2011-003 "Collection of Legal Research Fee Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856".
- 8. Additional details shall be provided in subsequent issuances regarding the succeeding phases.

IV. PENALTY CLAUSE

Any establishment found to be in violation of the provisions of this issuance shall be subjected to sanctions and penalties as prescribed under RA 9711 and its IRR.

N.



V. REPEALING CLAUSE

The list in Annex A supersedes the list of medical devices in section A of FDA Memorandum Circular No. 2014-0005 and FDA Memorandum Circular No. 2014-0005-A.

Provisions on previous circulars and memoranda that are inconsistent with this issuance are hereby modified, withdrawn, repealed, and/or revoked accordingly.

VI. SEPARABILITY CLAUSE

If any provision in this Circular, or application of such provision to any circumstances, is held invalid, the remainder of the provisions of this Circular shall not be affected.

VII. EFFECTIVITY

This Circular shall take effect fifteen (15) days after its publication in a newspaper of general circulation and upon acknowledgement of receipt of a copy hereof by the Office of the National Administrative Register.

ROLAND ENRIQUE D. DOMINGO, MD, DBPO
Undersecretary of Health

Officer-in-Charge, Director General

20100210115210

M.



ANNEX A

b. Absorbable Hemostatic 3 ACCESS/INJECTION PC 4 ACETABULAR 5 ADAPTOR/CONNECTO 6 ADHESIVE, ALL TYPES a. Adhesive Tape b. Adhesive Bandage 7 ADMINISTRATION SET a. With needle b. Without needle b.1. Fluid/Medicine/Paren b.2. Blood/Body Liquids/O 8 ANCHOR, PREFORMEL 9 ANESTHESIA SET 10 ANNULOPLASTY RINO 11 APHERESIS KIT/ CELL 12 ARTIFICIAL SALIVA 13 BANDAGE a. All types b. Self Adhering Wrap 14 BASE PASTE 15 BIOPSY NEEDLE/INSTI 16 BLOOD BAG 17 BLOOD TRANSFUSION	Agents Non-Collagen Based Agents, Collagen Based ORTS R (ALL TYPES) C, ALL TYPES / DELIVERY SYSTEM Iteral Nutrition Gases	A C/D C/D C C C A A A A B A/B B A/C D B A A A A A
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19 BONE WAX 20 BREATHING CIRCUIT 21 BURR, DENTAL/SURGI 22 CANNULA, ALL TYPES a. Reusable b. In contact with the CNS		В
20 BREATHING CIRCUIT 21 BURR, DENTAL/SURGI 22 CANNULA, ALL TYPES a. Reusable b. In contact with the CNS	ECTION/ TRANSFUSION KIT	В
21 BURR, DENTAL/SURGI 22 CANNULA, ALL TYPES a. Reusable b. In contact with the CNS		C/D
22 CANNULA, ALL TYPES a. Reusable b. In contact with the CNS		В
a. Reusable b. In contact with the CNS		A/B
b. In contact with the CNS		
		A
c. Through body orifice	and CCS ²	D
		A,B,C
d. Short term ³ use, Single	use, Disposable use	B
23 CAP (DISINFECTION, S	EAL, TAPER, DEAD END)	A
24 CARDIOTOMY RESERV		В
25 CATHETER, ALL TYPE	3	d c
a. Short ³ term use		В
b. Long ⁴ term use		
c. Through body orifice		C
d. In contact with the CNS	¹ and CCS ²	A,B,C
26 CAVITY LINER		D
27 CEMENT, DENTAL/BOX	TE.	В
a. Cement, Dental	NL,	
b. Cement, Bone Synthetic		<u>B</u>
c. Cement, Bone Natural	F. () - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 -	C/D



28	CENTRAL VENOUS BLOOD PRESSURE KIT	
29		D
30	CHEST DRAINAGE KIT	A
31	CLINICAL THERMOMETER	В
	a. Active type	
	b. Analog typte (Execpt merurial type)	В
32	CLIP	A
12	a. Invasive	
	b. Non-invasive	C/D
33	CLIP APPLIER	A
	a. Reusable	
	b. Single use	A
34		В
34	CLOSURE DEVICE; SKIN STAPLER (INCLUDING REMOVER) a. Non invasve	
	b. Invasive	В
35		C
33	a. Endovascular Coil	
	b. Neurovascular Coil	C/D
36		D
37		D
37		
	a. Condom All Types	C
	b. Condom with spermicide c. Condom - Natural Membrane	D
38		D
39	CONICAL/CORNEAL RING SEGMENT CONTACT LENS SOLUTION	B/C
· 40		C
41	CONTACT LENS, INCLUDING COSMETIC CONTACT LENSES CORSET CAST	B
42		A
<u> </u>	a. Cotton	
	b. Paddie, Cottonoid	A
43		В
43	CYTOLOGY BRUSH (Biopsy, General & Plastic Surgery) a. Body orifice	B 110 B
		A
44	b. Surgically Invasive	В
44	DENTAL RESTORATIVE MATERIAL	В
	a. Filler, agent, tooth bonding	В
45	b. Etching Varnish Suspension	A/B
46	DIALYSATE CONCENTRATE FOR HEMODIALYSIS DIALYZER	С
47	DIAMOND DISC	В
48		A
49	DISINFECTANT OF MEDICAL DEVICES DISSECTOR	C
47	A. Reusable	В
	B. Single Use	A
50		В
50 51	DRAINAGE POUCHE (ALL TYPES) DRESSING	A
31	a. Dressing	
		A
	b. Dressing w/ absorbable component	В
	c. Dressing with medicine d. Dressing with biologic	D
52	DRILL BIT, BONE/SURGICAL	D
53		A
54	DRUG DELIVERY EMBOLIZATION SYSTEM	D
24	DRY POWDER INHALER (WITHOUT MEDICINE)	A



55		A
56	The state of the s	В
57	EMBOLIC PROTECTIVE DEVICE/SYSTEM	D
58	THE THE TENT WE THEN THE TENT	
	a. Re-usable	A STATE OF THE REAL PROPERTY.
	b. Single Use	A B
59	EPIDURAL PROBE	
60	EVACUATOR	В
61	EYE LIGHT SHIELD	A
62	FEEDING SET	A
	a. Feeding Set thru body orifice	
	b. Feeding Set surgically invasive	В
63	FILLER	С
	a. Absorbable (All Types)	
	b. Non Absorbable	D
	FILTER (to filter bacterial and/or viral cross contamination which will be introduced to the	C
64	patient) patient and of vital cross containination which will be introduced to the	В
65	FLOWMETER (All Types)	
66	GASTRIC BAND	A
67	GAUZE	С
	a. Gauze	
	b. Gauze, internal sponge	A
	c. Gauze with medicine	В
	d. Gauze with biologic	D
68	GINGIVA FORMER	D
69	GLOVES.	В
02	a. Examining, Non-sterile gloves	inder A town
***************************************	b. Surgical, Sterile Gloves	A
70	GRAFT	В
10	a. Absorbable	C/D
	b. Non-Absorbable	D
71		С
72	GUIDEWIRE, GUIDE CATHETER HEART VALVE	В
73		D
74	IMPLANTABLE DEFIBRILLATOR	D
	IMPLANTABLE HEARING DEVICE	C
75	IMPLANTABLE LEAD	D
76	IMPLANTABLE PACEMAKERS	D
77	IMPLANTABLE PROSTHESIS	C/D
78	IMPRESSION MATERIAL	A
79	INFLATION DEVICE	A
80	INTRAOCULAR LENS	С
81	INTRAUTERINE CONTRACEPTIVE DEVICE (IUD)	D
82	INTRODUCER	В
83	KNOT PUSHER	18/00/2012
	a. Reusable	A
	b. Single use	В
84	LANCET	В
85	LARYNGEAL MASK	В
01	LUBRICATING GEL/JELLY	
86	a. External	
80		A
86	b. Internal LUER LOCK	A A



88	LUMBAR PUNCTURE TRAY/KIT	l C
89	MASK (silicone facemask, full mask, anesthesia, oxygen)	В
90	MOISTURE/LUBRICATING EYEDROP	
91	NASAL SPRAY (WITHOUT CLAIMS)	B
92	NASOPHARYNGEAL AIRWAY	A
93	NEEDLE (all types) except for tattoo and acupuncture	A
94	NEUROVASCULAR REMODELLING DEVICE	В
95	NON-STEROIDAL CREAM/ SKIN BARRIER (TOPICAL)	D
96	OPHTHALMIC DROP/SOLUTION	B
97	OPHTHALMIC VISCOELASTIC DEVICE	B
98	ORTHOPAEDIC WIRE	B/D
99	PEN INJECTOR	B/C
100	PERCUTAENOUS RETRIEVAL DEVICE	A
101	PLASTER OF PARIS	B
102	PLASTER/PLASTIC STRIP, ALL TYPES.	A
Of Colombia	a. Gauze	A
	b. Gauze, internal sponge	A B
	c. Gauze with medicine	
	d. Gauze with biologic	D
103	RECONSTRUCTION KIT/DEVICE; FIXATION DEVICE	D
104	RENAL DILATATION SET	B/C
105	REVASCULARIZATION DEVICE	B
106	RETRACTOR	D
	a. Reusable	
	b. Single-use	A B
107	SCALP VEIN INFUSION SET	B .
108	SEALANT	В
	a. Wound Sealant	В
	b. From animal source	D
109	SHUNT SYSTEM	
	a. All types, except for CNS ¹ and CCS ²	C
	b. For CNS ¹ and CCS ²	
110	SILICON OIL IN VIAL FOR OPHTHALMIC USE	D
111	SKIN BARRIER FOR OSTOMY USE	
112	SKIN TRACTION SYSTEM	A
113	SODIUM HYALURONATE	A
	a. Animal source	
	b. Non animal source	D
114	SPINAL ANAESTHESIA KIT	B
115	SPINE SYSTEM	
	a. Implantable with Direct contact with CNS ¹	
***************************************	b. Implantable	D
	c. External or Non-implantable	C
116	STENT	A
	a. Short Term³ except those touching CNS¹ and CCS²	
	b. Long Term ⁴ except those touching CNS ¹ and CCS ²	B
1	c. Short ³ or Long Term ⁴ touching CNS ¹ and CCS ²	C
117	STOMA ADHESIVE PROTECTIVE POWDER/WAFER	D
	STOP COCK	A
119	SURGICAL BLADES, ALL TYPES	A
	A. Reusable	
		A



····		
***************************************	B. Single Use	В
120	SURGICAL DRAPE, STERILE	В
	a. Drape	
	b. Drape with Self Retaining Finger Cot	A
121	SURGICAL KNIFE, STERILE	B
122	SURGICAL MESH	В
123	SUTURE (WITH OR WITHOUT NEEDLE)	С
	a. Suture, Nonabsorbable, Synthetic	
	a.1 In contact with CNS ¹ , CCS ²	
	a.2 In contact with deep tissue	D
***************************************	b. Suture, Absorbable (from animal source)	В
***************************************	c. Suture, Absorbable, Synthetic	D
	d. Suture, Dental	D
	e. Suture, Non-absorbable, short-term	B
	f. Suture, Steel	В
124	SUTURE ANCHOR	C
	a. Non-absorbable	MALL MARKET
	b. Absorbable	C
125	SYNTHETIC CAST PADDING	D
126	SYRINGE	A
	a. Syringe with Needle	
	b. Syringe without Needle	В
127	TAPE, SURGICAL/MEDICAL	A
128	THROMBECTOMY SET	A
129	TISSUE EXPANDER	D
	a. For breast implant	
	b. Other parts of the body	D
130	TRACHEOSTOMY KIT	C
131	TROCAR SYSTEM	В
	a. Single use	是是14日子子(1475年)。
- Constitution	b. Reusable	B
132	TUBE, Other Types	A
133	UMBILICAL CLAMP	A/B
134	VASCULAR ACCESS SYSTEM	A
35	VENTICULAR PROBE	D
36	WOUND DRAINAGE KIT	D
37	ALL OTHER IMPLANTABLE MEDICAL DEVICES (IN PARTS OR IN SYSTEM)	В
	a. Active Implants	MENTAL PROPERTY
	b. Heart Implants	D
	c. Brain Implants	D D
	d. Breast Implants	D
	e. Spinal Implants	D
	f. Dental Implants including Abutment	<u>D</u>
	g. Orthopaedic Implants	<u>B</u>
	h. All other implants	C C

Footnote:

CNS1 Central Nervous System - refers to the brain, meninges and spinal cord.

CCS² Central Circulatory System -means the major internal blood vessels including the following:

- · arteriae pulmonales (pulmonary artery);
- · aorta ascendens (ascending aorta);



- · arteriae coronariae (coronary artery);
- arteria carotis communis (common carotid artery);
- arteria carotis externa (external carotid artery);
- arteria carotis interna (internal carotid artery);
- · arteriae cerebrates (cerebella arteries);
- truncus brachiocephalicus (brachiocephalic trunk);
- · venae cordis (cardiac veins):
- · venae pulmonales (pulmonary vein):
- venae cava superior (superior vena cava);
- · venae cava inferior (inferior vena cava):
- · arcus aorta (aortic arch);
- thoracica aorta (thoracic aorta);
- · abdominalis aorta (abdominal aorta);
- · arteriae ilica communis (common iliac arteries);
- aorta descendens to the bifurcatio aortae (descending aorta to the bifurcation of aorta)

Short term use³ Normally intended for continuous use for between 60 minutes and 30 days Long term use⁴ Normally intended for continuous use for more than 30 days



LIST OF EXEMPTED GENERAL MEDICAL DEVICES AND IN VITRO MEDICAL DEVICES

CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES

1-Nitroso-2-Naphthol (Fluorometric), Free Tyrosine

2,4-Dinitrofluorobenzene (Spectroscopic), Nitrogen (Amino-Nitrogen)

2,4-Dinitrophenylhydrazine, Lactate Dehydrogenase

5-Amp-Phosphate Release (Colorimetric Test), 5'- Nucleotidase

5-Fluorouracil Assay

Acetylcholine Chloride, Specific Reagent For Pseudo Cholinesterase

Acid Phosphatase (Prostatic), Tartrate Inhibited

Acid Phosphatase, Beta Glycerophosphate

Acid Phosphatase, Disodium Phenylphosphate

Acid Phosphatase, Naphthyl Phosphate

Acid Phosphatase, Nitrophenylphosphate

Acid Phosphatase, Thymol Blue Monophosphate

Acid Phosphatase, Thymolphthale Inmonophosphate

Acid, Alpha-Ketobutyric And Nadh (U.V.), Hydroxybutyric Dehydrogenase

Acid, Ascorbic, 2,4-Dinitrophenylhydrazine (Spectrophotometric)

Acid, Delta-Aminolevulinic, Ion-Exchange Columns With Colorimetry

Acid, Ferric Ion-Sulfuric, Cholesterol

Acid, Folic, Radioimmunoassay

Acid, Hydroxyazobenzene-Benzoic, Albumin

Acid, Lactic, Enzymatic Method

Acid, Nitrous And Nitrosonaphthol, 5-Hydroxyindole Acetic Acid/Serotonin

Acid, Oxalacetic And Nadh Oxidation (U.V.), Malic Dehydrogenase

Acid, Phosphoric-Tungstic (Spectrophotometric), Chloride

Acid, Pyruvic, Enzymatic (U.V.)

Acid, Trifluoroacetic, Vitamin A, Hexane Extraction

Acid, Uric, Acid Reduction Of Ferric Ion

Acid, Uric, Uricase (Colorimetric)

Acid, Uric, Uricase (Gasometric)

Acid, Uric, Uricase (Oxygen Rate)

Acid, Uric, Uricase (U.V.)

Acid, Vanilmandelic, Diazo, P-Nitroaniline/Vanillin

Acid, Vanilmandelic, Electrophoretic Separation

Adsorbents, Ion-Exchange

Alcohol Control Materials

Alcohol Dehydrogenase, Specific Reagent For Ethanol Enzyme Method

Alizarin Sulfonate, Calcium

Alkaline Picrate, Colorimetry, Creatinine

Alpha-Naphthyl Phosphate, Alkaline Phosphatase Or Isoenzymes

Amikacin Serum Assay

Ammonium Molybdate And Ammonium Vanadate, Phospholipids

Amyloclastic, Amylase

Analyzer, Chemistry (Photometric, Discrete), For Clinical Use

Analyzer, Chemistry (Sequential Multiple, Continuous Flow) Clinical Use

Analyzer, Chemistry, Centrifugal, For Clinical Use

Analyzer, Chemistry, Micro, For Clinical Use

Analyzer, Enzyme, For Clinical Use