

Drugs Controller General (India)
Directorate General of Health Services
FDA Bhawan, Kotla Road, New Delhi

NOTICE

File No: 29/Misc./3/2017-DC(292)

Date: 01 NOV 2017

Subject: Classification of medical devices and in vitro diagnostic medical devices under the provisions of the Medical Devices Rules, 2017 - Reg.

Safety, quality and performance of medical devices are regulated under the provisions of the Drugs and Cosmetics Act, 1940 and rules made thereunder. For the regulation of medical devices for their with respect to the import, manufacture, clinical investigation, sale and distribution, the Central Government, after consultation with the Drugs Technical Advisory Board, has notified Medical Devices Rules, 2017 vide G.S.R. 78 (E) dated 31.01.2017 which are to be commence from 01.01.2018.

In this connection, in exercise of the powers conferred under sub-rule (3) of rule 4 of Medical Devices Rules, 2017, the undersigned is hereby classify the medical devices and *in vitro* diagnostic medical devices, Appendix -1, based on the intended use of the device, risk associated with the device and other parameters specified in the First Schedule.

List of medical devices and in vitro diagnostic medical devices placed at Annexure-1 is subjected to the followings:

1. General intended use given against each of the devices is for guidance to the applicants intends to furnish application of import or manufacture of medical devices under the provisions of Medical Devices Rules, 2017. However, a device may have specific intended use as specified by its manufacturer.
2. The component and accessories to a medical device or companion *in vitro* diagnostic medical devices has been classified separately.
3. It is also recognised that some of the medical devices or *in vitro* diagnostic medical devices may have dual use and they may be classified accordingly.
4. This list is dynamic and is subject to revision from time to time under the provisions of the Medical Devices Rules, 2017.


(Dr. G. N. Singh)

Drugs Controller General (India)

To,

1. All Stake holders.
2. CDSCO Website.
3. Guard File.

Notice

File No. 29/Misc/3/2018-DC(18)

Date: 16.08.2018

In continuation to the earlier Notice vide File No: 29/Misc./3/2017-DC(292) dated 01.11.2017 and amended classification list dated 06.06.2018 regarding Classification of medical devices and in vitro diagnostic medical devices under the provisions of the Medical Devices Rules, 2017, the following Medical Devices have been added in the annexure I :

S. No.	Notified Category	Device name	General Intended Use	Risk Class
1.	Surgical Dressings	Suture Anchor (Spartan PEEK Suture Implant)	Soft Tissue Repair	C
2.	Disposable Hypodermic Needles	Special bevelled needles for implantable vascular access system	Power - injectable safety non-coring needle is a device intended for insertion into the septum of a subcutaneously implanted port for the infusion of fluids and drugs, as well as blood sampling through the port. It is manually activated during needle removal, and is designed to aid in the prevention of accidental needle-sticks. When used with ports that are indicated for power injection of contrast media into the central venous system, the needle is also indicated for power injection of contrast media.	C
3.	Internal Prosthetic Replacements	Auditory Brainstem Implant System	An auditory brain stem implant is a small device that is surgically implanted in the brain of a deaf person whose auditory nerves is lacking or damaged. The auditory nerves conduct the sound signals from the ear to the brain. The implant enables otherwise the deaf people to have a sensation of hearing.	D
4.	Surgical Dressings	Sternal fixation Reconstructive implant	Sternal Fixation System is intended for use in primary or secondary closure/repair of the sternum following sternotomy or fracture of the sternum to stabilize the sternum and promote fusion.	C
5.	Internal Prosthetic Replacements	Dural Graft Implant	Dural Graft Implant is intended for use in procedures where the repair or	C

			substitution of the patient's dura mater is needed.	
6.	Catheters	Implantable infusion pumps with Catheters	Intended to treat chronic pain and spasticity patients. The pump is inserted below the ribs and it designed to continually transport medication to the site of action. Doses are accurate, user friendly and the device does not restrict movement.	D
7.	Catheters	Laser Sheath	Intended for use as adjuncts to conventional lead extraction tools in patients suitable for transvenous removal of chronically implanted pacing or defibrillator leads constructed with silicone or polyurethane outer insulation	C
8.	Internal Prosthetic Replacements	Gluteus implants	Implant for augmentation of buttocks	C
9.	Internal Prosthetic Replacements	Calf implants	Implant for augmentation of Calf	C
10.	Blood Bags	Blood bags without anticoagulant	It is indicated for the collection of human blood and the preservation of blood components.	C
11.	Blood Bags	Blood bags with anticoagulant	It is indicated for the collection of human blood and the preservation of blood components.	C
12.	Catheters	Trocars	A trocar is made up of an obturator (which may be a metal or plastic sharpened or non-bladed tip), a cannula(basically a hollow tube), and a seal. The trocar functions as a portal for the subsequent placement of other instruments, such as graspers, scissors, staplers, etc. It is also intended to remove air or fluid for the pleural space in a closed, one way fashion.	B
13.	Catheters	Ureteral stent	Indicated to relieve obstructions in variety of benign, malignant and post-traumatic condition in the ureter. These conditions include stones and/or stone fragments or other Ureteral obstructions such as those associated with ureteral strictures, malignancy of abdominal organs, retroperitoneal fibrosis or ureteral trauma or in association with the Extracoporeal Shock wave	C

			lithotripsy (ESWL). The stent may be placed using endoscopic or percutaneously using standard or radiographic technique.	
14.	Heart Valves	Transcatheter Heart Valve	It is intended for people with symptomatic aortic stenosis who are considered an intermediate or high risk patient for standard valve replacement surgery.	D
15.	Surgical Dressings	Liquid bandage	Prevention of infection by limiting exposure to dirt and germs in case of minor cuts, abrasions and blisters.	B
16.	Disposable Perfusion Sets	Hemoconcentrator set	A hemoconcentrator is a fluid removal device used during cardio bypass surgery. The device is inserted into the extracorporeal circuit where it acts to control hemodilution, maintain hematocrit levels and reduce the need for additional blood products during and after surgery.	C
17.	Disposable Perfusion Sets	Apheresis Kit	Intended for the collection and separation of blood components	C
18.	Disposable Perfusion Sets	Blood Filter System	Intended for collection and preparation of various blood components	C
19.	Internal Prosthetic Replacements	Injectable implant for the treatment of vesicoureteral reflux	Treatment of vesicoureteral reflux	C
20.	Surgical Dressings	Bone wax/Haemostat	To stop bleeding at bones in orthopaedics and traumatology, thoracic surgery, dental, oral jaw surgery, neurosurgery.	C
21.	Disposable Hypodermic Syringes	Hyaluronic acid (cross linked) Pre-filled syringe	For intradermal implantation and facial soft tissue augmentation.	C
22.	Disposable Hypodermic Syringes	Crosslinked sodium hyaluronate	It is indicated as viscoelastic supplement or a replacement for synovial fluid in human joints. It is suited for treatment of symptoms of human joint dysfunctions such as osteoarthritis. The actions of the product are lubrication and mechanical support.	C
23.	Disposable Hypodermic Syringes	Hyaluronic acid with Lidocaine (cross linked) Pre-filled syringe	It is indicated for the treatment of fine lines and medium sized skin depressions and correcting infraorbital skin depressions via deep injection	C

24.	Disposable Perfusion Sets	Heat and moisture exchange/filter	It is intended to use for airway management by anaesthesia/respiratory care department.	B
25.	Catheters	Balloon dilators for Gastroenterology	Used to dilate strictures of the gastrointestinal tract, including strictures of the esophagus, pylorus, duodenum and colon.	C
26.	Internal Prosthetic Replacements	Hernia mesh	Indicated to reinforce soft tissue where weakness exists, i.e., repair of hernias and chest wall defects.	C
27.	Disposable Hypodermic Needles	Dental needles	Dental needles are used to deliver local anaesthetic to the operative site in order to make a patient as comfortable as possible.	B
28.	Disposable Hypodermic Needles	Spinal Needles	Used for diagnostic sampling of cerebrospinal fluid, delivering anesthetics and for the introduction of contrast medium	B
29.	Disposable Hypodermic Syringes	Ophthalmic Viscosurgical Device	Viscoelastic solution for Intraocular use during eye surgery.	C
30.	Catheters	Negative pressure wound therapy bandage	Intended to generate negative pressure or suction to remove wound exudates , infection materials and tissue debris from the wound bed which may promote wound healing.	C
31.	Ablation Devices	Needle Electrode	The needle electrode family is intended to be used in conjunction with the RF generator for the thermal coagulation necrosis of soft tissues, including partial or complete ablation of nonresectable liver lesions.	C
32.	Ablation Devices	Radio Frequency (RF) Generator	Intended for general use in electrosurgical coagulation of tissue.	C
33.	Surgical dressings	Absorbent Cotton wool	It is intended to used for applying medication to, or absorbing small amounts of body fluids	A

Notice

File No. 29/Misc/3/2018-DC(85)

Date: 06.06.2018

In continuation to the earlier Notice vide File No: 29/Misc./3/2017-DC(292) dated 01.11.2017 regarding Classification of medical devices and in vitro diagnostic medical devices under the provisions of the Medical Devices Rules, 2017, the Annexure-1 is hereby revised for the following changes:

1. Deletion of S.N. 333 i.e. Sterile Drapes.
2. Revision of risk class of following products:

S.N.	Product Name	Earlier Risk Classification	Revised Risk Classification
256	Intra Osseous Fixation Wire	Class B	Class C
259	Bone Wire	Class B	Class C
260	Bone Cap	Class B	Class C
321	Plates, Clippers, Screws	Class B	Class C

**LIST OF MEDICAL DEVICES AND IN VITRO DIAGNOSTICS
ALONG WITH THEIR RISK CLASS AS PER THE PROVISIONS
OF RULE 4 OF THE MEDICAL DEVICES RULES 2017**

(A) List of Medical Devices under provisions of sub-rule (1) rule 4 of the Medical Devices Rules, 2017

#	Notified Device Category/Drug	Device Name	Risk Class	General Intended Use
1.	Ablation Device	Vein Ablation Device	Class C	It is a non-thermal, minimally-invasive choice for treating the source of varicose veins, providing patients with immediate recovery and a return to normal daily routines
2.	Ablation Device	Thermal Ablation Device	Class C	Destruction of tissue by application of heat. Ablation of the endometrium as a treatment for menorrhagia is performed by placing a balloon filled with hot water in the uterine cavity.
3.	Ablation Device	Radiofrequency Ablation Device	Class D	A medical procedure in which part of the electrical conduction system of the heart, tumour or other dysfunctional tissue is ablated using the heat generated from high frequency alternating current
4.	Ablation Device	Percutaneous Conduction Tissue Ablation	Class D	Clinical applications using hollow needles (cryoprobes) through which cooled, thermally conductive, fluids are circulated.
5.	Ablation Device	Suction Ablation Catheter System	Class D	Intended for use in inactivating portions of the heart's conduction system to prevent abnormal heartbeat rates, comprises a tubular body having an open, distal end and a proximal aperture for applying suction through the catheter and through the distal end.

6.	Ablation Device	Uterine balloon therapy devices	Class C	System is a closed-cycle cryosurgical device intended to ablate the endometrial lining of the uterus in premenopausal women with menorrhagia (excessive bleeding) due to benign causes for whom childbearing is complete.
7.	Ablation Device	RF Conductive MR steerable electrode catheter	Class C	It is intended for intracardiac ablation.
8.	Bone Cements	Bone cement	Class C	Intended for use in arthroplastic procedures of the hip, knee, and other joints for the fixation of polymer or metallic prosthetic implants to living bone.
9.	Cardiac Stents	Coronary stent	Class D	A coronary stent is a tube-shaped device placed in the coronary arteries that supply blood to the heart, to keep the arteries open in the treatment of coronary heart disease.
10.	Cardiac Stents	Bioresorbable Vascular Scaffold (BVS) System	Class D	An absorbable stent which is placed into a blood vessel (coronary artery) during angioplasty to help keep the coronary artery open.
11.	Cardiac Stents	Bifurcation Stent	Class C	Intended for improving the side branch luminal diameter of arterial bifurcation liaisons.
12.	Catheters	Fiberoptic Oximeter Catheter	Class B	Intended for monitoring the balance between oxygen delivery and consumption at the bedside
13.	Catheters	A-V Shunt or Fistula Adapter	Class B	A blood access device and accessories is a device intended to provide access to a patient's blood for haemodialysis or other chronic uses.
15.	Catheters	Transcervical(Ami noscope) Endoscope and	Class B	It is a device designed to permit direct viewing of the foetus and amniotic sac by means of an open tube introduced

		accessories		into the uterus through the cervix.
16.	Catheters	Forceps, endoscopic	Class B	Grasping Forceps device is intended to be used to grasp tissue, retrieve foreign bodies, and remove tissue from within the gastrointestinal tract.
17.	Catheters	Transabdominal (Fetoscope) Aminoscope and Accessories	Class C	It is a device designed to permit direct visual examination of the foetus by a telescopic system via abdominal entry. The device is used to ascertain foetal abnormalities
18.	Catheters	Anaesthetic Conduction Kit	Class C	An anaesthesia conduction kit is a device used to administer to a patient conduction, regional, or local anaesthesia. The device may contain syringes, needles, and drugs.
19.	Catheters	Angiographic Guide Wire	Class D	It delivers radio opaque media and therapeutic agents to selected sites in the vascular system. It is also used to lead a guide wire or a catheter into the target site.
20.	Catheters	Cardiac Catherization Kit	Class D	Cardiac catheterization is a general term for a group of procedures that are performed using this method, such as coronary angiography and left ventricle angiography
21.	Catheters	Vena Cava Filter Sets	Class C	It is indicated for the prevention of recurrent pulmonary embolism via placement in the vena cava to treat various disease conditions.
22.	Catheters	Vessel Dialator for percutaneous Catheterization	Class B	A vessel dilator for percutaneous catheterization is a device which is placed over the guide wire to enlarge the opening in the vessel, and which is then removed before sliding the catheter over the guide wire.
23.	Catheters	Tracheobronchial Suction Catheter	Class B	Clearing the airways of mucus, pus, or aspirated materials to improve oxygenation and ventilation.
24.	Catheters	Cervical Drain	Class B	The device is used to avoid postoperative wound and respiratory complications such as excessive edema, hematoma, infection, re-intubation, delayed extubation, or respiratory distress

25.	Catheters	Rectal Balloon	Class B	Reducing the intrafraction motion and improving the sparing of rectal wall by reducing the rectal volume in the high-dose region, resulting in significant reduction in rectal toxicity.
26.	Catheters	Balloon for Cerebrovascular Occlusion	Class D	Balloon used to treat Blockage or closing of Cerebrovascular vessels/carotid arteries
27.	Catheters	Intra-Aortic System Balloon and Control	Class D	It is a mechanical device that increases myocardial oxygen perfusion while at the same time increasing cardiac output
28.	Catheters	Biliary Stone Retrieval Basket	Class B	Intend to extract stones in an antegrade fashion through an ampullary orifice previously treated by endoscopic sphincterotomy or less commonly with balloon dilation
29.	Catheters	Tracheostomy Tube/Tracheal Tube	Class B	A breathing tube inserted into a tracheotomy used to obtain a closed circuit for ventilation
30.	Catheters	Vial Adapter	Class B	It is indicated to allow multiple needleless access to injection medication vials for transfer or withdrawal of fluids from the vial.
31.	Catheters	Suprapubic, non-disposable Cannula	Class B	an emergency measure for the relief of acute urinary retention or condition which require temporary and permanent drainage of bladder.
32.	Catheters	Nasopharyngeal Catheter/Nasopharyngeal	Class A	A catheter (for adults) passed through the nares and advanced to the depth of the nasopharynx to remove air choke or obstruction. A Resuscitator.
33.	Catheters	Esophageal obturator	Class B	Inserted through a patient's mouth to aid ventilation of the patient during emergency resuscitation by occluding (blocking) the esophagus, thereby permitting positive pressure ventilation through the trachea.
34.	Catheters	Balloon Catheter for Retinal Reattachment	Class B	An instrument for reattachment of a detached retina to the inner wall of the eyeball. It can be inserted into the interior of the eyeball.
35.	Catheters	Gastric, Colonic, etc.) Irrigation and Aspiration Catheter	Class B	Used for instilling fluids into, withdrawing fluids from, splinting, or suppressing bleeding of the alimentary tract.

36.	Catheters	Suction Catheter Tip and	Class B	Suction Catheters feature a whistle tip and a thumb control port for precise and accurate suctioning.
37.	Catheters	Angiographic Catheter	Class B	Designed to provide a pathway for delivering contrast media to selected sites in the device vascular system including the carotid arteries.
38.	Catheters	Arterial Catheter	Class B	Intended to be used in conjunction with steerable guidewires in order to access discrete regions of the coronary and peripheral arterial vasculature.
39.	Catheters	Balloon Catheter Type	Class B	"Soft" catheter with an inflatable "balloon" at its tip which is used during a catheterization procedure to enlarge a narrow opening or passage within the body.
40.	Catheters	Balloon Dialation Vessel Catheter	Class B	Intended for use in Percutaneous Transluminal Angioplasty of the renal, tibial, popliteal, femoral and peroneal arteries. These catheters are not for use in coronary arteries.
41.	Catheters	Bartholin Gland Catheter	Class B	Catheter is used for the treatment of abscesses and cysts of the Hartholin gland.
42.	Catheters	Bronchography Catheter	Class B	Intended to deliver therapeutic and diagnostic agents that are indicated or labeled for airway, tracheal or
43.	Catheters	Cholangiography Catheter	Class B	Diagnostic evaluation of the bile ducts during laparoscopic cholecystectomy procedures
44.	Catheters	Anesthetic Conduction Catheter	Class B	An anesthesia conduction catheter is a flexible tubular device used to inject local anesthetics into a patient and to provide continuous regional anesthesia
45.	Catheters	Anesthesia conduction filter	Class C	A microporous filter used while administering to a patient injections of local anesthetics to minimize particulate (foreign material) contamination of the injected fluid
46.	Catheters	Continuous Flush Catheter	Class B	Intended for the controlled and selective infusion of
47.	Catheters	Continous Irrigation Catheter	Class B	Intended to be used to introduce fluids into body cavities other than blood vessels, drain fluids from body cavities, or evaluate certain physiologic conditions.

48.	Catheters	Coude Catheters	Class B	It is a urinary catheter, It may be used to inject liquids used for treatment or diagnosis of bladder conditions.
49.	Catheters	Depezzzer Catheter	Class B	A tubular, flexible instrument, passed through body channels for withdrawal of fluids from a body cavity.
50.	Catheters	Double lumen Female Urethrographic Catheter	Class B	Intended for vascular access infusion and withdrawal of blood, blood products, and fluids, plasma pheresis, hyperalimentation, central venous blood sampling and continuous and intermittent drug infusion.
51.	Catheters	Epidural Catheter	Class B	Epidural catheter is a very thin, flexible tube that is implanted into spine
52.	Catheters	Esophageal Balloon Catheter	Class B	intended for use in adult and adolescent populations
53.	Catheters	Eustachian Catheter	Class B	It is used to test Eustachian tube patency
54.	Catheters	Guiding Catheter	Class B	The guide catheter provides support for device advancement .
55.	Catheters	Haemodialysis Catheter	Class B	A catheter used for exchanging blood to and from the haemodialysis machine from the patient.
56.	Catheters	Central Venous Catheters	Class C	It is indicated for use in patients requiring administration of solutions, blood sampling, central venous pressure monitoring and injection of contrast media.
57.	Catheters	Intramuscular Pressure Monitoring Catheter	Class B	A modified fibre optic transducer-tipped catheter system for measuring intramuscular pressures during exercise was determined.
58.	Catheters	Introducer Sheath	Class C	Intended to provide easier access to the femoral, popliteal and infrapopliteal arteries.
59.	Catheters	Intravenous Catheter	Class B	A catheter that is inserted into a vein for supplying medications or nutrients directly into the bloodstream or for diagnostic purposes such as studying blood pressure
60.	Catheters	Jejunostomy Catheter	Class B	Used for intraoperative feeding jejunostomy
61.	Catheters	Multiple Lumen Catheter	Class B	Intended for monitoring central venous pressure (CVP), sampling blood, and

|  | | simultaneous administration of |

				multiple IV solutions or drugs.	
62.	Catheters	Nasal Catheter	Oxygen	Class B	It is a device used to deliver supplemental oxygen or increased airflow to a patient or person in need of respiratory help.
63.	Catheters	Embolic system	Filter	Class D	It is indicated for general use as a guidewire and embolic protection system during angioplasty and stenting procedures in carotid arteries with reference vessel diameters of 2.5 to 5.5mm.
64.	Catheters	Carotid Filter System		Class C	Used while performing angioplasty and stenting procedures in carotid arteries.
65.	Catheters	RETRIEVAL SNARE		Class C	intended for use in the retrieval and manipulation of atraumatic foreign bodies located in the coronary and peripheral cardiovascular system and the extra-cranial neurovascular anatomy.
66	Catheters	RETRIEVAL SNARE		Class D	intended for use in the retrieval and manipulation of atraumatic foreign bodies located in the coronary and peripheral system and the extra cranial neurovascular anatomy.
67.	Catheters	Nephrostomy Catheter		Class B	A nephrostomy is a tube that's used to drain urine from a kidney into a bag outside the body.
68.	Catheters	Peritoneal Catheter	Dialysis	Class B	That allows dialysis fluid to enter the abdominal cavity, dwell inside for a while, and then drain back out again
69.	Catheters	Radiographic (Non Vascular) Catheter		Class B	Interventional radiologists obtain images using needles and narrow tubes called catheters, rather than by making large incisions into the body as in traditional surgery.
70.	Catheters	Rectal Catheter		Class B	It is inserted into the rectum in order to relieve flatulence which has been chronic and which has not been alleviated by other methods.
71.	Catheters	Retention Catheter	Type	Class B	This type of catheter is placed into the bladder and secured there for a period of time.
72.	Catheters	Retention Catheter	Type	Class B	It has a balloon at the distal end, which is inflated with sterile water or saline to

		Balloon Catheter		prevent the catheter from slipping out of the bladder
73.	Catheters	Salpngography Catheter	Class B	Used for injection of contrast medium into the fallopian tube(s) for selective

				salpingography.
74.	Catheters	Single Needle Hemodialysis Catheter/Blood lines	Class B	The single-needle dialysis, in which case only one cannula or a single-lumen catheter is used to access the blood
75.	Catheters	Straight Catheter	Class B	It is used in patients with neurogenic bladder or spinal cord injury, lessens the risk of urinary tract infection
76.	Catheters	Subclavian Catheter	Class B	Catheters can be placed in veins in the neck (internal jugular vein), chest (subclavian vein or auxiliary vein),
77.	Catheters	Suprapubic Catheter	Class B	A suprapubic catheter is a thin, sterile tube used to drain urine from bladder.
78.	Catheters	Umbilical Artery Catheter	Class B	Umbilical artery catheterization provides direct access to the arterial blood supply and allows accurate measurement of arterial blood pressure, a source of arterial blood sampling, and intravascular access for fluids and medications
79.	Catheters	Upper Urinary Tract Catheter	Class B	The catheter to the bladder and subsequently to the upper urinary tract
80.	Catheters	Urethral Catheter/Nelaton Catheter/ Foley Catheter	Class B	A long, small gauge catheter designed for insertion directly into a ureter, either through the urethra and bladder or posteriorly via the kidney.
81.	Catheters	Urethrographic Male Catheter	Class B	A catheter used to pass into a man's bladder.
82.	Catheters	Chorionic Villus Sampling Catheter	Class B	An ultrasound guides a thin catheter through the cervix to your placenta. The chorionic villi cells are gently suctioned into the catheter.
83.	Catheters	Sclerotherapy Needle/ Catheter	Class B	Sclerotherapy Needles are designed to provide access for injection therapy applications and may also be used for polypectomy and endoscopic mucosal resection (EMR)
84.	Catheters	Water Jet Renal Catheter	Class B	A device used to dislodge stones from renal calyces (recesses of the pelvis of the kidney) by means of a pressurized stream of water through a conduit.

85.	Catheters	Hemodialysis Catheter (Long Term)	Class C	A dialysis catheter is a catheter used for exchanging blood to and from the hemodialysis machine from the patient. The dialysis catheter contains two lumens: Venous. Arterial
86.	Catheters	Percutaneous Intravascular Long Term Catheter	Class C	The device allows for repeated access to the vascular system for long-term use of 30 days or more, and it is intended for administration of fluids, medications, and nutrients; the sampling of blood;
87.	Catheters	Percutaneous Long Term Intraspinal Catheter	Class C	To conduct a preimplant intra spinal infusion screening trial procedure prior to implanting a pump
88.	Catheters	Implanted Subcutaneous Intravascular Port & Catheter	Class C	The device allows for repeated access to the vascular system for the infusion of fluids and medications and the sampling of blood
89.	Catheters	Subcutaneous Intraspinal Port & Catheter	Class C	Catheters used for both epidural Intrathecal infusion include short-term externalized catheters and long-term catheters that are tunnelled in the subcutaneous tissue
90.	Catheters	Peripheral, Transluminal Angioplasty Catheter	Class C	A catheter for treating peripheral vascular diseases
91.	Catheters	Cardiac Thermodilution Catheter	Class D	A catheter used in thermodilution for introduction of the cold liquid indicator into the cardiovascular system or for the assessment of a patient's hemodynamic condition through simultaneous right atrial, right ventricular, and pulmonary artery or wedge pressure monitoring, cardiac output determination, and for infusing solutions.
92.	Catheters	Cardiovascular Catheter	Class D	A thin, hollow tube called a catheter is inserted into a large blood vessel that leads to heart.
93.	Catheters	Cerebrospinal Catheter	Class D	For treatment or prevention of cranial/spinal cerebrospinal fluid fistula.
94.	Catheters	Atherectomy Coronary Catheter	Class D	A catheter containing a rotating cutter and a collecting chamber for debris, used for atherectomy and

				endarterectomy.
95.	Catheters	Electrode Recording Probe, Electrode Recording Catheter	Class D	A cardiac catheter containing one or more electrodes; it may be used to pace the heart or to deliver high energy shocks.
96.	Catheters	Oximetry catheters, Oximetry Paceport catheter	Class B	It is indicated for the assessment of a patient's hemodynamic condition through direct intracardiac and pulmonary artery pressure monitoring, cardiac output determination, continuous mixed venous oxygen saturation monitoring, and for infusing solutions
97.	Catheters	Embolectomy Catheter	Class D	indicated for the removal of fresh, soft emboli and
98.	Catheters	Flow Directed Catheter	Class B	Used for venous sampling and pressure monitoring.
99.	Catheters	Ultrasonic imaging Catheter	Class B	intended for ultrasound examination of peripheral pathology only
100.	Catheters	Intraaortic Balloon Catheter	Class D	It is indicated for use in patients undergoing cardiopulmonary bypass.
101.	Catheters	Intracardiac Mapping, High Density Array Catheter	Class D	A high density array catheter once used in the right atrium to map and diagnosis complex arrhythmias and assess the effectiveness of ablation treatment.
102.	Catheters	Coronary Dilation Catheter	Class C	It is intended for balloon dilatation of a hemodynamically significant coronary artery or bypass graft stenosis in patients evidencing coronary ischemia for the purpose of improving myocardial perfusion.
103.	Catheters	Intravascular Occluding Catheter	Class D	It is a catheter with an inflatable or detachable balloon tip that is used to block a blood vessel to treat malformations, e.g., aneurysms of intracranial blood vessels
104.	Catheters	Intravascular Diagnostic Catheter	Class D	Used to record intracardiac pressures, to sample blood, and to introduce substances into the heart and vessels.
105.	Catheters	Occlusion Catheter	Class D	Insertion of a device or develop at any time during the course of intravenous (IV) therapy.

106.	Catheters	Percutaneous Catheter	Class D	A needle catheter getting access to a blood vessel, followed by the introduction of a wire through the lumen (pathway) of the needle.
107.	Catheters	Diagnostic Radiology Catheters	Class C	Angiography catheters are designed to be used for delivering radiopaque media to selected sites in the vascular system in conjunction with routine diagnostic procedures.
108.	Catheters	Perfusion Catheter	Class D	Perfusion catheter allowing localised perfusion of drugs not only into the vessel lumen, but also directly into the vessel wall at low pressure, during coronary intervention. -
109.	Catheters	Pericardium Drainage Catheter	Class D	Catheter drainage of the pericardium
110.	Catheters	Atherectomy Peripheral Catheter	Class D	Intended for use in atherectomy of the peripheral vasculature.
111.	Catheters	Septostomy Catheter	Class D	Used to enlarge interatrial openings
112.	Catheters	Thrombectomy Catheter	Class D	Thrombectomy catheter is specifically designed to treat deep vein thrombosis (DVT) in large-diameter upper and lower peripheral veins.
113.	Catheters	Transluminal, Coronary Angioplasty, Percutaneous Catheter	Class D	The catheter is placed in the opening or ostium of one the coronary arteries
114.	Catheters	Ventricular Catheter	Class C	It is used to monitor pressure in patients with brain injuries, intracranial bleeds or other brain abnormalities that lead to increased fluid build-up.
115.	Catheters	Balloon Repair Kit Catheter	Class C	A device used to repair or replace the balloon of a balloon catheter. The kit contains the materials, such as glue and balloons, necessary to affect the repair or replacement.

116.	Catheters	Micro-catheter	Class C	It is intended to access the peripheral and neurovasculature for the controlled selective infusion of physician-specified therapeutic agents such as embolization materials and or diagnostic materials such as contrast media
117.	Catheters	Imaging Catheter	Class C	Intended for use with the various medical imaging consoles.
118.	Catheters	Central Nervous System Shunt including Neurological catheters and other Components	Class D	It is a device or combination of devices used to divert fluid from the brain or other part of the central nervous system to an internal delivery site or an external receptacle for the purpose of relieving elevated intracranial pressure or fluid volume.
119.	Catheters	Endoscopic Ligation Devices	Class B	It is used for proximal and distal ligation of vessels during endoscopic vessel harvesting procedures.
120.	Catheters	Dialysate Tubing and Connector	Class B	A tubing connector adapted for peritoneal dialysis connections between tubing sets and containers of dialysate
121.	Catheters	Urinary Drainage Unit	Class B	A closed urinary drainage system consists of a catheter inserted into the urinary bladder and connected via tubing to a drainage bag
122.	Catheters	Tympanostomy Tube	Class C	It is a small tube inserted into the eardrum in order to keep the middle ear aerated for a prolonged period of time, and to prevent the accumulation of fluid in the middle ear
123.	Catheters	In-Vitro Fertilization/ Embryo Transfer Catheter	Class B	A cellular transfer catheter is provided for implantation of cellular material into the uterus of a patient

124.	Catheters	Sclerotherapy Needle/ Catheter	Class B	It is designed to provide access for injection therapy applications and may also be used for polypectomy and endoscopic
125.	Catheters	Fluid Delivery tubing	Class B	Tube used to deliver fluid in body
126.	Catheters	Colon Tube	Class B	Colon Tubes also called "Tips" or even Catheters are inserted from the anus, through the rectum to deliver your enema solution into the colon (large intestine).
127.	Catheters	Connecting Tube	Class B	Used to provide connection to a drainage bag.
128.	Catheters	Decompression Tube	Class B	Decompression using a rectal tube may assist in the treatment only if the sigmoid colon is involved.
129.	Catheters	Double Lumen for intestinal Decompression and/or Intubation Tube	Class B	Tracheal intubation, usually simply referred to as intubation, is the placement of a flexible plastic tube into the trachea (windpipe) to maintain an open airway or to serve as a conduit through which to administer certain drugs.
130.	Catheters	Closed Wound Drainage Tube or System	Class B	A surgical drain is a tube used to remove pus, blood or other fluids from a wound. They are commonly placed by surgeons or interventional radiologists.
131.	Catheters	Oesophageal Blakemore Tube	Class B	It is a medical device inserted through the nose or mouth and used occasionally in the management of upper gastrointestinal hemorrhage due to oesophageal varices .
132.	Catheters	Oesophageal Sengstaken Tube	Class B	It is used only in emergencies where bleeding from presumed varices is impossible to control with medication alone
133.	Catheters	Feeding Tube	Class B	A feeding tube is a device that's inserted into your stomach through your abdomen. It's used to supply nutrition when you have trouble eating

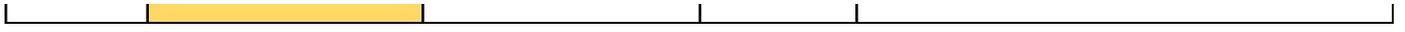
134.	Catheters	Gastro-Enterostomy Tube	Class B	Tube is placed through the abdominal wall into the stomach and then through the duodenum into the jejunum.
135.	Catheters	Gastrointestinal Tube	Class B	A gastrostomy tube (also called a G-tube) is a tube inserted through the abdomen that delivers nutrition directly to the stomach
136.	Catheters	Heart-Lung Bypass Unit Tube	Class B	A tube will be placed in your heart to drain blood to the machine.
137.	Catheters	Levine Tube	Class B	Used for the aspiration of gastric and intestinal contents and administration of tube feedings or medications.
138.	Catheters	NasoGastric Tube/ Ryles Tube	Class B	It is a special tube that carries food and medicine to the stomach through the nose. It can be used for all feedings or for giving a person extra calories.
139.	Catheters	Nephrostomy Tube	Class B	The nephrostomy tube drains urine from kidney into a collecting bag outside the body.
140.	Catheters	Orthodontic Tube	Class B	An orthodontic small metal part welded on the outside of a molar band, which contains slots to hold archwires, lip bumpers, facebows and other devices used to move the teeth.
141.	Catheters	Rectal Tube	Class B	A rectal tube, also called a rectal catheter, is a long slender tube which is inserted into the rectum in order to relieve flatulence .
142.	Catheters	Stomach Evacuator(Gastric Lavage) Tube	Class B	Passage of a tube via the mouth or nose down into the stomach followed by sequential administration and removal of small volumes of liquid.
143.	Catheters	Tonsil Suction Tube	Class B	Used to suck out stones in tonsils.
144.	Catheters	Tracheal (Endotracheal) Tube	Class B	Inserts the tube with the help of a laryngoscope, an instrument that permits to see the upper portion of the trachea, just below the vocal cords.
145.	Catheters	Closed Suction System	Class B	It is intended for endotracheal suctioning to provide a patient airway by removing excess fluids, secretions, exudates and transudate through the artificial airway.

146.	Catheters	Anastomosis Bypass Tube	Class C	It is anchored to mucosa and submucosa 3 centimetres proximal to a site of colocolonic anastomosis and later spontaneously evacuated by way of the rectum.
147.	Catheters	Endolymphatic Shunt Tube	Class B	During a surgical procedure in which it is placed in the membranous labyrinth of the inner ear to drain excess fluid.
148.	Catheters	Orthodontic Guide Wire	Class B	A wire conforming to the alveolar or dental arch that can be used with dental braces as a source of force in correcting irregularities in the position of the teeth
149.	Catheters	Intra-aortic balloon and control system	Class D	It is a medical device which is placed in the aorta to improve cardiovascular functioning during certain life-threatening emergencies.
150.	Catheters	Ventricular bypass (assistive)	Class D	A ventricular bypass (assistive) device is a device that assists the left or right ventricle in maintaining circulatory blood flow.
151.	Catheters	Catheter Guide Wire	Class D	It is intended to facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). The PTCA Guide Wires are not to be used in the cerebral blood vessel
152.	Catheters	Catheter Guide	Class D	It is intended to facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). PTCA Guide Wires are not to be used in the cerebral blood vessel.
153.	Catheters	Wire	Class C	An esophageal stent is a stent (tube) placed in the oesophagus to keep a blocked area open so the patient can swallow soft food and liquids
	Catheters			Biliary stents provide bile drainage from the gallbladder, pancreas and bile ducts to

154.		Biliary stents	Class C	the duodenum in conditions such as ascending cholangitis due to obstructing gallstones

155.	Catheters	Duodenal stents	Class C	Duodenal Stent is indicated for the palliative treatment of gastroduodenal obstructions
156.	Catheters	Colonic stent	Class C	A colonic stent is a flexible, hollow tube designed to keep a segment of the colon (large bowel) open when it has become blocked(obstructed). This blockage is commonly caused by a tumour inside the bowel or by outside pressure on the bowel wall.
157.	Catheters	Pancreatic stent	Class C	Pancreatic duct stents are often placed in patients who have chronic pancreatitis
158.	Catheters	Carotid Stent System	Class D	Indicated for the treatment of patients at high risk for adverse events from carotid endarterectomy who require carotid revascularization.
159.	Catheters	Peripheral Stent System	Class C	A Peripheral stent is a tube-shaped device placed in the peripheral arteries that supply blood into body organ.
160.	Contraceptives	Tubal Rings/ Fallopian Rings	Class C	Contraception devices for female sterilization
161.	Contraceptives	Male / Female Condoms	Class C	Condom with nonoxynol-9, micro-condom, prophylactic (condom) – latex sheath, non-latex, condoms with natural membrane, intra vaginal condoms etc.
162.	Contraceptives	Cu-T	Class D	Indicated for intrauterine contraception for up to 10 years.
163.	Disinfectants	Disinfectants	Class B	An agent that destroys pathogenic and other kinds of microorganisms by chemical or physical means. A disinfectant destroys most recognized pathogenic microorganisms, but not necessarily all microbial forms, such as bacterial spores. It is intended to disinfect a medical device.
164.	Disposable Hypodermic Needles	Aspiration Needle	Class B	Used for either laparoscopic aspiration or injection

165.	Disposable Hypodermic Needles	Aspiration and Injection Needle	Class B	A thin needle is inserted into an area of abnormal-appearing tissue or body fluid. As with other types of biopsies, the sample collected during fine needle aspiration can help make a diagnosis or rule out conditions such as cancer.
166.	Disposable Hypodermic Needles	Insulin Needles/Pen Needles for insulin	Class B	Used to inject insulin for the treatment of diabetes.
167.	Disposable Hypodermic Needles	Medication Injector	Class B	A subcutaneous injection is a method of administering medication.
168.	Disposable Hypodermic Needles	Biopsy Needle Kit	Class B	A set of neurosurgical instruments designed to allow multiple biopsies from one or more targets in one trajectory
169.	Disposable Hypodermic Needles	Angiographic Needle	Class B	Angiographic needle has a unique hub design with an ergonomic feel and a black triangle indicator to orient the bevel.
170.	Disposable Hypodermic Needles	Mammary Biopsy Needle	Class B	The growth sample is suctioned out through a needle or cut out using a surgical procedure
171.	Disposable Hypodermic Needles	Blood Collecting Needle	Class B	Intended to be used with evacuated blood collection tube for collection of venous blood.
172.	Disposable Hypodermic Needles	Bone Marrow Needle	Class B	Needle inserted in Bone Marrow to collect sample
173.	Disposable Hypodermic Needles	Gynaecological Cerclage Needle	Class B	It is a loop like instrument used to suture the cervix.
174.	Disposable Hypodermic Needles	Cholangiography Needle	Class B	The aspirating needle is passed through the patient's skin and liver tissue until the tip penetrates one of the hepatic ducts
175.	Disposable Hypodermic Needles	Anaesthetic Conduction Needle	Class B	An anaesthesia conduction needle is a device used to inject local anaesthetics into a patient to provide regional anaesthesia
176.	Disposable Hypodermic Needles	Emergency Airway Needle	Class B	Emergency airway puncture is the placement of a hollow needle through the throat into the airway. It is done to treat life-threatening choking.



177.	Disposable Hypodermic Needles	Endoscopic Needle	Class B	Used to sample targeted submucosal gastrointestinal lesions through the accessory channel of an ultrasound endoscope.
178.	Disposable Hypodermic Needles	Fistula Needle	Class B	To connect blood lines with the blood vessels through needles when dialysis is carried out
179.	Disposable Hypodermic Needles	Epidural Needle	Class B	Intended for transient delivery of anesthetics to provide regional anesthesia or to facilitate placement of an epidural catheter
180.	Disposable Hypodermic Needles	Gastro-Urology Needle	Class B	Intended for gastroenterology biopsy
181.	Disposable Hypodermic Needles	Single Lumen Hypodermic Needle	Class B	A hypodermic single lumen needle is a device intended to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin.
182.	Disposable Hypodermic Needles	Neurosurgical Suture Needle	Class B	A needle used in suturing during neurosurgical procedures or in the repair of nervous tissue.
183.	Disposable Hypodermic Needles	Oocyte Aspiration Needle	Class B	Mission to collect the maximum amount of undamaged oocytes in a short time as possible.
184.	Disposable Hypodermic Needles	Pneumoperitoneum Simple Needle	Class B	Inserting a Veress needle through the abdominal wall inside the peritoneal cavity.
185.	Disposable Hypodermic Needles	Prefillable Glass Barrel with needle	Class B	Intended for the automatic self-administration of drugs and biologics from standard Glass Barrel.
186.	Disposable Hypodermic Syringes	Injector Type actuator syringe	Class C	A syringe actuator for an injector is an electrical device that controls the timing of an injection by an angiographic or indicator injector and synchronizes the injection with the electrocardiograph signal.
187.	Disposable Hypodermic Syringes	Aspiration Syringe	Class B	Used for either laparoscopic aspiration or injection
188.	Disposable Hypodermic Syringes	Irrigating Syringes	Class B	cleaning debris away from the area the dentist is working on

189.	Disposable Hypodermic Syringes	Insulin Syringes	Class B	Used to inject insulin for the treatment of diabetes.
	Disposable Hypodermic Syringes	Auto Disable Syringe for single use	Class B	Intend to inject fluids into or withdraw fluids from the body.
191.	Disposable Hypodermic Syringes	Traditional single use syringe without safety feature (Sterile hypodermic syringes for single use)	Class B	Intend to inject fluids into or withdraw fluids from the body.
192.	Disposable Hypodermic Syringes	Auto-disable (AD) syringes for immunization	Class B	Intend to inject fluids into or withdraw fluids from the body.
193.	Disposable Hypodermic Syringes	Re use Prevention (RUP) syringes for therapeutic injections (Syringes with re-use prevention feature)	Class B	Intend to inject fluids into or withdraw fluids from the body.
194.	Disposable Hypodermic Syringes	Sharps Injury Protection (SIP) Plastic needle shield to be added to a syringe	Class B	Intend to inject fluids into or withdraw fluids from the body.
195.	Disposable Perfusion Sets	Sharps Injury Blood Administration kits	Class B	It is used to administer blood from a container to a patient's vascular system through a needle or catheter inserted

				into a vein
196.	Disposable Perfusion Sets	Measured Volume IV Set	Class B	It is intended for use in the administration of fluids from a container into the patient's vascular system through a vascular access device.
197.	Disposable Perfusion Sets	Transfusion or Perfusion sets for single use	Class B	Transfusion Set is used to administer blood/drugs to a patient's vascular system through a needle or catheter inserted into a vein.
198.	Disposable Perfusion Sets	Custom Perfusion System	Class C	Indicated for use in the extra corporeal circuit during cardio pulmonary bypass surgery procedure.
199.	Disposable Perfusion Sets	Manifolds	Class B	Indicated for fluid flow directional control and for providing access port/ports for administration of a solution.
200.	Disposable Perfusion Sets	3 way stop cock as an accessory to perfusion sets	Class B	It is indicated for fluid flow directional control and for providing access port for administration of solution, withdrawal of fluid and pressure monitoring
201.	Disposable Perfusion Sets	Y-Connector as an accessory to perfusion sets	Class A	It can be used to connect to a perfusion sets or catheter for infusion of contrast media etc.
202.	Disposable Perfusion Sets	I V Flow regulator	Class B	An IV system and administration device offering precision care and consistent delivery.
203.	Disposable Perfusion Sets	Extension Sets	Class B	Extension sets are sterile devices for single use only. They are intended to be used as part of a system for the infusion of fluids/medications in medical applications.
204.	Disposable Perfusion Sets	Infusion Pump or Elastomeric Infusion Device	Class C	The Infusion Pumps intended for slow, continuous delivery through clinically acceptable routes of administration such as intravenous (IV), intra-arterial (IA), and subcutaneous or epidural infusion of medications directly into an intra-operative site or subcutaneously for post operative pain management.

205.	Drug Eluting Stents	Drug eluting stent	Class D	Stent, coronary, drug-eluting - a metal scaffold with a drug coating placed via a delivery catheter into the coronary artery or saphenous vein graft to maintain the lumen. The drug coating is intended to inhibit restenosis.
206.	Heart Valves	Heart valve	Class D	A device intended to perform the function of any of the heart's natural valves.
207.	Internal Prosthetic Replacements	Tissue Expanders	Class C	Intended to be used in breast reconstruction or treatment of soft tissue deformities such as used following mastectomy or for treatment of underdeveloped breasts.
208.	Internal Prosthetic Replacements	Bio Patches	Class C	Intended for reconstruction and repair of defects of pericardium.
209.	Internal Prosthetic Replacements	Vascular graft/occluders/Cardiac Patches	Class D	Intended to repair, replace, or bypass sections of native or artificial vessels, excluding coronary or cerebral vasculature, and to provide vascular access.
210.	Internal Prosthetic Replacements	Vascular embolization device	Class D	It is an intravascular implant intended to control hemorrhaging due to aneurysms, certain types of tumors.
211.	Internal Prosthetic Replacements	Voice / laryngeal Prothesis	Class C	The device is intended to direct pulmonary air flow to the pharynx in the absence of the larynx, for permitting esophageal speech.
212.	Internal Prosthetic Replacements	Cardiovascular prosthetic devices	Class D	An intra-cardiac patch or pledgete which is a medical device placed in the heart and is used to repair septal defects, for patch grafting, to repair tissue, and to buttress sutures.

213.	Internal Prosthetic Replacements	Hearing Prosthesis System	Class C	The prostheses are intended for partial ossicular replacement to restore functionality to the middle ear .
214.	Internal Prosthetic Replacements	Annuloplasty ring	Class C	An annuloplasty ring implanted around the mitral or tricuspid heart valve for reconstructive treatment.
215.	Internal Prosthetic Replacements	Total ossicular replacement prosthesis	Class D	It is a device intended to be implanted for the functional reconstruction of segments of the ossicular chain and facilitates the conduction of sound wave from the tympanic membrane to the inner ear.
216.	Internal Prosthetic Replacements	Ear, nose, and throat and facial synthetic polymer material or implant	Class C	It is a device material that is intended to be implanted for use as a space-occupying substance in the reconstructive surgery of the head and neck.
217.	Internal Prosthetic Replacements	Mandibular implant facial prosthesis	Class C	Intended to be implanted for use in the functional reconstruction of mandibular deficits.
218.	Internal Prosthetic Replacements	Sacculotomy tack (Cody tack)	Class C	Intended to be implanted to relieve the symptoms of vertigo.
219.	Internal Prosthetic Replacements	Endolymphatic shunt	Class C	Intended to be implanted to relieve the symptoms of vertigo.
220.	Internal Prosthetic Replacements	An endolymphatic shunt tube with valve	Class C	It is a device that consists of a pressure-limiting valve associated with a tube intended to be implanted in the inner ear to relieve symptoms of vertigo and hearing loss.
221.	Internal Prosthetic Replacements	Fallopian tube prosthesis	Class C	A device designed to maintain the patency (openness) of the fallopian tube and is used after reconstructive surgery.
222.	Internal Prosthetic Replacements	Vaginal stent	Class C	A device used to enlarge the vagina by stretching, or to support the vagina and to hold a skin graft after reconstructive surgery.
223.	Internal Prosthetic Replacements	Eye sphere implant	Class D	An eye sphere implant is a device intended to be implanted in the eyeball to occupy space following the removal of the contents of the eyeball with the sclera left intact.

224.	Internal Prosthetic Replacements	Keratoprosthesis	Class D	It is a device intended to provide a transparent optical pathway through an opacified cornea, either intraoperatively or permanently, in an eye.
225.	Internal Prosthetic Replacements	Bone heterograft	Class D	Intended to be implanted that is made from bovine bones and used to replace human bone following surgery in the cervical region of the spinal column.
226.	Internal Prosthetic Replacements	Intramedullary fixation rod	Class C	Intended to be implanted into the medullary (bone marrow) canal of long bones for the fixation of fractures.
227.	Internal Prosthetic Replacements	Endosseous dental implant	Class C	Intended to be surgically placed in the bone of jaw arches to provide support for prosthetic devices, such as artificial teeth.
228.	Internal Prosthetic Replacements	Dental implant	Class C	A dental implant is a surgical component that interfaces with the bone of the jaw or skull to support a dental prosthesis such as crown, bridge, denture, facial prosthesis or to act as an orthodontic anchor.
229.	Internal Prosthetic Replacements	Bone grafting material	Class C	Intended to fill, augment, or reconstruct periodontal or bony defects of the oral and maxillofacial region.
230.	Internal Prosthetic Replacements	Total temporomandibular joint prosthesis	Class D	Intended to be implanted in the human jaw to replace the mandibular condyle and augment the glenoid fossa to functionally reconstruct the temporomandibular joint.
231.	Internal Prosthetic Replacements	Glenoid fossa prosthesis	Class D	Intended to be implanted in the temporomandibular joint to augment a glenoid fossa or to provide an articulation surface for the head of a mandibular condyle.
232.	Internal Prosthetic Replacements	Mandibular condyle prosthesis	Class D	Intended to be implanted in the human jaw to replace the mandibular condyle and to articulate within a glenoid fossa.
233.	Internal Prosthetic Replacements	An interarticular disc prosthesis	Class D	Intended to be an interface between the natural articulating surface of the mandibular condyle and glenoid fossa.

234.	Internal Prosthetic Replacements	Penile inflatable implant	Class D	A penile inflatable implant is a device which is implanted in the penis, connected to a reservoir filled with radiopaque fluid implanted in the abdomen, and a subcutaneous manual pump implanted in the scrotum. This device is used in the treatment of erectile impotence.
235.	Internal Prosthetic Replacements	Penile rigidity implant	Class C	A device that is implanted in the corpora cavernosa of the penis to provide rigidity. It is intended to be used in men diagnosed as having erectile dysfunction
236.	Internal Prosthetic Replacements	Artificial Urinary Sphincters implants	Class C	It is used to prevent incontinence by occluding the urethra.
237.	Internal Prosthetic Replacements	Implanted mechanical/hydraulic urinary continence device	Class C	An implanted mechanical/hydraulic urinary continence device is a device used to treat urinary incontinence by the application of continuous or intermittent pressure to occlude the urethra.
238.	Internal Prosthetic Replacements	Cochlear implant	Class D	A cochlear implant is an implanted electronic hearing device, designed to produce useful hearing sensations to a person with severe to profound nerve deafness by electrically stimulating nerves inside the inner ear.
239.	Internal Prosthetic Replacements	Retinal implant	Class D	The retinal implant is meant to partially restore useful vision to people who have lost their vision due to degenerative eye conditions
240.	Internal Prosthetic Replacements	Breast implant	Class C	Breast implant is used to increase the breast size.
241.	Internal Prosthetic Replacements	Tracheal prosthesis	Class C	It is intended to be implanted to restore the structure and/or function of the trachea or trachealbronchial tree
242.	Internal Prosthetic Replacements	Polymeric Surgical Mesh	Class C	The polymeric mesh comprises an absorbable polymeric fibre and a non-absorbable polymeric fibre knitted together to form an interdependent, co-knit mesh structure.
243.	Internal Prosthetic Replacements	Endosseous dental implant abutment	Class C	Intended for use as an aid in prosthetic rehabilitation.

244.	Internal Prosthetic Replacements	A testicular prosthesis	Class D	A testicular prosthesis is an implanted device that consists of a solid or gel-filled silicone rubber prosthesis that is implanted surgically to resemble a testicle.
	Internal Prosthetic Replacements	Aneurysm Implant (detachable coils/clips)	Class D	It is intended for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae.
246.	Intra Ocular Lenses	Intraocular lens	Class C	Intraocular lens (IOL) are lens implanted in the eye used to treat cataracts or myopia
247.	IV Cannulae	Intravenous Cannula	Class B	The IV Cannula is a passive device to provide for the infusion of fluids, drugs, and/or blood components, or to facilitate the placement of Vascular Access devices .
248.	IV Cannulae	Arterial Cannula	Class B	Inserted into an artery, commonly the radial artery, and is used during major operations and in critical care areas to measure beat-to-beat blood pressure and to draw repeated blood samples.
249.	IV Cannulae	Coronary Artery Cannula	Class B	Cannulation technique for left-sided coronary artery surgery.
250.	IV Cannulae	Hemodialysis Cannula	Class B	Allowing the arterial blood to flow to the dialyzer and the dialyzed blood to return from the dialyzer to the circulation through the cannula in the vein.
251.	IV Cannulae	Vena Cava Cannula	Class B	Inserted into Vena Cava, taking deoxygenated blood to heart.
252.	IV Cannulae	Venous Cannula	Class B	It is intended for use as a single cannula for both venous drainage and reinfusion of blood via an internal jugular vein during extracorporeal life support procedures.
253.	IV Cannulae	Ventricular Cannula	Class B	For use in neurosurgical procedures. It is specially designed to penetrate delicate brain tissue and give continued access to brain's ventricular system.
254.	IV Cannulae	A-V Shunt Cannula	Class C	It is inserted into one of the client's blood vessels to facilitate repeated hemodialysis.

255.	IV Cannulae	Cannula or Lymph Duct	Class B	A lymph duct is a great lymphatic vessel that empties lymph into one of the subclavian veins
256.	Orthopaedic Implants	Intra Osseous Fixation Wire	Class C	Stabilization of fractured bony parts by direct fixation to one another with surgical wires
257.	Orthopaedic Implants	Cortical Fixation Implant / rigidloop Adjustable Cortical Fixation System	Class C	Cortical Fixation System is a machined titanium implant designed to provide fixation in the repair of tendons and ligaments.
258.	Orthopaedic Implants	Intervertebral Body Fusion Device / Fuse Spinal System	Class C	It is indicated for use with autogenous bone graft in skeletally mature patients with degenerative disc disease ("DDD") at one or two contiguous spinal levels.
259.	Orthopaedic Implants	Bone Wire	Class C	Intended to be used for bone stabilization in the hand and wrist.
260.	Orthopaedic Implants	Bone cap	Class C	Intended to be implanted to cover the end of a bone.
261.	Orthopaedic Implants	Orthopedic implant & accessories	Class C	Intended to replace a missing joint or bone or to support a damaged bone.
262.	Orthopaedic Implants	Intervertebral body fusion device	Class D	The device is inserted into the intervertebral body space of the cervical or lumbosacral spine, and is intended for intervertebral body fusion
263.	Orthopaedic Implants	Pedicle screw spinal system	Class C	It is used to intended to provide immobilization and stabilization of spinal segments
264.	Orthopaedic Implants	Ankle joint metal/composite semi-constrained cemented prosthesis	Class C	An ankle joint metal/composite semi-constrained cemented prosthesis is a device intended to be implanted to replace an ankle joint.
265.	Orthopaedic Implants	Ankle joint metal/polymer non-constrained cemented prosthesis	Class C	A device intended to be implanted to replace an ankle joint. The device limits minimally translation in one or more planes. It has no linkage across-the-joint.
266.	Orthopaedic Implants	Elbow joint metal/polymer constrained cemented prosthesis	Class C	An elbow joint metal/polymer constrained cemented prosthesis is a device intended to be implanted to replace an elbow joint.

267.	Orthopaedic Implants	Elbow joint metal/polymer semi-constrained cemented prosthesis	Class C	An elbow joint metal/polymer semi-constrained cemented prosthesis is a device intended to be implanted to replace an elbow joint
268.	Orthopaedic Implants	elbow joint radial (hemi-elbow) polymer	Class C	An elbow joint radial (hemi-elbow) polymer prosthesis is a device intended to be implanted made of medical grade silicone elastomer used to replace the proximal end of the radius.
269.	Orthopaedic Implants	Elbow joint humeral (hemi-elbow) metallic uncemented prosthesis	Class C	A device intended to be implanted made of alloys, such as cobalt-chromium-molybdenum, that is used to replace the distal end of the humerus formed by the trochlea humeri and the capitulum humeri
270.	Orthopaedic Implants	elbow joint humeral (hemi-elbow) metallic uncemented prosthesis	Class C	A device intended to be implanted made of alloys, such as cobalt-chromium-molybdenum, that is used to replace the distal end of the humerus formed by the trochlea humeri and the capitulum humeri
271.	Orthopaedic Implants	Finger joint metal/metal constrained uncemented prosthesis	Class C	A device intended to be implanted to replace a metacarpophalangeal or proximal interphalangeal (finger) joint
272.	Orthopaedic Implants	Finger joint metal/metal constrained cemented prosthesis	Class C	A finger joint metal/metal constrained cemented prosthesis is a device intended to be implanted to replace a metacarpophalangeal (finger) joint
273.	Orthopaedic Implants	Finger joint polymer constrained prosthesis	Class C	A device intended to be implanted to replace a metacarpophalangeal or proximal interphalangeal (finger) joint
274.	Orthopaedic Implants	hip joint metal constrained cemented or uncemented prosthesis	Class D	A hip joint metal constrained cemented or uncemented prosthesis is a device intended to be implanted to replace a hip joint
275.	Orthopaedic Implants	Hip joint metal/polymer constrained cemented or uncemented	Class D	A hip joint metal/polymer constrained cemented or uncemented prosthesis is a device intended to be implanted to replace a hip joint

		prosthesis		
276.	Orthopaedic Implants	Hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis.	Class D	It is a prosthesis intended to be implanted to replace a hip joint
277.	Orthopaedic Implants	hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis	Class D	Intended to be implanted to replace a hip joint
278.	Orthopaedic Implants	hip joint metal/composite semi-constrained cemented prosthesis	Class C	A hip joint metal/composite semi-constrained cemented prosthesis is a two-part device intended to be implanted to replace a hip joint
279.	Orthopaedic Implants	Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis	Class C	Intended to be implanted to replace a hip joint
280.	Orthopaedic Implants	Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis.	Class C	Intended to be implanted to replace a hip joint
281.	Orthopaedic Implants	A knee joint femorotibial metallic constrained cemented prosthesis is a device intended to be implanted to replace part of a	Class C	Intended to be implanted to replace part of a knee joint

		knee joint		
282.	Orthopaedic Implants	Shoulder joint metal/metal or metal/polymer constrained cemented prosthesis	Class C	Intended to be implanted to replace a shoulder joint
283.	Orthopaedic Implants	Wrist joint carpal lunate polymer prosthesis	Class C	Intended to be implanted to replace the carpal lunate bone of the wrist.
284.	Orthopaedic Implants	Wrist joint metal/polymer semi-constrained cemented prosthesis	Class C	Intended to be implanted to replace a wrist joint.
285.	Orthopaedic Implants	Wrist joint metal constrained cemented prosthesis	Class C	Intended to be implanted to replace a wrist joint
286.	Orthopaedic Implants	Wrist joint polymer constrained prosthesis	Class C	Intended to be implanted to replace a wrist joint
287.	Orthopaedic Implants	Wrist joint carpal trapezium polymer prosthesis	Class C	Intended to be implanted to replace the carpal trapezium bone of the wrist
288.	Orthopaedic Implants	Wrist joint carpal scaphoid polymer prosthesis	Class C	Intended to be implanted to replace the carpal scaphoid bone of the wrist.
290.	Orthopaedic Implants	Toe joint phalangeal (hemi- toe) polymer prosthesis	Class C	Intended to be implanted to replace the base of the proximal phalanx of the toe.
291.	Orthopaedic Implants	Toe joint polymer constrained prosthesis	Class C	Intended to be implanted to replace the first metatarsophalangeal (big toe) joint

292.	Orthopaedic Implants	Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis.	Class C	A shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis.
293.	Orthopaedic Implants	Shoulder joint glenoid (hemi-shoulder) metallic cemented prosthesis	Class C	It is intended to be implanted to replace part of a shoulder joint
294.	Orthopaedic Implants	Shoulder joint metal/polymer/metal nonconstrained or semi-constrained porous-coated uncemented prosthesis	Class C	It is a device intended to be implanted to replace a shoulder joint
295.	Orthopaedic Implants	Shoulder joint metal/polymer semi-constrained cemented prosthesis	Class C	Intended to be implanted to replace a shoulder joint
296.	Orthopaedic Implants	shoulder joint metal/polymer non-constrained cemented prosthesis	Class C	Intended to be implanted to replace a shoulder joint
297.	Orthopaedic Implants	Knee joint tibial (hemi-knee) metallic resurfacing uncemented prosthesis	Class C	Intended to be implanted to replace part of a knee joint
298.	Orthopaedic Implants	Knee joint patellar (hemi-knee) metallic resurfacing uncemented prosthesis	Class C	Intended to be implanted to replace the retropatellar articular surface of the patellofemoral joint
299.	Orthopaedic Implants	knee joint femoral (hemi-knee) metallic uncemented prosthesis	Class C	Intended to be implanted to replace part of a knee joint.

300.	Orthopaedic Implants	knee joint patellofemorotibial metal/polymer	Class C	Intended to be implanted to replace a knee joint
301.	Orthopaedic Implants	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis.	Class C	Intended to be implanted to replace a knee joint
302.	Orthopaedic Implants	Knee joint patellofemorotibial polymer/metal/metal constrained cemented prosthesis	Class C	Intended to be implanted to replace a knee joint
303.	Orthopaedic Implants	knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis	Class C	It is intended to be implanted to replace part of a knee joint in the treatment of primary patellofemoral arthritis or chondromalacia
304.	Orthopaedic Implants	Knee joint femorotibial (unicompartamental) metal/polymer porous-coated uncemented prosthesis	Class C	Intended to be implanted to replace part of a knee joint
305.	Orthopaedic Implants	Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis	Class C	Intended to be implanted to replace part of a knee joint
306.	Orthopaedic Implants	Knee joint femorotibial metal/polymer non-constrained cemented prosthesis	Class C	Intended to be implanted to replace part of a knee joint
307.	Orthopaedic Implants	Knee joint femorotibial metal/polymer constrained cemented	Class C	Knee joint femorotibial metal/polymer constrained cemented prosthesis

		prosthesis		
308.	Orthopaedic Implants	Knee joint femorotibial metal/polymer constrained cemented prosthesis	Class C	Intended to be implanted to replace part of a knee joint
309.	Orthopaedic Implants	Knee joint femorotibial metal/composite semi-constrained cemented prosthesis	Class C	Intended to be implanted to replace part of a knee joint.
310.	Orthopaedic Implants	Knee joint femorotibial metal/composite non-constrained cemented prosthesis	Class C	Intended to be implanted to replace part of a knee joint
311.	Orthopaedic Implants	Hip joint metal/polymer or ceramic/polymer semiconstrained resurfacing cemented prosthesis.	Class C	Intended to be implanted to replace the articulating surfaces of the hip while preserving the femoral head and neck
312.	Orthopaedic Implants	Hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis	Class D	Intended to be implanted to replace a hip joint
313.	Orthopaedic Implants	hip joint metal constrained cemented or uncemented prosthesis	Class D	Intended to be implanted to replace a hip joint
314.	Orthopaedic Implants	Hip joint metal/polymer constrained cemented or uncemented	Class D	Intended to be implanted to replace a hip joint

		prosthesis		
315.	Orthopaedic Implants	Hip joint femoral (hemi-hip) metallic resurfacing prosthesis	Class D	Intended to be implanted to replace a portion of the hip joint
316.	Orthopaedic Implants	A hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis	Class D	Intended to be implanted to replace the head and neck of the femur
317.	Orthopaedic Implants	A hip joint femoral (hemi-hip) trunnion-bearing metal/polyacetal cemented prosthesis	Class D	Intended to be implanted to replace the head and neck of the femur
318.	Orthopaedic Implants	Hip joint femoral (hemi-hip) trunnion-bearing metal/polyacetal cemented prosthesis.	Class D	Intended to be implanted to replace the head and neck of the femur
319.	Orthopaedic Implants	A hip joint (hemi-hip) acetabular metal cemented prosthesis	Class D	Intended to be implanted to replace a portion of the hip joint
320.	Orthopaedic Implants	Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis.	Class D	Intended to be implanted to replace a portion of the hip joint
321.	Orthopaedic Implants	Plates, clipsScrews	Class C	rigid, limb brace, lumbar, lumbo-sacral, rib fracture, sacroiliac, thoracic oethosis.
322.	Orthopaedic Implants	Spinal intervertebral body fixation orthosis	Class C	The device is used to apply force to a series of vertebrae to correct "sway back," scoliosis (lateral curvature of the spine), or other conditions.

323.	Orthopaedic Implants	Spinal interlaminar fixation orthosis	Class C	A device intended to be implanted made of an alloy, that consists of various hooks and a posteriorly placed compression or distraction rod. The device is used primarily in the treatment of scoliosis
324.	Orthopaedic Implants	Resorbable calcium salt bone void filler device	Class C	A resorbable calcium saltbone void filler device is a resorbable implant intended to fill bony voids or gaps of the extremities, spine, and pelvis
325.	Orthopaedic Implants	Smooth or threaded metallic bone fixation fastener	Class C	It may be used for fixation of bone fractures, for bone reconstructions, as a guide pin for insertion of other implants, or it may be implanted through the skin so that a pulling force (traction) may be applied to the skeletal system.
326.	Orthopaedic Implants	Sacroiliac joint fixation	Class C	The sacroiliac joints fixation may serve as protective mechanism for the lumbosacral region.
327.	Orthopaedic Implants	Cervical Artificial Disc	Class D	Cervical Artificial Disc is indicated for reconstruction of the disc.
328.	Scalp Vein Set	Scalp Vein Set	Class B	Intended to be used for insertion into the patient's vascular system (single use only) as an in-dwelling device to administer fluids intravenously or to sample blood.
329.	Surgical Dressings	Surgical Staples	Class B	Surgical staples are specialized staples used in surgery in place of sutures to close skin wounds, connect or remove parts of body during surgery.
330.	Surgical Dressings	Surgical Dressings	Class A	Dressing aerosol, non-adherent, dressing, periodontal, kit, dressing pad, dressing.
331.	Surgical Dressings	Surgical Dressings	Class B	Dressing-gel, dressing- permeable, moisture dressing, tracheostomy tube dressing, wound and burn dressings, hydrogel dressing, wound and burn, occlusive.
332.	Surgical Dressings	Cotton Grudges		Adhesive bandages, Gauge bandages, Medical Absorbent (fiber) bandages.

333.	Surgical Dressings	Wound Dressings/Bacteriostatic Wound Dressings	Class C	Includes Beads, Hydrophilics For Wound Exudate Absorption for wound care.
334.	Surgical Dressings	Casting tapes/Splint Rolls	Class B	A prosthetic and orthotic accessory, intended for medical purposes to support, protect, or aid in the use of a cast, orthosis (brace), or prosthesis.
335.	Surgical Dressings	Haemostatic Gelatine Sponge /Haemostat	Class C	Intended for the control of surface bleeding from vascular access sites and percutaneous catheters or tubes.
336.	Surgical Dressings	Surgical Dressings	Class C	Material dressing, surgical, polylactic acid dressings.
337.	Surgical Dressings	Absorbable Hemostatic Based	Class D	An absorbable haemostatic agent or dressing is a device intended to produce haemostasis by accelerating the clotting process of blood. It is absorbable.
338.	Surgical Dressings	Umbilical occlusion device	Class A	These devices may be a clip, tie, tape, or other article used to close the blood vessels in the umbilical cord of a newborn infant.
339.	Surgical Dressings	Bolster Suture	Class A	Non-latex plastic bolsters are used to hinder pressure of any temporary suture against the body during surgery.
340.	Surgical Dressings	Suture Non Absorbable Synthetic	Class C	Non-absorbable suture is comprised of surgical steel as well as synthetic non-absorbable sutures for use in general soft tissue approximation and ligation.
341.	Surgical Dressings	Suture Absorbable	Class C	The device is intended for use in general soft tissue approximation and ligation.
342.	Surgical Dressings	Endovascular suturing system	Class C	It is a medical device intended to provide fixation and sealing between an endovascular graft and the native artery.
343.	Surgical Dressings	Fixation, non-absorbable for pelvic use	Class C	Attaching suture or stapling ligaments of the pelvic floor.
344.	Surgical Dressings	Tissue adhesive for the topical use	Class C	Intended for topical closure of surgical incisions including laparoscopic incisions and simple traumatic lacerations.

345.	Surgical Dressings	Tissue adhesive for non-topical use	Class D	Intended for use in adhesion of internal tissues and vessels, for example; adhesives used in the embolization of brain arteriovenous malformation or for use in ophthalmic surgery.
346.	Surgical Dressings	Alcohol Swabs	Class A	It is a single use, sterile device containing 70% Isopropyl alcohol used for scrubbing and allowing drying and will disinfect needless access sites prior to use..
347.	Surgical Dressings	Ligature Wire	Class B	offer a spot-welded auxiliary hook which may be added to any bracket by simply tying in the arch wire
348.	Surgical Dressings	Surgical Sealant	Class B	For use in vascular reconstructions to achieve adjunctive hemostasis by mechanically sealing areas of leakage.
349.	Surgical Dressings	Wound Closure Device	Class B	Wound Closure Devices are indicated for soft tissue approximation.
350.	Surgical Dressings	Intracardiac patch	Class D	intracardiac patch or pledget made of polypropylene, polyethylene terephthalate, or polytetrafluoroethylene is a fabric device placed in the heart that is used to repair septal defects, for patch grafting, to repair tissue, and to buttress sutures.

**(B) List of In Vitro Diagnostics Medical Devices under provisions of sub-rule
(2) rule 4 of the Medical Devices Rules, 2017**

S. N.	Category	<i>in vitro</i> diagnostic medical device	Risk Class	Intended use
	Clinical Chemistry Reagents/ Kits for estimation of various Parameters exemplified as:			
1.		Acid Phosphatase (total or prostatic) test reagents/kits	Class B	An acid phosphatase (total or prostatic) test reagent/kit is a medical device, intended for the estimation of acid phosphatase in serum/plasma.
2.		Albumin test reagents/kits	Class B	An albumin test reagent/kit is a medical device intended for the estimation of albumin in serum/plasma.
3.		Alkaline phosphatase or isoenzymes test reagents/kits	Class B	An alkaline phosphatase or isoenzymes test reagent/kit is a medical device intended for the estimation of alkaline phosphatase or its isoenzymes in serum/plasma.
4.		Ammonia test reagents/kits	Class B	An ammonia test reagent/kit is a medical device intended for the estimation of ammonia levels in blood, serum/plasma.
5.		Amylase test reagents/kits	Class B	An amylase test reagent/kit is a medical device intended for the estimation of the enzyme amylase in serum, saliva / urine.
6.		Bicarbonate / carbon dioxide test reagents/kits	Class B	A bicarbonate/carbon dioxide test reagent/kit is a medical device for the estimation of bicarbonate/carbon dioxide in plasma, serum/whole blood.
7.		bilirubin (total and direct) test reagents/kits	Class B	A bilirubin (total and direct) test reagent/kit is a medical device intended for the estimation of bilirubin (total and direct) in serum/plasma.
8.		Calcium test reagents/kits	Class B	A calcium test reagent/kit is a medical device intended for the estimation of total calcium in serum.

9.	Chloride test reagents/kits	Class B	A chloride test reagent/kit is a medical device intended for the estimation of chloride in plasma, serum, sweat /urine.
10.	cholesterol (total) test reagents/kits	Class B	A cholesterol (total) test reagent/kit is a medical device intended for the estimation of cholesterol in serum or plasma.
11.	HDL cholesterol test reagents/kits	Class B	A HDL cholesterol test reagent/kit is a medical device intended for the estimation of HDL cholesterol in serum / plasma.
12.	LDL cholesterol test reagents/kits	Class B	A LDL cholesterol test reagent/kit is a medical device intended for the estimation of LDL cholesterol in serum/plasma.
13.	Lipoprotein test reagents/kits	Class B	A lipoprotein test reagent/kit is a medical device intended for the estimation of lipoproteins in serum / plasma.
14.	Cholinesterase test reagents/kits	Class B	A cholinesterase test reagent/kit is a medical device intended for the estimation of cholinesterase in serum /plasma. .
15.	Creatine Kinase and its isoenzyme test reagents/kits	Class B	A creatine phosphokinase/creatine kinase or isoenzymes including CKMB, CKBB and CKMM test reagent/kit is a medical device intended for the estimation of the enzyme creatine phosphokinase or its isoenzymes in serum / plasma. .
16.	Copper test reagents/kits	Class B	Copper test reagent/kit is a medical device intended for the estimation of copper in plasma, serum / urine.
17.	Creatinine test reagents/kits	Class B	A creatinine test reagent/kit is a medical device intended for the estimation of creatinine in serum, plasma / urine.
18.	Gamma Glutamyl Transferase (GGT) and isoenzymes test reagents/kits	Class B	A Gamma Glutamyl Transferase (GGT) and isoenzymes test reagent/kit is a medical device intended for the estimation of the enzyme Gamma Glutamyl Transferase (GGT) in serum / plasma.

19.	Glucose test reagents/kits	Class B	A Glucose test reagent/kit is a medical device intended for the estimation of glucose in blood/plasma/ body fluids.
20.	Glucose-6-Phosphate Dehydrogenase (G6PD) and its isoenzymes test reagents/kits	Class B	A Glucose-6-Phosphate Dehydrogenase(G6PD)test reagents/kit is a medical device intended for the estimation of Glucose-6-Phosphate Dehydrogenase or its isoenzymes in serum / plasma. .
21.	Glycosylated Hemoglobin or its variants test reagents/kits	Class B	Glycosylated Hemoglobin or its variants test reagents/kits are medical devices intended for the estimation of glycosylated hemoglobin or its variants including A1a, A1b, and A1c in blood.
22.	Hemoglobin test reagents/kits	Class B	A hemoglobin test reagent/kit is a medical device intended for the estimation of hemoglobin in blood.
23.	Iron test reagents/kits	Class B	An iron test reagent/kit is a medical device intended for the estimation of iron in serum /plasma.
24.	Ferritin test reagents/kits		An Ferritin test reagent/kit is a medical device intended for the estimation of ferritin in serum / plasma
25.	Iron-binding capacity test reagents/kits	Class B	Iron-binding capacity test reagents/kits are medical devices intended for the estimation of iron-binding capacity in serum / plasma.
26.	Lactate Dehydrogenase and its isoenzymes test reagents/kits	Class B	A Lactate Dehydrogenase and its isoenzymes test reagent/kit is a medical device intended for the estimation of enzyme Lactate Dehydrogenase and its isoenzymes in serum / plasma.
27.	Lipase test reagents/kits	Class B	A lipase test reagent/kit is a medical device intended for the estimation of lipase in serum / plasma.
28.	Magnesium test reagents/kits	Class B	A magnesium test reagent/kit is a medical device intended for the estimation of magnesium levels in serum / plasma.

29.	Phosphorus (inorganic) test reagents/kits	Class B	A phosphorus (inorganic) test reagent/kit is a medical device intended for the estimation of inorganic phosphorus in serum, plasma / urine.
30.	Potassium test reagents/kits	Class B	A potassium test reagent/kit is a medical device intended for the estimation of potassium in serum, plasma / urine.
31.	Aspartate Amino Transferase (AST/SGOT) test reagents/kits	Class B	An Aspartate Amino Transferase (AST/SGOT) test reagent/kit is a medical device intended for the estimation of the enzyme Aspartate Amino Transferase (AST/SGOT) in serum / plasma.
32.	Alanine Amino Transferase (ALT/SGPT) test reagents/kits	Class B	An Alanine Amino Transferase (ALT/SGPT) test reagent/kit is a medical device intended for the estimation of enzyme Alanine Amino Transferase (ALT/SGPT) in serum / plasma.
33.	Sodium test reagents/kits	Class B	A Sodium test reagent/kit is a medical device intended for the estimation of sodium in serum/ plasma / urine.
34.	Total protein test reagents/kits	Class B	A Total Protein test reagent/kit is a medical device intended for the estimation of total protein(s) in serum / plasma.
35.	Protein (fractionation) test reagents/kits	Class B	A Protein (fractionation) test reagent/kit is a medical device intended for the estimation of protein fractions in blood, urine, cerebrospinal fluid / other body fluids.
36.	Protein-bound iodine test reagents/kits	Class B	A Protein-bound iodine test reagent/kit is a medical device intended for the estimation of protein-bound iodine in serum / plasma.
37.	Triglycerides test reagents/kits	Class B	A Triglyceride test reagent/kit is a medical device intended for the estimation of triglycerides in serum / plasma.

38.		Urea (BUN) test reagents/kits	Class B	A Urea (BUN) test reagent/kit is a medical device intended for the estimation of urea/Blood Urea Nitrogen (BUN) in plasma/ serum / urine.
39.		Uric Acid test reagents/kits	Class B	A Uric Acid test reagent/kit is a medical device intended for the estimation of uric acid in serum/ plasma / urine.
40.		Micro-Protein test reagents/kits	Class B	A Micro-protein test reagent/kit is a medical device intended for the estimation of micro-proteins including micro-albumin in urine.
41.		Zinc test reagents/kits	Class B	A Zinc test reagent/kit is a medical device intended for the estimation of zinc in serum / plasma.
42.		Other clinical chemistry test reagents/kits	Class B*	Clinical chemistry test reagent/kit intended for the estimation of analytes/ parameters (other than listed above) in serum/ plasma/ urine or other body fluids.
	Hematology Reagents/ Kits for			
43.	estimation of Complete Blood Counts ,	Blood cell Diluents	Class B	A blood cell Diluent is a medical device used to dilute blood for further testing, such as Complete Blood Count(CBC) .
44.	exemplified as:	Lyse reagents/kits for differential counts	Class B	A Lyse reagent/kit is a medical device used for lysing of cells for the estimation of Complete Blood Count(CBC).
45.		Rinse/Detergent/Cleaners reagents/kits	Class B	A Rinse/Detergent/Cleaner reagent/kit is a medical device used for cleaning various parts of Hematology analyzers like probes, needles, baths, tubing etc.
	Reagents/ Kits for estimation of parameters in the urine, exemplified as:			
46.		Ascorbic Acid/ Bilirubin /Blood Cells/Glucose/ Ketone / Leukocyte peroxidase / Specific	Class B	Ascorbic Acid/ Bilirubin /Blood Cells/Glucose/ Ketone / Leukocyte peroxidase / Specific gravity/Urobilinogen Nitrite / pH /

		gravity/Urobilinogen Nitrite / pH / Protein / Albumin & other urinary analytes test reagents /Strips/kits		Protein / Albumin & other urinary analytes test reagents /Strips/kits, are medical devices intended for the preliminary estimation of diagnostic markers in urine.
	In - vitro			
47.	Diagnostic Medical Devices for Self -Testing	Glucose test reagents/kits	Class B	A glucose test reagent/kit is a medical device intended for the preliminary self testing of glucose levels in blood/body fluids.
48.		Human Chorionic Gonadotropin (hCG) test reagents/kits	Class B	A human Chorionic Gonadotropin (hCG) test reagent/kit is a medical device intended for the preliminary self testing of hCG in urine/body fluids.
49.		Luteinizing Hormone (LH) test reagents/kits	Class B	A Luteinizing Hormone (LH) test reagent/kit is a medical device intended for the preliminary self testing of Luteinizing Hormone (LH) in urine/body fluids.
50.		Glycosylated hemoglobin or its variants Test reagents/kits	Class B	Glycosylated Hemoglobin or its variants test reagents/kits are medical devices intended for the preliminary self testing of Glycosylated Hemoglobin or its variants including A1a, A1b, and A1c in blood.
51.		Cholesterol test reagents/kits	Class B	A Cholesterol test reagent/kit is a medical device intended for preliminary self testing of cholesterol in blood /body fluids.
52.		Follicle Stimulating Hormone (FSH) test reagents/kits	Class B	A Follicle Stimulating Hormone (FSH) test reagent/kit is a medical device intended for the preliminary self testing of Follicle Stimulating Hormone (FSH) in urine /body fluids
53.		Other In - vitro Diagnostic Medical Devices for Self - Testing	Class B*	

54.	In - vitro Diagnostic Medical Device for near patient testing			
55.		Blood Gas Analysis test reagents/kits	Class C	A Blood Gas Analysis test reagent/kit for near patient testing, is a medical device intended for the estimation of certain gases (such as oxygen and carbon dioxide etc.) dissolved in arterial blood.
56.		Anticoagulant monitoring test reagents/kits	Class C	An Anticoagulant monitoring test reagent/kit for near patient testing, is a medical device intended for the estimation of coagulation parameters (such as PT, TT, APTT etc.) in plasma/blood.
57.		Diabetes management test reagents/kits	Class C	A Diabetes management test reagent/kit for near patient testing, is a medical device intended for the of monitoring of diabetes in body fluids.
58.		C- Reactive Protein (CRP)test reagents/kits	Class C	A C- Reactive Protein (CRP) test reagent/kit for near patient testing, is a medical device intended for the estimation of C -Reactive Protein (CRP) in serum and other body fluids
59.		H. pylori test reagents/kits	Class C	An H. pylori test reagent/kit for near patient testing, is a medical device intended for the estimation of H. pylori in blood/body fluids.
60.		Troponin test reagents/kits	Class C	A Troponin test reagent/kit for near patient testing, is a medical device intended for the estimation of Troponin T,I and its variants in blood/body fluids
61.		Other in vitro Diagnostic Medical Devices for near patient test reagents/kits	Class C*	In vitro Diagnostic Medical Device for near patient test reagent/kit intended for the estimation of analytes/ parameters (other than listed above) in serum, plasma, urine or other body fluids.
	Reagents/ Kits for estimation of			

62.	parameters of ToRCH& other infectious agents exemplified as under:	Toxoplasma gondii test reagents/kits	Class C	A Toxoplasma gondii test reagent/kit is a medical device intended for the detection of Toxoplasma gondii in serum/body fluids.
63.		Rubella virus I test reagents/kits	Class C	A Rubella virus test reagent/kit is a medical device intended for the detection of Rubella virus in serum/body fluids.
64.		Cytomegalovirus test reagents/kits	Class C	A Cytomegalovirus test reagent/kit is a medical device intended for the detection of Cytomegalovirus in serum/body fluids.
65.		Herpes simplex virus reagents/kits	Class C	A Herpes simplex virus test reagent/kit is a medical device intended for the detection of Herpes simplex virus in serum/body fluids.
66.		Chlamydia pneumoniae test reagents/kits	Class C	A Chlamydia pneumoniae test reagent/kit is a medical device intended for the detection of Chlamydia pneumonia in serum/body fluids.
67.		Methicillin-Resistant Staphylococcus aureus test reagents/kits	Class C	A Methicillin-Resistant Staphylococcus aureus test reagent/kit is a medical device intended for the detection of Methicillin-Resistant Staphylococcus aureus in serum/body fluids
68.		Enterovirus test reagents/kits	Class C	An Enterovirus test reagent/kit is a medical device intended for the detection of enterovirus) in serum/body fluids.
		Reagents/ Kits for detection of Cancer Markers exemplified as :		
69.		Alpha-fetoprotein test reagents/kits	Class C	An Alpha-fetoprotein test reagent/kit is a medical device intended for the detection of Alpha-fetoprotein in serum/body fluids.
70.		Beta-2 microglobulin test reagents/kits	Class C	A Beta-2 microglobulin test reagent/kit is a medical device intended for the detection of Beta-2 microglobulin in serum/body fluids
71.		Bladder tumour antigen (BTA) test reagents/kits	Class C	A Bladder tumour antigen (BTA) test reagent/kit is a medical device intended for the detection of Bladder tumour antigen (BTA)in serum/body fluids

72.	CA15-3 test reagents/kits	Class C	A CA15-3 antigen (BTA) test reagent/kit is a medical device intended for the detection of CA15-3 in serum/body fluids
73.	CA27.29 test reagents/kits	Class C	A CA27.29 test reagent/kit is a medical device intended for the detection of CA27.29 in serum/body fluids
74.	CA125 test reagents/kits	Class C	A CA125 test reagent/kit is a medical device intended for the detection of CA125 in serum/body fluids
75.	CA72-4 test reagents/kits	Class C	A CA72-4 test reagent/kit is a medical device intended for the detection of CA72-4 in serum/body fluids
76.	CA19-9 test reagents/kits	Class C	A CA19-9 test reagent/kit is a medical device intended for the detection of CA19-9 in serum/body fluids
77.	Calcitonin test reagents/kits	Class C	A Calcitonin test reagent/kit is a medical device intended for the detection of Calcitonin in serum/body fluids
78.	Carcinoembryonic antigen (CEA) test reagents/kits	Class C	A Carcinoembryonic antigen (CEA) test reagent/kit is a medical device intended for the detection of Carcinoembryonic antigen (CEA) in serum/body fluids
79.	Chromogranin A test reagents/kits	Class C	A Chromogranin A test reagent/kit is a medical device intended for the detection of Chromogranin A in serum/body fluids
80.	Estrogen / Progesterone receptors test reagents/kits	Class C	A Estrogen / Progesterone test reagent/kit is a medical device intended for the detection of Estrogen / Progesterone in serum/body fluids
81.	HER2 (Human Epidermal Growth Factor receptor, test reagents/kits	Class C	A HER2 (Human Epidermal Growth Factor receptor test reagent/kit is a medical device intended for the detection of HER2 (Human Epidermal Growth Factor receptor in serum/body fluids

82.	human Chorionic Goadotropin (hCG) test system test reagents/kits		A human Chorionic Goadotropin (hCG) test reagent/kit is a medical device intended for the detection of human Chorionic Goadotropin (hCG) in serum/body fluids
83.	Lipid associated sialic acid test reagents/kits	Class C	A Lipid associated sialic acid test reagent/kit is a medical device intended for the detection of Lipid associated sialic acid in serum/body fluids
84.	Neuron -Specific Enolase (NSE) test reagents/kits	Class C	A Neuron -Specific Enolase (NSE) test reagent/kit is a medical device intended for the detection of Neuron -Specific Enolase (NSE) in serum/body fluids
85.	NMP22 test reagents/kits	Class C	A NMP22 test reagent/kit is a medical device intended for the detection of NMP22 in serum/body fluids
86.	Prostate-Specific Antigen (PSA) test reagents/kits	Class C	A Prostate-Specific Antigen (PSA) test reagent/kit is a medical device intended for the detection of Prostate-Specific Antigen (PSA) in serum/body fluids
87.	Prostatic Acid Phosphatase (PAP) test reagents/kits	Class C	A Prostatic Acid Phosphatase (PAP) test reagent/kit is a medical device intended for the detection of Prostatic Acid Phosphatase (PAP) test reagents/kits in serum/body fluids
88.	Prostate Cancer Antigen 3 gene (PCA 3) test reagents/kits	Class C	A Prostate Cancer Antigen 3 gene (PCA 3) test reagent/kit is a medical device intended for the detection of Prostate Cancer Antigen 3 gene (PCA 3) in serum/body fluids
89.	Prostate-Specific Membrane Antigen (PSMA) test reagents/kits	Class C	A Prostate-Specific Membrane Antigen (PSMA) test reagent/kit is a medical device intended for the detection of Prostate-Specific Membrane Antigen (PSMA) in serum/body fluids
90.	S-100 test reagents/kits	Class C	A S-100 test reagent/kit is a medical device intended for the detection of S-100 in serum/body fluids

91.		TA-90 test reagents/kits	Class C	A TA-90 test reagent/kit is a medical device intended for the detection of TA-90 in serum/body fluids
92.		Thyroglobulin test reagents/kits	Class C	A Thyroglobulin test reagent/kit is a medical device intended for the detection of Thyroglobulin in serum/body fluids
93.		Tissue Polypeptide Antigen (TPA) test reagents/kits	Class C	A Tissue Polypeptide Antigen (TPA) test reagent/kit is a medical device intended for the detection of Tissue Polypeptide Antigen (TPA) in serum/body fluids
94.		Other Reagents/ Kits for detection of Cancer Markers	Class C*	
	Reagents/ Kits for estimation of Coagulation parameters exemplified as:			
95.		PT (Prothrombin Time) test reagents/kits	Class C	A Prothrombin Time (PT) test reagent/kit is a medical device intended for the estimation of prothrombin time in plasma/body fluids.
96.		TT (Thrombin Time) test reagents/kits	Class C	A Thrombin Time (TT) test reagent/kit is a medical device intended for the estimation of Thrombin Time in plasma/body fluids
97.		Activated Partial Thromboplastin Time (APTT) tests reagents/kits	Class C	A Activated Partial Thromboplastin Time (APTT) test reagent/kit is a medical device intended for the estimation of Activated Partial Thromboplastin Time in plasma/body fluids
98.		Activated whole blood clotting time tests reagents/kits		A Activated whole blood clotting time test reagent/kit is a medical device intended for the estimation of Activated whole blood clotting Time in plasma/body fluids
99.		Fibrinogen/Fibrin degradation products tests reagents/kits	Class C	A Fibrinogen/Fibrin degradation products test reagent/kit is a medical device intended for the estimation of fibrinogen/fibrin degradation products in plasma/body fluids

100.		D-Dimer tests reagents/kits	Class C	A D-Dimer test reagent/kit is a medical device intended for the estimation of D-Dimer test in plasma/body fluids
101.		Other Reagents/ Kits for estimation of Coagulation parameters	Class C*	
	Reagents/ Kits for monitoring of drug levels used for therapy or abuse exemplified as under			
102.		Aminoglycoside antibiotics test reagents/kits	Class C	Aminoglycoside antibiotics test reagents/kits are medical devices intended for the estimation of Aminoglycoside antibiotics in serum/body fluids.
103.		Antiepileptics test reagents/kits	Class C	Antiepileptics test reagents/kits are medical devices intended for the estimation of Antiepileptics in serum/body fluids.
104.		Antipsychotics test reagents/kits	Class C	Antipsychotics test reagents/kits are medical devices intended for the estimation of Antipsychotics in serum/body fluids.
105.		Mood stabilisers, test reagents/kits	Class C	Mood stabilisers test reagents/kits are medical devices intended for the estimation of Mood stabilisers in serum/body fluids
106.		Biologic monoclonal antibody drugs test reagents/kits	Class C	Biologic monoclonal antibody drugs test reagents/kits are medical devices intended for the estimation of Biologic monoclonal antibody drugs in serum/body fluids
107.		Buprenorphine (BUP) test reagents/kits	Class C	Buprenorphine (BUP) test reagents/kits are medical devices intended for the estimation of Buprenorphine (BUP) in serum/body fluids
108.		Amphetamine (AMP) test reagents/kits	Class C	Amphetamine (AMP) test reagents/kits are medical devices intended for the estimation of Amphetamine (AMP) in serum/body fluids
109.		Barbiturates (BAR) test reagents/kits	Class C	Barbiturates (BAR) test reagents/kits are medical devices intended for the estimation of Barbiturates (BAR) in serum/body fluids

110.	Opiate test system test reagents/kits	Class C	Opiate test reagents/kits are medical devices intended for the estimation of opiates in serum/body fluids
111.	Benzodiazepines (BZO) Test reagents /kits	Class C	Benzodiazepines (BZO) test reagents/kits are medical devices intended for the estimation of Benzodiazepines (BZO) in serum/body fluids
112.	Cocaine (COC) Test reagents /kits	Class C	Cocaine (COC) test reagents/kits are medical devices intended for the estimation of Cocaine (COC) in serum/body fluids
113.	Cotinine (COT) Test reagents /kits	Class C	Cotinine (COT) test reagents/kits are medical devices intended for the estimation of Cotinine (COT) in serum/body fluids
114.	Ketamine (KET) Test reagents /kits	Class C	Ketamine (KET) test reagents/kits are medical devices intended for the estimation of Ketamine (KET) in serum/body fluids
115.	Ecstasy (MDMA) Test reagents /kits	Class C	Ecstasy (MDMA) test reagents/kits are medical devices intended for the estimation of Ecstasy (MDMA) in serum/body fluids
116.	Methamphetamine (MET) Test reagents /kits	Class C	Methamphetamine (MET) test reagents/kits are medical devices intended for the estimation of Methamphetamine (MET) in serum/body fluids
117.	Morphine (MOP) Test reagents /kits	Class C	Morphine (MOP) test reagents/kits are medical devices intended for the estimation of Morphine (MOP) in serum/body fluids
118.	Methaqualone (MQL) Test reagents /kits	Class C	Methaqualone (MQL) test reagents/kits are medical devices intended for the estimation of Methaqualone (MQL) in serum/body fluids
119.	Methadone (MTD) Test reagents /kits	Class C	Methadone (MTD) test reagents/kits are medical devices intended for the estimation of Methadone (MTD) in serum/body fluids
120.	Oxycodone (OXY) Test reagents /kits	Class C	Oxycodone (OXY) test reagents/kits are medical devices intended for the estimation of Oxycodone (OXY) in

				serum/body fluids
121.		Phencyclidine (PCP) Test reagents /kits	Class C	Phencyclidine (PCP) test reagents/kits are medical devices intended for the estimation of Phencyclidine (PCP) in serum/body fluids
122.		Propoxyphene (PPX) Test reagents /kits	Class C	Propoxyphene (PPX) test reagents/kits are medical devices intended for the estimation of Propoxyphene (PPX) in serum/body fluids
123.		Tricyclic Antidepressants (TCA) Test reagents /kits	Class C	Tricyclic Antidepressants (TCA) test reagents/kits are medical devices intended for the estimation of Tricyclic Antidepressants (TCA) in serum/body fluids
124.		Marijuana (THC) Test reagents /kits	Class C	Marijuana (THC) test reagents/kits are medical devices intended for the estimation of Marijuana (THC) in serum/body fluids
125.		Tramadol (TRA) Test reagents /kits	Class C	Tramadol (TRA) test reagents/kits are medical devices intended for the estimation of Tramadol (TRA) in serum/body fluids
126.		Fentanyl (FEN) Test reagents /kits	Class C	Fentanyl (FEN) test reagents/kits are medical devices intended for the estimation of Fentanyl (FEN) in serum/body fluids
127.		Methadone Metabolite (EDDP) Test reagents /kits	Class C	Methadone Metabolite (EDDP) test reagents/kits are medical devices intended for the estimation of Methadone Metabolite (EDDP) in serum/body fluids
128.		Other Reagents/ Kits for monitoring of drug levels used for therapy or abuse	Class C*	
	Reagents/			
129.	Kits for detection of autoimmune disorders exemplified as:	Anti Nuclear Antibodies test reagents/kits	Class B	Anti Nuclear Antibodies test reagent/kit is a medical device for the screening of auto-antibodies to nuclear antigens in human specimens.

130.	Anti Transglutaminase Antibodies test reagents/kits	Class B	Anti Transglutaminase Antibodies test reagent/kit is a medical device for the screening of auto-antibodies to Transglutaminase in human specimens.
131.	Anti Ganglioside Antibodies test reagents/kits	Class B	Anti Ganglioside Antibodies test reagent/kit is a medical device for the screening of auto-antibodies to Ganglioside in human specimens
132.	Anti-Cyclic Citrullinated Peptide (CCP) Antibodies test reagents/kits	Class B	Anti CyclicCitrullinated Peptide (CCP) Antibodies test reagent/kit is a medical device for the screening of CCP auto-antibodies in human specimens.
133.	Rheumatoid Factor (RF) immunological test reagents/kits	Class B	Rheumatoid Factor (RF) immunological test reagent/kit is a medical device for the screening of Rheumatoid Factor in human specimens.
134.	Anti Smooth Muscle Antibody test reagents/kits	Class B	Anti Smooth Muscle Antibody test reagent/kit is a medical device for the screening of auto-antibodies to smooth muscles in human specimens.
135.	Glutamic Acid Decarboxylase (GAD) Antibody test reagents/kits	Class B	Glutamic Acid Decarboxylase (GAD) Antibodytest reagent/kit is a medical device for the screening of auto-antibodies to Glutamic Acid Decarboxylase (in human specimens
136.	Anti ovary antibodies test reagents/kits	Class B	Anti ovary antibodies test reagent/kit is a medical device for the screening of auto-antibodies to ovarian antigens in human specimens
137.	Anti sperm Antibodies test reagents/kits	Class B	Anti sperm antibodies test reagent/kit is a medical device for the screening of auto-antibodies to spermatozoa in human specimens.
138.	Anti-IA2 test reagents/kits	Class B	Anti IA-2 antibodies test reagent/kit is a medical device for the screening of auto-antibodies to IA-2 (tyrosine phosphatase) in human specimens

139.		Anti-Acetylcholine Receptor test reagents/kits	Class B	Anti-Acetylcholine Receptor test reagent/kit is a medical device for the screening of auto-antibodies to Acetylcholine Receptor in human specimens
140.		Anti Thyroid gland antibody test reagents/kits	Class B	Anti Thyroid gland antibodies test reagent/kit is a medical device for the screening of auto-antibodies to thyroid gland antigens in human specimens
141.		ANCA test reagents/kits	Class B	The ANCA test reagent/kit is a medical device for the screening of Anti-Neutrophil Cytoplasmic Antibodies (ANCA) in human specimens .
142.		Anti-double stranded DNA (anti-dsDNA)test reagents/kits	Class B	The Anti-double stranded DNA (Anti-dsDNA) test reagent/kit is a medical device for the screening of auto-antibodies to Double stranded DNA in human specimens
143.		Anti-Extractable Nuclear Antigen(Anti-ENA)test reagents/kits	Class B	The Anti-Extractable Nuclear Antigen(Anti-ENA)test reagent/kit is a medical device for the screening of auto-antibodies to Extractable Nuclear Antigens like Smith (Sm) Antigens, Ribonuclears Protein (RNP), anti SSA (Ro) etc. in human specimens.
144.		Anti-Intrinsic Factor test reagents/kits	Class B	The Anti-Intrinsic Factor test reagent/kit is a medical device for the screening of antibodies against intrinsic factor in human specimens.
145.		Anti- <i>Saccharomyces Cerevisiae</i> Antibodies (ASCA) test reagents/kits	Class B	The Anti- <i>Saccharomyces Cerevisiae</i> Antibodies (ASCA) test reagent/kit is a medical device for the screening of antibodies against <i>Saccharomyces Cerevisiae</i> in human specimens.
146.		Other Reagents/ Kits for detection of autoimmune disorders	Class B*	
147.	Reagents/			

148.	Kits for detection of markers for Congenital disorders exemplified as under	Triple Screen Test reagents/kits for Down's Syndrome	Class C	Triple Screen Test reagent/kit for Down's Syndrome is a medical device intended for the screening of Down's Syndrome in serum/plasma.
149.		Quadruple Screen Test reagents/kits for Down's Syndrome	Class C	Quadruple Screen Test reagent/kit for Down's Syndrome is a medical device intended for the screening of Down's Syndrome in serum/plasma
150.		Chorionic Villus Sample Test reagents/kits for Down's Syndrome	Class C	Chorionic Villus Sample Test reagent/kit for Down's Syndrome is a medical device intended for the detection of Down's Syndrome in body fluids.
151.		Maternal Serum Alpha-Fetoprotein (MSAFP) test reagents/kits for spina bifida	Class C	Maternal Serum Alpha-Fetoprotein (MSAFP) Test reagents/kits for is a medical device intended for the screening of spina bifida in serum.
152.		Others Reagents/ Kits for detection of Congenital disorders	Class C*	
	Reagents/			
153.	Kits for detection of Cardiac Markers exemplified as under	Creatine Kinase (CK) and CKMB test reagents/kits	Class B	Creatine Kinase (CK) and CKMB test reagent/kit are medical devices intended for the estimation of Creatine Kinase (CK) and CKMB in blood / body fluids.
154.		Myoglobin test reagents/kits	Class B	Myoglobin Test reagent/kit for is a medical device intended for the estimation of myoglobin in blood /body fluids.
155.		Troponin test reagents/kits	Class C	A Troponin test reagent/kit for near patient testing, is a medical device intended for the estimation of Troponin T,I and its variants in blood /body fluids
156.		BNP &NT pro BNP test reagents/kits	Class C	BNP &NT pro BNP Test reagent/kit for is a medical device intended for theestimation of BNP &NT pro BNP in blood / body fluids
	Reagents/			
157.	Kits for human Genetic testing	Genetic test reagents/kits for Cystic Fibrosis	Class C	Genetic test reagent/kit for Cystic Fibrosis is a medical device intended for the detection of Cystic Fibrosis in human specimens.

158.	exemplified as:	Genetic test for Huntington's chorea	Class C	Genetic test reagent/kit for Huntington's chorea is a medical device intended for the detection of Huntington's chorea in human specimens.
159.		Other Reagents/ Kits for human Genetic testing	Class C*	
	Reagents/ Kits for the management of life threatening infections exemplified as under:			
160.		HIV Viral Load test reagents/kits	Class C	HIV Viral Load test reagent/kit is a medical device intended for the estimation of HIV Viral Load in blood/body fluids.
161.		HBV Viral Load test reagents/kits	Class C	HBV Viral Load test reagent/kit is a medical device intended for the estimation of HBV Viral Load in blood/body fluids.
162.		HCV Viral Load test reagents/kits	Class C	HCV Viral Load test reagent/kit is a medical device intended for the estimation of HCV Viral Load in blood/body fluids.
163.		CD4 Count & % test reagents/kits	Class C	CD4 Count & % test reagent/kit is a medical device intended for the estimation of CD4 Count & % in blood/body fluids.
164.		CD8 Count & % test reagents/kits	Class C	CD8 Count & % test reagent/kit is a medical device intended for the estimation of CD8 Count & % in blood/body fluids.
165.		CD4/CD8 Ratio test reagents/kits	Class C	CD4/CD8 Ratio test reagent/kit are a medical device intended for the estimation of CD4/CD8 Ratio in blood/body fluids.
166.		Other Reagents/ Kits for the management of life threatening infections	Class C*	
		Reagents/ Kits for the detection of sexually transmitted		
167.	Treponema pallidum test reagents and kits		Class C	Treponema pallidum test reagent/kit is a medical device intended for the detection of Treponema pallidum in blood/body fluids.

168.	agent exemplified as under:	Neisseria gonorrhoeae test reagents and kits	Class C	Neisseria gonorrhoeae test reagent/kit is a medical device intended for the detection of Neisseria gonorrhoeae in blood/body fluids
169.		Human Papilloma Virus (HPV) test reagents and kits	Class C	Human Papilloma Virus (HPV) test reagent/kit is a medical device intended for the detection of Human Papilloma Virus in blood/body fluids
170.		Chlamydia test reagents and kits	Class C	Chlamydia test reagent/kit is a medical device intended for the detection of Chlamydia in blood/body fluids
171.		Herpes Virus test reagents and kits	Class C	Herpes Virus test reagent/kit is a medical device intended for the detection of Herpes Virus in blood/body fluids
172.		Other Reagents/ Kits for the detection of sexually transmitted agent	Class C*	
173.	Reagents/ Kits for the Antigen detection of infectious agents with a risk of limited propagation exemplified as:			
174.		Malaria Antigen test reagents and kits	Class C	Malaria Antigen test reagent/kit is a medical device intended for the detection of Malaria Antigen in blood/body fluids
175.		Dengue virus Antigen test reagents and kits	Class C	Dengue virus Antigen test reagent/kit is a medical device intended for the detection of Dengue virus Antigen in blood/body fluids
176.		Chikungunya Antigen test reagents and kits	Class C	Chikungunya Antigen test reagent/kit is a medical device intended for the detection of Chikungunya Antigen in blood/body fluids
177.		Leptospira Antigen test reagents and kits	Class C	Leptospira Antigen test reagent/kit is a medical device intended for the detection of Leptospira Antigen in blood/body fluids
178.		Japanese Encephalitis Antigen test reagents and kits	Class C	Japanese Encephalitis Antigen test reagent/kit is a medical device intended for the detection of Japanese Encephalitis Antigen in blood/body fluids

179.	Typhoid Antigens test reagents and kits	Class C	Typhoid Antigens Test reagent/kit is a medical device intended for the detection of Typhoid Antigens in blood/body fluids
180.	Influenza A Antigen test reagents and kits	Class C	Influenza A Antigen test reagent/kit is a medical device intended for the detection of Influenza A Antigen in blood/body fluids
181.	Influenza B Antigen test reagents and kits	Class C	Influenza B Antigen test reagent/kit is a medical device intended for the detection of Influenza B Antigen in blood/body fluids
182.	Strep A Antigen test reagents and kits	Class C	Strep A Antigen test reagent/kit is a medical device intended for the detection of Strep A Antigen in blood/body fluids
183.	Strep B Antigen test reagents and kits	Class C	Strep B test Antigen reagent/kit is a medical device intended for the detection of Strep B Antigen in blood/body fluids
184.	Chagas Antigen test reagents and kits	Class C	Chagas disease Antigen test reagent/kit is a medical device intended for the detection of Chagas disease Antigen in blood/body fluids
185.	Filariasis Antigen test reagents and kits	Class C	Filariasis test Antigen reagent/kit is a medical device intended for the detection of Filariasis Antigen in blood/body fluids
186.	Kala Azar Antigen test reagents and kits gen	Class C	Kala Azar Antigen test reagent/kit is a medical device intended for the detection of Kala Azar Antigen in blood/body fluids
187.	Rotavirus Antigen test reagents and kits	Class C	Rotavirus Antigen test reagent/kit is a medical device intended for the detection of Rotavirus Antigen in blood/body fluids
188.	S. pneumonia Antigen test reagents and kits	Class C	S. pneumonia Antigen test reagent/kit is a medical device intended for the detection of S. pneumonia Antigen in blood/body fluids
189.	H. pylori Antigen Antigen test reagents and kits Antigen	Class C	H. pylori Antigen test reagent/kit is a medical device intended for the detection of H. pylori Antigen in blood/body fluids

190.		Other Reagents/ Kits for the detection of infectious agents with a risk of limited propagation	Class C*	Reagents/ Kits, other than above, for the Antigen detection of infectious agents with a risk of limited propagation
191.	Reagents/ Kits for the detection of Antibodies to infectious agents with a risk of limited propagation exemplified as under			
192.		Malaria Antibody test reagents and kits	Class B	Malaria Antibody test reagent/kit is a medical device intended for the detection of Malaria Antibody in blood/body fluids
193.		Dengue Antibody test reagents and kits	Class B	Dengue Antibody test reagent/kit is a medical device intended for the detection of Dengue Antibody in blood/body fluids
194.		Chikungunya Antibody test reagents and kits	Class B	Chikungunya Antibody test reagent/kit is a medical device intended for the detection of Chikungunya Antibody in blood/body fluids
195.		Leptospira Antibody test reagents and kits	Class B	Leptospira Antibody test reagent/kit is a medical device intended for the detection of Leptospira Antibody in blood/body fluids
196.		Japanese Encephalitis Antibody test reagents and kits	Class B	Japanese Encephalitis Antibody test reagent/kit is a medical device intended for the detection of Japanese Encephalitis Antibody in blood/body fluids
197.		Typhoid Antibody test reagents and kits	Class B	Typhoid Antibody test reagent/kit is a medical device intended for the detection of Typhoid Antibody in blood/body fluids

198.		Cryptococcus neoformans Antibody test reagents and kits	Class B	Cryptococcus neoformans Antibody test reagent/kit is a medical device intended for the detection of Cryptococcus neoformans Antibody in blood/body fluids
199.		Neisseria meningitides Antibody test reagents and kits	Class B	Neisseria meningitides Antibody test reagent/kit is a medical device intended for the detection of Neisseria meningitides Antibody in blood/body fluids
200.		Vibrio cholera Antibody test reagents and kits	Class B	Vibrio cholera Antibody test reagent/kit is a medical device intended for the detection of Vibrio cholera Antibody in blood/body fluids
201.		Influenza A Antibody test reagents and kits	Class B	Influenza A Antibody test reagent/kit is a medical device intended for the detection of Influenza A Antibody in blood/body fluids
202.		Influenza B Antibody test reagents and kits	Class B	Influenza B Antibody test reagent/kit is a medical device intended for the detection of Influenza B Antibody in blood/body fluids
203.		Strep A Antibody test reagents and kits	Class B	Strep A Antibody test reagent/kit is a medical device intended for the detection of Strep A Antibody in blood/body fluids
204.		Strep B Antibody test reagents and kits	Class B	Strep B Antibody test reagents/kits is a medical device intended for the detection of Strep B Antibody in blood/body fluids
205.		Chagas Antibody test reagents and kits	Class B	Chagas Antibody test reagent/kit is a medical device intended for the detection of Chagas Antibody in blood/body fluids
206.		Filariasis Antibody test reagents and kits	Class B	Filariasis Antibody test reagent/kit is a medical device intended for the detection of Filariasis Antibody in blood/body fluids
207.		Kala Azar Antibody test reagents and kits	Class B	Kala Azar Antibody test reagents/kits is a medical device intended for the detection of Kala Azar Antibody in blood/body fluids

208.		Rotavirus Antibody test reagents and kits	Class B	Rotavirus Antibody test reagents/kits is a medical device intended for the detection of Rotavirus Antibody in blood/body fluids
209.		S. pneumonia Antibody test reagents and kits	Class B	S. pneumonia Antibody test reagent/kit is a medical device intended for the detection of S. pneumonia Antibody in blood/body fluids
210.		H. pylori Antibody test reagents and kits	Class B	H.pylori Antibody test reagent/kit is a medical device intended for the detection of H.pylori Antibody in blood/body fluids
211.		Other Reagents/ Kits for the detection of Antibodies to infectious agents with a risk of limited propagation	Class B*	
	In vitro Diagnostic Medical Devices for Blood Grouping or Tissue Typing			
212.		All other than, the ABO system; the Duffy system; the Kell system; the Kidd system; the Rhesus system, test reagents/kits.	Class C	
213.	in vitro Diagnostic Medical	ABO System test reagents/kits	Class D	Intended for blood grouping or tissue typing.
214.		Rhesus (D) System test reagents/kits	Class D	

215.	Devices for Blood Grouping or Tissue Typing	The Duffy system test reagents/kits	Class D	
216.		The Kell system test reagents/kits	Class D	
217.		The Kidd system test reagents/kits	Class D	
218.		HLA test reagents/kits	Class D	
	Reagents/ Kits for the detection of transmissible agents - screening & confirmatory			
219.		HIV test reagents/kits	Class D	HIV test reagents/kits is a medical device intended for the detection of HIV in blood/body fluids.
220.		HBV test reagents/kits	Class D	HBV test reagents/kits is a medical device intended for the detection of HBV in blood/body fluids
221.		HCV test reagents/kits	Class D	HCV test reagents/kits is a medical device intended for the detection of HCV in blood/body fluids
222.		Syphilis screening reagents/kits	Class D	Syphilis test reagents/kits is a medical device intended for the screening of Syphilis in blood/body fluids
223.		Malaria screening reagents/kits	Class D	Malaria test reagents/kits is a medical device intended for the screening of Malaria in blood/body fluids
	Other in vitro Medical Devices			
224.		TSH test reagents/kits	Class B	TSH test reagent/kit is a medical device intended for the estimation TSH in blood/body fluids.
225.		Total /Free triiodothyronine (T3) test reagents/kits	Class B	Total /Free triiodothyronine (T3) test reagent/kit is a medical device intended for the estimation Total /Free triiodothyronine (T3) in blood/body fluids
226.		Total / Free thyroxine (T4) test reagents/kits	Class B	Total / Free thyroxine (T4) test reagent/kit is a medical device intended for the estimation of Total / Free thyroxine (T4) in blood/body

			fluids
227.	Dehydroepiandrosterone (DHEA-S) (free and sulfate) test reagents/kits	Class B	Dehydroepiandrosterone (DHEA-S) (free and sulfate) test reagent/kit is a medical device intended for the estimation of DHEA-S (free and sulfate) in blood/body fluids
228.	Estrogen test reagents/kits	Class B	Estrogen test reagent/kit is a medical device intended for the estimation of Estrogen in blood/body fluids
229.	Progesterone test reagents/kits	Class B	Progesterone test reagent/kit is a medical device intended for the estimation of Progesterone in blood/body fluids
230.	Testosterone (Free and Total) test reagents/kits	Class B	Testosterone (Free and Total) test reagent/kit is a medical device intended for the estimation of Testosterone (Free and Total) in blood/body fluids
231.	Sex Hormone Binding Globulin (SHBG) test reagents/kits	Class B	Sex Hormone Binding Globulin (SHBG) test reagent/kit is a medical device intended for the estimation of Sex Hormone Binding Globulin (SHBG) in blood/body fluids
232.	Cortisol test reagents/kits	Class B	Cortisol test reagent/kit is a medical device intended for the estimation of Cortisol in blood/body fluids
233.	Insulin test reagents/kits	Class B	Insulin test reagent/kit is a medical device intended for the estimation of Insulin in blood/body fluids
234.	Luteinizing Hormone(LH) test reagents/kits	Class B	Luteinizing Hormones(LH) test reagent/kit is a medical device intended for the estimation of Luteinizing Hormone (LH) in blood/body fluids
235.	Follicle Stimulating Hormone(FSH) test reagents/kits	Class B	Follicle Stimulating Hormone (FSH) test reagent/kit is a medical device intended for the estimation of Follicle Stimulating Hormone(FSH) in blood/body fluids
236.	Prolactin test reagents/kits	Class B	Prolactin test reagent/kit is a medical device intended for the estimation of Prolactin in blood/body fluids

237.		Other test reagents/kits for hormones	Class B	Test reagents/kits for the estimation of other than above hormones in blood/body fluids
238.		Vitamin B test reagents/kits	Class B	Vitamin B test reagent/kit is a medical device intended for the estimation of Vitamin B in blood/body fluids
239.		Vitamin D test reagents/kits	Class B	Vitamin D test reagent/kit is a medical device intended for the estimation of Vitamin B in blood/body fluids
240.		Vitamin A test reagents/kits	Class B	Vitamin A test reagent/kit is a medical device intended for the estimation of Vitamin A in blood/body fluids
241.		Vitamin E test reagents/kits	Class B	Vitamin E test reagent/kit is a medical device intended for the estimation of Vitamin E in blood/body fluids
242.		Vitamin K test reagents/kits	Class B	Vitamin K test reagent/kit is a medical device intended for the estimation of Vitamin K in blood/body fluids
243.		Other test reagents/kits for vitamins	Class B	Test reagents/kits for the estimation of other than above vitamins in blood/body fluids
244.		Homocystein test reagents/kits	Class B	Homocystein test reagent/kit is a medical device intended for the estimation of Homocystein in blood/body fluids
245.		allergens test reagents/kits	Class B	Test reagents/kits intended for the estimation of allergens in blood/body fluids
246.	calibrators/controls for above all in vitro	Calibrators	-	Calibrators intended to be used with a reagent should be treated in the same class as the In vitro diagnostic medical device reagent.
247.	diagnostic medical devices	Controls	-	Controls intended to be used with a reagent should be treated in the same class as the In vitro diagnostic medical device reagent

Note: Anticoagulant Solutions, Embolization Particles, chitosan scaffold (for cartilage repair), Riboflavin (for Corneal Collagen cross-linking), silicone oil endotamponade, Intraocular Gases and Injectable Fillers shall be regulated as drugs under the provisions of the Drugs and Cosmetics Act, and Drugs and Cosmetics Rules, 1945.
