

No.DCG (I/Misc./2017 (68)
Central Drugs Standard Control Organisation
Directorate General of Health Services
Office of Drugs Controller General India
FDA Bhawan, Kotla Road, New Delhi

Dated: 29th June, 2017.

Notice

The Drugs & Cosmetics Act, 1940 is an Act to regulate import, manufacture, distribution and sale of drugs and cosmetics. It extends to the whole of India. Further, the Drugs & Cosmetics Rules, 1945 have been put in place which are updated from time to time for uniform implementation of the statutory requirements.

The devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Govt. by notification in official Gazette, after consultation with the Board, fall under the definition of drug. The list of devices notified so far are appended below:

S.No.	NAME OF THE DEVICE
1.	Disposable Hypodermic Syringes
2.	Disposable Hypodermic Needles
3.	Disposable Perfusion Sets
4.	In vitro Diagnostic Devices for HIV, HbsAg and HCV
5.	Cardiac Stents
6.	Drug Eluting Stents
7.	Catheters
8.	Intra Ocular Lenses
9.	I.V. Cannulae
10.	Bone Cements
11.	Heart Valves
12.	Scalp Vein Set
13.	Orthopedic Implants
14.	Internal Prosthetic Replacements
15.	Ablation Device

[The Medical Devices Rules, 2017*](#) have been notified and would come into force with effect from 1st day of January, 2018. Criteria for Classification of medical

devices including in vitro diagnostics have been specified in Rule 4, Chapter II of the rules which deals with regulation of Medical Devices in Indian context and in line with International Classification. A draft list of Medical Devices and in vitro diagnostics along with their risk based classification is annexed.

It is expected that the importers, manufacturers, distributors and supply chain personnel shall voluntarily adhere with the safety, performance and quality aspects as stated in the said medical devices Rule, 2017 for creating proper eco-system for its effective regulation.

In order to facilitate the process a special cell has also been created consisting of concerned JDC (I), DDC (I) and ADC (I) to address the issues, if any.


(Dr. G.N. Singh)
Drugs Controller General (India)

To

1. All State/UT Drugs Controllers
2. All Medical Devices and Diagnostics Associations

Copy to:

- (i) PPS to Secretary (H&FW)/DGHS/AS & DG (CGHS)/JS (R)
- (ii) CDSCO website

DRAFT LIST OF MEDICAL DEVICES AND IN VITRO DIAGNOSTICS ALONG WITH THEIR RISK CLASS**A - LIST OF MEDICAL DEVICES ALONG WITH THEIR RISK CLASS**

S.N.	Device Name	Risk Class	Intended Use
1.	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.	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.	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.	Percutaneous Conduction Tissue Ablation	Class D	Clinical applications using hollow needles (cryoprobes) through which cooled, thermally conductive, fluids are circulated.
5.	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.	Fiberoptic Oximeter Catheter	Class D	Intended for monitoring the balance between oxygen delivery and consumption at the bedside
7.	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.
8.	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.

9.	External infusion Pump	Class B	The device designed to provide nutrition to patients who are unable to ingest food, either because of recent surgery or because of the inability of various digestive organs to function properly
10.	Transcervical(Aminoscope) Endoscope and accessories	Class B	It is a device designed to permit direct viewing of the foetus and amniotic sac by means of an open tube introduced into the uterus through the cervix.
11.	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.
12.	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
13.	Anastomosis Device for Microvascular Surgery	Class C	Suitable in microvascular surgery for repairing severed blood vessels and inserting vein grafts.
14.	Anastomosis Device for Gastroenterology Urology Use	Class C	It is a surgical procedure to establish communication between two formerly distant portions of the intestine
15.	Anastomotic Microvascular Device	Class B	It uses in the anastomosis of veins and arteries normally encountered in microsurgical procedures
16.	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.
17.	Angiographic Guide Wire and Accessories	Class B	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.
18.	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
19.	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.
20.	Angioscope	Class B	Used to visually examine the interior of a blood vessel.

21.	Aspiration Needle and Syringe	Class B	Used for either laparoscopic aspiration or injection
22.	Ophthalmic Laser and Accessories	Class C	An ophthalmic laser is an AC-powered device intended to coagulate or cut tissue of the eye, orbit, or surrounding skin by a laser beam
23.	Tracheobronchial Suction Catheter	Class B	Clearing the airways of mucus, pus, or aspirated materials to improve oxygenation and ventilation.
24.	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.	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.	Balloon for Cerebrovascular Occlusion	Class D	Balloon used to treat Blockage or closing of Cerebrovascular vessels/carotid arteries
27.	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.	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.	Contact Lens Bifocal and Daily	Class B	Worn to correct vision, or for cosmetic or therapeutic reasons
30.	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
31.	Biopsy Kit	Class B	Involving sampling of cells or tissues for examination.
32.	Bolster Suture	Class A	Non-latex plastic bolsters are used to hinder pressure of any temporary suture against the body during surgery.
33.	Embolic System Particles	Class C	Embolization particles are small and irregular flakes of polyvinyl alcohol, which are used for permanent occlusion within a blood vessel.

34.	Tracheostomy Tube/Tracheal Tube	Class B	A breathing tube inserted into a tracheotomy used to obtain a closed circuit for ventilation
35.	Irrigating Syringes	Class B	cleaning debris away from the area the dentist is working on
36.	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 .
37.	Cyclodialysis eye Cannula	Class A	It is useful in the treatment of glaucoma where it creates a channel between the anterior chamber of the eye and the subarachnoid space
38.	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.
39.	Suprapubic, non-disposable Cannula and Trocar	Class B	an emergency measure for the relief of acute urinary retention or condition which require temporary and permanent drainage of bladder.
40.	Aortic Cannula	Class B	The Aortic Cannula is a passive device to provide for the infusion of fluids, drugs, and/or blood components or to provide access to the Aorta.
41.	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.
42.	Coronary Artery Cannula	Class B	Cannulation technique for left-sided coronary artery surgery.
43.	Arthroscopy Drainage Cannula	Class B	It is designed to provide maximized outflow, without interruption, during arthroscopic procedures (surgical procedure on a joint)
44.	Lacrimal Cannula	Class B	Used for probing and irrigating the lachrymal passages.
45.	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.
46.	Cannula Injection	Class B	It is a small tube with an edge that is not sharp and an extrusion port or pore near the tip which is designed for a traumatic sub dermal injections of fluids or gels

47.	Uterine Insufflation Cannula	Class B	An Injection of radiopaque medium is given to visualize the interior of the uterus and fallopian tubes and air is used for insufflations of fallopian tubes with carbon di oxide to test their patency.
48.	Continuous Positive Airway Pressure Nasal Oxygen Cannula	Class B	It is a form of positive airway pressure ventilator, which applies mild air pressure on a continuous basis to keep the airways continuously open in a person who is able to breathe spontaneously on their own
49.	Nasal Oxygen Cannula	Class B	Is a device used to deliver supplemental oxygen or increased airflow to a patient or person in need of respiratory help.
50.	General & Plastic Surgery Cannula	Class B	Used for general surgery and cosmetic surgery
51.	Vena Cava Cannula	Class B	Inserted into Vena Cava, taking deoxygenated blood to heart.
52.	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.
53.	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.
54.	Bronchial Cannulae	Class B	A cannula used for holding the suction tube during the aspiration of bronchial secretions through a specific diameter bronchoscope
55.	Endoscopic/ Laparoscopic Surgical Instrument	Class B	An electrosurgical cutting and coagulation device and accessories is a device intended to remove tissue and control bleeding by use of high-frequency electrical current.
56.	Intrafallopian System Cannula	Class B	Cannula inserted inside Fallopian tube.
57.	A-V Shunt Cannula	Class C	It is inserted into one of the client's blood vessels to facilitator repeated hemodialysis.
58.	Cannulact or Lymph Duct	Class B	A lymph duct is a great lymphatic vessel that empties lymph into one of the subclavian veins
59.	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. AResuscitator.

60.	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.
61.	Oropharyngeal	Class B	The device inserted into a patient's pharynx through the mouth to provide a patent airway.
62.	Cricothyrotomy Kit	Class B	Indicated to provide emergency airway access when conventional ventilation by intubation or face mask cannot be performed
63.	Incontinence Urosheath Device	Class A	A urine collector and accessories is a device intended to collect urine. The device and accessories consist of tubing, a suitable receptacle, connectors, mechanical supports, and may include a means to prevent the backflow of urine or ascent of infection.
64.	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.
65.	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.
66.	Suction Tip and Catheter	Class B	Suction Catheters feature a whistle tip and a thumb control port for precise and accurate suctioning.
67.	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.
68.	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, to facilitate placement and exchange of guidewires and other interventional devices.
69.	Balloon Type Catheter	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.
70.	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.
71.	Bartholin Gland Catheter	Class B	Catheter is used for the treatmenti of abscesses and cysts of the Hartholin gland.

72.	Bronchography Catheter	Class B	Intended to deliver therapeutic and diagnostic agents that are indicated or labeled for airway, tracheal or bronchial delivery into selected and sub-selected regions of the airway tree
73.	Cholangiography Catheter	Class B	Diagnostic evaluation of the bile ducts during laparoscopic cholecystectomy procedures
74.	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
75.	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
76.	Anesthesia conduction kit	Class C	Intended for use in the administration of anesthetic agents into the epidural space.
77.	Continuous Flush Catheter	Class B	Intended for the controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature.
78.	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.
79.	Coude Catheters	Class B	It is a urinary catheter, It may be used to inject liquids used for treatment or diagnosis of bladder conditions.
80.	Depezzar Catheter	Class B	A tubular, flexible instrument, passed through body channels for withdrawal of fluids from a body cavity.
81.	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 drag infusion.
82.	Epidural Catheter	Class B	Epidural catheter is a very thin, flexible tube that is implanted into spine
83.	Esophageal Balloon Catheter	Class B	intended for use in adult and adolescent populations to endoscopically dilate strictures of the esophagus.
84.	Eustachian Catheter	Class B	It is used to test Eustachian tube patency

85.	Guiding Catheter	Class B	The guide catheter provides support for device advancement .
86.	Haemodialysis Catheter	Class B	A catheter used for exchanging blood to and from the haemodialysis machine from the patient.
87.	Intramuscular Pressure Monitoring Catheter	Class B	A modified fibre optic transducer-tipped catheter system for measuring intramuscular pressures during exercise was determined.
88.	Introducer Sheath	Class C	Intended to provide easier access to the femoral, popliteal and infrapopliteal arteries.
89.	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
90.	Jejunostomy Catheter	Class B	Used for intraoperative feeding jejunostomy
91.	Multiple Lumen Catheter	Class B	Intended for monitoring central venous pressure (CVP), sampling blood, and simultaneous administration of multiple IV solutions or drugs.
92.	Nasal Oxygen Catheter	Class B	It is a device used to deliver supplemental oxygen or increased airflow to a patient or person in need of respiratory help.
93.	Nephrostomy Catheter	Class B	A nephrostomy is a tube that's used to drain urine from a kidney into a bag outside the body.
94.	Peritoneal Dialysis Catheter	Class B	That allows dialysis fluid to enter the abdominal cavity, dwell inside for a while, and then drain back out again
95.	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.
96.	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.
97.	Retention Type Catheter	Class B	This type of catheter is placed into the bladder and secured there for a period of time.
98.	Retention Type Balloon Catheter	Class B	It has a balloon at the distal end, which is inflated with sterile water or saline to prevent the catheter from slipping out of the bladder

99.	Salpingography Catheter	Class B	Used for injection of contrast medium into the fallopian tube(s) for selective salpingography.
100.	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
101.	Straight Catheter	Class B	It is used in patients with neurogenic bladder or spinal cord injury, lessens the risk of urinary tract infection
102.	Subclavian Catheter	Class B	Catheters can be placed in veins in the neck (internal jugular vein), chest (subclavian vein or auxiliary vein),
103.	Suprapubic Catheter	Class B	A suprapubic catheter is a thin, sterile tube used to drain urine from bladder.
104.	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
105.	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.
106.	Upper Urinary Tract Catheter	Class B	The catheter to the bladder and subsequently to the upper urinary tract
107.	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.
108.	Urethrographic Male Catheter	Class B	A catheter used to pass into a man's bladder.
109.	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.
110.	Percutaneous Retrieval Device	Class B	Embolization of the occlusion device after percutaneous closure of atrial septal defect (ASD) is a potential disastrous complication.
111.	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)

112.	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.
113.	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
114.	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;
115.	Percutaneous Long Term Intraspinal Catheter	Class C	To conduct a preimplant intra spinal infusion screening trial procedure prior to implanting a pump
116.	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
117.	Subcutaneous Intraspinal Port & Catheter	Class C	Catheters used for both epidural Intrathecal infusion include short-term externalized catheters and long-term catheters that are tunneled in the subcutaneous tissue
118.	Peripheral, Transluminal Angioplasty Catheter	Class D	A catheter for treating peripheral vascular diseases
119.	Cardiac Thermolulution Catheter	Class D	A catheter used in thermolulution for introduction of the cold liquid indicator into the cardiovascular system.
120.	Cardiovascular Catheter	Class D	A thin, hollow tube called a catheter is inserted into a large blood vessel that leads to heart.
121.	Cerebrospinal Catheter	Class D	For treatment or prevention of cranial/spinal cerebrospinal fluid fistula.
122.	Atherectomy Coronary Catheter	Class D	A catheter containing a rotating cutter and a collecting chamber for debris, used for atherectomy and endarterectomy.
123.	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.
124.	Embolectomy Catheter	Class D	indicated for the removal of fresh, soft emboli and thrombi from vessels in the arterial system

125.	Flow Directed Catheter	Class D	Used for venous sampling and pressure monitoring.
126.	Ultrasonic imaging Catheter	Class D	intended for ultrasound examination of peripheral pathology only
127.	Intraaortic Balloon Catheter	Class D	It is indicated for use in patients undergoing cardiopulmonary bypass.
128.	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.
129.	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
130.	Intravascular Diagnostic Catheter	Class D	Used to record intracardiac pressures, to sample blood, and to introduce substances into the heart and vessels.
131.	Occlusion Catheter	Class D	Insertion of a device or develop at any time during the course of intravenous (IV) therapy.
132.	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.
133.	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. -
134.	Pericardium Drainage Catheter	Class D	Catheter drainage of the pericardium
135.	Atherectomy Peripheral Catheter	Class D	Intended for use in atherectomy of the peripheral vasculature.
136.	Septostomy Catheter	Class D	Used to enlarge interatrial openings
137.	Thrombectomy Catheter	Class D	Thrombectomy catheter is specifically designed to treat deep vein thrombosis (DVT) in large-diameter upper and lower peripheral veins.
138.	Transluminal, Coronary Angioplasty, Percutaneous Catheter	Class D	The catheter is placed in the opening or ostium of one the coronary arteries

139.	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.
140.	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.
141.	Pacemaker Lead (Catheter)	Class D	A catheter that is inserted near your collarbone or through your leg (groin) artery.
142.	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
143.	Imaging Catheter	Class C	Intended for use with the various medical imaging consoles.
144.	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.
145.	Angiographic Injector and Syringe	Class B	It is a device used to inject contrast material into the heart, great vessels, and coronary arteries to study the heart and vessels by x-ray photography.
146.	Auto transfusion Appartus	Class B	It is a device used to collect and reinfuse the blood lost by a patient due to surgery or trauma
147.	Colonoscope (Gastro-Urology)	Class B	The endoscopic examination of the large bowel and the distal part of the small bowel with a CCD camera or a fibre optic camera on a flexible tube passed through the anus.
148.	Disposable Hypodermic Syringes	Class B	Intend to inject fluids into or withdraw fluids from the body.
149.	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.
150.	Custom Perfusion System	Class C	Indicated for use in the extra corporeal circuit during cardio pulmonary bypass surgery procedure.

151.	Sealant, pit and Fissure	Class C	Sealant is a protective plastic coating, which is applied to the biting surfaces of the back teeth.
152.	Contraceptive Occlusion Tubal Device	Class C	A contraceptive tubal occlusion device (TOD) and introducer is a device designed to close a fallopian tube with a mechanical structure. The devices are used to prevent pregnancy
153.	Suture Non Absorable 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.
154.	Suture Absorable	Class C	The device is intended for use in general soft tissue approximation and ligation.
155.	Dialysate Tubing and Connector	Class B	A tubing connector adapted for peritoneal dialysis connections between tubing sets and containers of dialysate
156.	Semi-Automatic Peritoneal Dialysate Delivery System	Class C	The source of dialysate may be sterile prepackaged dialysate or dialysate prepared from dialysate concentrate and sterile purified water .
157.	Peritoneal Automatic Delivery System	Class C	Controls and monitors the dialysate circulating through the dialysate compartment of the dialyzer
158.	Peritoneal Dialysis Unit	Class B	Peritoneal dialysis (PD) is a treatment for patients with severe chronic kidney disease.
159.	Hollow Fiber Capillary Dialyzer	Class C	Intended for single use acute and chronic haemodialysis.
160.	Penrose Drain	Class B	A Penrose drain is a surgical device, placed in a wound to drain fluid.
161.	Sump Drain	Class B	A drain consisting of an outer tube vented to the outside with a smaller tube within it that is attached to a suction pump; both have multiple perforations that allow fluid and air to be carried away through the suction tube.
162.	Vent Drain	Class B	To release or discharge (steam, for example) through an opening.
163.	Urinary Drainage Unit	Class A	A closed urinary drainage system consists of a catheter inserted into the urinary bladder and connected via tubing to a drainage bag

164.	Wound Drainage and closed drainage system	Class B	Intended for evacuation of biological fluid from wound or body cavity during surgical procedure or in wound care management.
165.	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
166.	Embolic Protection Device	Class D	Embolic protection devices are used to capture and remove debris that becomes dislodged during an interventional procedure
167.	Artificial Embolization Device	Class D	Used for the treatment of unresectable/inoperable hypervascularized tumours.
168.	Pharyngoscope	Class A	An instrument for inspecting the pharynx.
169.	Anoscope	Class B	It is inserted a few inches into the anus in order to evaluate problems of the anal canal
170.	Choledochoscope	Class B	Used to see into the central bile duct which is a narrow channel.
171.	Cystourethroscope	Class B	An endoscope used for the visual examination of the posterior urethra and bladder
172.	Endoscope and Accessories	Class B	An endoscope and accessories is a device used to provide access, illumination, and allow observation or manipulation of body cavities, hollow organs, and canals.
173.	Fiber optic Endoscope	Class B	An endoscope can consist of: a rigid or flexible tube. a light delivery system to illuminate the organ or object under inspection. The light source is normally outside the body and the light is typically directed via an optical fibre system
174.	Neurological Endoscope	Class B	A neurological endoscope is an instrument with a light source used to view the inside of the ventricles of the brain
175.	Transcervical (Amnioscope) and Accessories	Class B	A transcervical endoscope is a device designed to permit direct viewing of the foetus and amniotic sac by means of an open tube introduced into the uterus through the cervix.
176.	Oesophagus Gastro Suodenoscope	Class B	To examine the lining of oesophagus, stomach, and duodenum. The oesophagus is the muscular tube that connects your throat to stomach and the duodenum, which is the upper part of small intestine

177.	Esophagoscope	Class B	An endoscope for inspecting the interior of the oesophagus
178.	gastro scope	Class B	An endoscope for inspecting the interior of the stomach
179.	Hysteroscope	Class B	An endoscope used for the visual examination of the cervix and interior of the uterus
180.	Laparoscope	Class B	A usually rigid endoscope that is inserted through an incision in the abdominal wall and is used to examine visually the interior of the peritoneal cavity—called also peritoneoscope
181.	Mediastinoscope	Class B	An endoscope used in mediastinoscopy
182.	Panendoscope	Class B	A cystoscope that gives a wide- angle view of the bladder.
183.	Peritoneoscope	Class B	A usually rigid endoscope that is inserted through an incision in the abdominal wall and is used to examine visually the interior of the peritoneal cavity—called also peritoneoscope
184.	Proctoscope	Class B	An instrument used for dilating and visually inspecting the rectum and lower portion of the sigmoid colon
185.	Resectoscope	Class B	An instrument consisting of a tubular fenestrated sheath with a sliding knife within it that is used for surgery within cavities
186.	Fiberoptic Intubation Scope	Class B	Fiberoptic intubation involves threading an endotracheal tube over the shaft of a flexible fiberoptic scope.
187.	Nephroscope	Class B	An endoscope used for inspecting and passing instruments into the interior of the kidney
188.	Sigmoidoscope	Class B	An endoscope designed to be passed through the anus in order to permit inspection, diagnosis, treatment, and photography especially of the sigmoid colon—called also proctosigmoidoscope
189.	Sphincteroscope	Class B	An endoscope and accessories is a device used to provide access, illumination, and allow observation or manipulation of body cavities, hollow organs, and canals

190.	Ophthalmoscope	Class B	The Ophthalmoscope allows easy entry into the eye, and a 5X larger field of view of the fundus in an undilated eye, providing better images of the retinal changes caused by hypertension, diabetic retinopathy, glaucoma, and papilledema.
191.	Surgical Polymeric 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
192.	Absorbable Hemostatic Collagen 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.
193.	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.
194.	Insulin Injector/Insulin Syringes/Insulin Needles/Pen Needles for insulin	Class B	Used to inject insulin for the treatment of diabetes.
195.	Medication Injector	Class B	A subcutaneous injection is a method of administering medication.
196.	Contrast Medium Automatic Injector	Class C	Contrast material are inserted, piston plungers that deliver the contrast from the syringes, and pressure tubing that connects the syringe and vascular system of the patient.
197.	Thermal Dilution Injector	Class C	A thermo dilution injector is presented in which a pneumatically powered piston operates the plunger of a syringe to deliver a measured amount of injectate in an accurately predetermined time period.
198.	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
199.	Dry Eye Insert	Class B	It is indicated in patients with moderate to severe dry eye syndromes, including kerato conjunctivitis sicca
200.	Myringotomy Tube Inserter	Class A	An instrument for grasping securely an aural ventilation tube whilst simultaneously presenting the device at the correct angle for the insertion of an aural ventilation tube
201.	Sacculotomy Tack Inserter	Class A	The device repetitively ruptures the utricular membrane as the membrane expands under increased endolymphatic pressure

202.	laryngoscope	Class B	The conventional laryngoscope consists of a handle containing batteries with a light source, and a set of interchangeable blades.
203.	Biopsy Needle Kit	Class B	A set of neurosurgical instruments designed to allow multiple biopsies from one or more targets in one trajectory
204.	Angiographic Needle	Class B	Angiographic needle has a unique hub design with an ergonomic feel and a black triangle indicator to orient the bevel.
205.	Mammary Biopsy Needle	Class B	The growth sample is suctioned out through a needle or cut out using a surgical procedure
206.	Blood Collecting Needle	Class B	Needle used to collect blood through syringe
207.	Bone Marrow Needle	Class B	Needle inserted in Bone Marrow to collect sample
208.	Gynaecological Cerclage Needle	Class B	It is a loop like instrument used to suture the cervix.
209.	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
210.	Anaesthetic Conduction Needle	Class B	An anaesthesia conduction needle is a device used to inject local anaesthetics into a patient to provide regional anaesthesia
211.	Dental Needle	Class B	Dental Needles have the ultra-sharp bevel design with triple faceting, which minimises patient trauma
212.	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.
213.	Endoscopic Needle	Class B	Used to sample targeted submucosal gastrointestinal lesions through the accessory channel of an ultrasound endoscope.
214.	Fistula Needle	Class B	To connect blood lines with the blood vessels through needles when dialysis is carried out
215.	Epidural Needle	Class B	Intended for transient delivery of anaesthetics to provide regional anesthesia or to facilitate placement of an epidural catheter

216.	Vacutainer Flashback needles	Class B	Intended to be used with evacuated blood collection tube for collection of venous blood.
217.	Y-Connector	Class C	It can be used to connect to a perfusion sets or catheter for infusion of contrast media etc.
218.	Retrieval Basket	Class C	To entrap and remove stones from biliary system
219.	3 way stop cock as an accessory	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
220.	Detachable coils	Class D	Intended for endovascular embolization of the intracranial aneurysms. Also intended for the embolization of other neurovascular abnormalities
221.	Gastro-Urology Needle	Class B	Intended for gastroenterology biopsy
222.	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.
223.	Neurosurgical Suture Needle	Class B	A needle used in suturing during neurosurgical procedures or in the repair of nervous tissue.
224.	Oocyte Aspiration Needle	Class B	Mission to collect the maximum amount of undamaged oocytes in a short time as possible.
225.	Ophthalmic Needle	Class B	Needle used for Ophthalmic Surgery
226.	Pneumoperitoneum Simple Needle	Class B	Inserting a Veress needle through the abdominal wall inside the peritoneal cavity.
227.	Radiographic Needle	Class B	Identifying lost surgical needles
228.	Sclerotherapy Needle/ Catheter	Class B	It is designed to provide access for injection therapy applications and may also be used for polypectomy and endoscopic
229.	Oxygen administration Kit	Class B	Administered for various cardiac and respiratory emergencies, emergency oxygen kits and supplies are available without a prescription for first aid

230.	Passer wire Orthopaedic	Class B	To fit through a small incision on the clavicle and curve around the coracoids
231.	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.
232.	Fluid Delivery tubing	Class B	Tube used to deliver fluid in body
233.	Gastro-Urology Probe and Director	Class B	Guiding probe, in particular for an endoscope for surgical endoscopy with laser light.
234.	Common duct Probe	Class B	Guiding probe, in particular for an endoscope for surgical endoscopy with laser light.
235.	ENT Probe	Class B	Guiding probe, in particular for an endoscope for surgical endoscopy with laser light.
236.	Periodontic Probe	Class B	A periodontal probe is an instrument in dentistry commonly used in the dental armamentarium.
237.	Trabeculotomy Probe	Class B	Trabeculotomy Probes are a commonly used tool in glaucoma surgeries.
238.	Laproscope Heating tissue Probe	Class B	A heater probe can achieve extreme temperatures that conduct heat to the tissue
239.	Laser Probe	Class B	It is a laser-based voltage and timing waveform acquisition system which is used to perform failure analysis on flip-chip integrated
240.	Radiofrequency Lesion Probe	Class B	A radiofrequency lesion probe is a device connected to a radiofrequency (RF) lesion generator to deliver the RF energy to the site within the nervous system where a lesion is desired
241.	Temperature Probe	Class B	Used to measure core body temperature via placement in the oesophagus,
242.	Nuclear Uptake Probe	Class B	A nuclear uptake probe is a device intended to measure the amount of radionuclide taken up by a particular organ or body region.

243.	Extra vascular Blood Flow Probe	Class C	An extra vascular blood flow probe is an extra vascular ultrasonic or electromagnetic probe used in conjunction with a blood flow meter to measure blood flow in a chamber or vessel.
244.	Ultrasonic Probe	Class C	Ultrasonic probe is a very important sensor which generate acoustic signals and also detect returned signals
245.	Pulmonary Artery Band	Class D	Intended to reduce excessive pulmonary blood flow and protect the pulmonary vasculature from hypertrophy and irreversible (fixed) pulmonary hypertension
246.	Bronchoscope Rigid Tube	Class B	It is intended to examine or treat the larynx and tracheobronchial tree. It is typically used with a fiberoptic light source and carrier to provide illumination.
247.	Gastroplasty Calibration Tube	Class B	Is used in silastic ring gastroplasty and is based on a tube of the desired size in the lumen.
248.	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).
249.	Connecting Tube	Class B	Used to provide connection to a drainage bag.
250.	Decompression Tube	Class B	Decompression using a rectal tube may assist in the treatment only if the sigmoid colon is involved.
251.	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.
252.	Drainage Tube	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.
253.	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 .
254.	Oesophageal Sengtaken Tube	Class B	It is used only in emergencies where bleeding from presumed varices is impossible to control with medication alone
255.	Feeding Tube	Class C	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

256.	Gastro-Enterostomy Tube	Class B	Tube is placed through the abdominal wall into the stomach and then through the duodenum into the jejunum.
257.	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
258.	Heart-Lung Bypass Unit Tube	Class B	A tube will be placed in your heart to drain blood to the machine.
259.	Laryngectomy Tube	Class B	It is a hollow tube made of metal or plastic. It is put into the breathing tube in your neck called the trachea so you can breathe
260.	Levine Tube	Class B	Used for the aspiration of gastric and intestinal contents and administration of tube feedings or medications.
261.	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
262.	Nephrostomy Tube	Class B	The nephrostomy tube drains urine from kidney into a collecting bag outside the body.
263.	Orthodontic Tube	Class B	An orthodontic small metal part welded on the outside of a molar bank, which contains slots to hold archwires, lip bumpers, facebows and other devices used to move the teeth.
264.	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 .
265.	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.
266.	Tonsil Suction Tube	Class B	Used to suck out stones in tonsils.
267.	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.
268.	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.
269.	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.

270.	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
271.	Bone Wire	Class B	Intended to be used for bone stabilization in the hand and wrist.
272.	Intra Osseous Fixation Wire	Class B	Stabilization of fractured bony parts by direct fixation to one another with surgical wires
273.	Ligature Wire	Class B	offer a spot-welded auxiliary hook which may be added to any bracket by simply tying in the arch wire
274.	Surgical Staples	Class A	Surgical staples are specialized staples used in surgery in place of sutures to close skin wounds, connect or remove parts of body during surgery.
275.	Scalp Vein Set	Class C	To administer parental fluid/medication into patient's vascular system.
276.	Collection bags	Class A	Bags intended for bile collecting, drainage purpose, stoma collection, urinary collection or for other external collection use.
277.	Collection Bags	Class B	Intended for breathing, , enteral feeding, haemostatic (blood collection), I.V. container and accessories
278.	Surgical Dressings	Class A	Dressing aerosol, non-adherent, dressing, periodontal, kit, dressing pad, dressing.
279.	Surgical Dressings	Class B	Dressing-gel, dressing- permeable, moisture dressing, tracheostomy tube dressing, wound and burn dressings, hydrogel dressing, wound and burn, occlusive.
280.	Cotton Grudges and bandages	Class B	Adhesive bandages, Gauge bandages, Pressure bandages, Traction bandages, Medical Absorbent (fiber) bandages.
281.	Sterile Drapes	Class B	It is intended for use during various surgeries.
282.	Wound Dressings/Bacteriostatic Wound Dressings	Class C	Includes Beads, Hydrophilics For Wound Exudate Absorption for wound care.
283.	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.

284.	Bio Patches	Class C	Intended for reconstruction and repair of defects of pericardium.
285.	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.
286.	Disinfectants and insecticides	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.
287.	Anticoagulant Solutions	Class B	For pre-storage leukocyte reduction of whole blood or whole blood or blood component initiated between 4 and 7 hours after collection if whole blood is stored at ambient temperature
288.	Manifolds	Class B	Indicated for fluid flow directional control and for providing access port/ports for administration of a solution.
289.	Haemostatic Gelatine Sponge /Haemostat	Class C	Intended for the control of surface bleeding from vascular access sites and percutaneous catheters or tubes.
290.	Surgical Dressings	Class C	Material dressing, surgical, polylactic acid dressings.
291.	Male / Female Condoms	Class C	Condom with nonoxynol-9, micro-condom, prophylactic (condom) – latex sheath, non-latex, condoms with natural membrane, intra vaginal condoms.
292.	Intra Uterine devices	Class C	Intrauterine device, contraceptive (iud), introducer, uterine balloon therapy devices
293.	Tubal Rings / Fallopian Rings	Class C	Contraception devices for female sterilization
294.	Surgical Wire	Class B	It is a medical device used to hold body tissues together after an injury or surgery.
295.	Vascular clip	Class D	A small titanium or polyglycolic acid vessel clamp used to occlude blood vessels or to perform vascular anastomoses.
296.	Pacemaker polymeric mesh bag	Class B	A pacemaker polymeric mesh bag is an implanted device used to hold a pacemaker pulse generator.

297.	Vena cava clip	Class D	An implanted extravascular device designed to occlude partially the vena cava for the purpose of inhibiting the flow of thromboemboli through that vessel.
298.	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.
299.	Vascular embolization device	Class D	It is an intravascular implant intended to control hemorrhaging due to aneurysms, certain types of tumors.
300.	Endovascular suturing system	Class C	It is a medical device intended to provide fixation and sealing between an endovascular graft and the native artery.
301.	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.
302.	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.
303.	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.
304.	Pacemaker repair or replacement material	Class C	A pacemaker repair or replacement material is an adhesive, a sealant, a screw, a crimp, a battery or any other material used to repair a pacemaker lead or to reconnect a pacemaker lead to a pacemaker pulse generator.
305.	Annuloplasty ring	Class C	An annuloplasty ring implanted around the mitral or tricuspid heart valve for reconstructive treatment.
306.	Heart valve	Class D	A device intended to perform the function of any of the heart's natural valves.
307.	Middle ear mold	Class C	It is a preformed device that is intended to be implanted to reconstruct the middle ear cavity during repair of the tympanic membrane.
308.	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.
309.	Ear, nose, and throat synthetic polymer material	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.

310.	Mandibular implant facial prosthesis	Class C	Intended to be implanted for use in the functional reconstruction of mandibular deficits.
311.	Sacculotomy tack (Cody tack)	Class C	Intended to be implanted to relieve the symptoms of vertigo.
312.	Endolymphatic shunt	Class C	Intended to be implanted to relieve the symptoms of vertigo.
313.	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.
314.	Tympanostomy tube	Class C	Intended to be implanted for ventilation or drainage of the middle ear.
315.	Hearing aids	Class C	It is a wearable sound-amplifying device intended to compensate for impaired hearing.
316.	Vaginal pessary	Class C	Device is placed in the vagina to support the pelvic organs and is used to treat conditions such as uterine prolapse, uterine retroposition) or gynecologic hernia.
317.	Fallopian tube prosthesis	Class C	A device designed to maintain the patency (openness) of the fallopian tube and is used after reconstructive surgery.
318.	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.
319.	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.
320.	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.
321.	Aqueous shunt	Class C	Intended to reduce intraocular pressure in the anterior chamber of the eye.
322.	Bone cap	Class B	Intended to be implanted to cover the end of a bone.
323.	Bone fixation cerclage	Class C	Intended to use in the fixation of fractures.

324.	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.
325.	Intramedullary fixation rod	Class C	Intended to be implanted into the medullary (bone marrow) canal of long bones for the fixation of fractures.
326.	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.
327.	bone fixation appliances and accessories	Class C	Used for fixation of fractures of the proximal or distal end of bones, for fusion of a joint; or for surgical procedures.
328.	Dental fillers	Class C	Intended for the purpose of repairing a tooth.
329.	Orthopedic implant & accessories	Class C	Intended to replace a missing joint or bone or to support a damaged bone.
330.	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.
331.	Endosseous dental implant abutment	Class C	Intended for use as an aid in prosthetic rehabilitation.
332.	Dental implant & accessories	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.
333.	Bone grafting material	Class C	Intended to fill, augment, or reconstruct periodontal or bony defects of the oral and maxillofacial region.
334.	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.
335.	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.
336.	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.

337.	An interarticular disc prosthesis	Class D	Intended to be an interface between the natural articulating surface of the mandibular condyle and glenoid fossa.
338.	Pacemaker lead adaptor	Class C	A device used to adapt a pacemaker lead so that it can be connected to a pacemaker pulse generator produced by a different manufacturer.
339.	Cardiovascular intravascular filter	Class C	It is placed in the inferior vena cava for the purpose of preventing pulmonary thromboemboli from flowing into the right side of the heart and the pulmonary circulation.
340.	Implantable cardiac pacemaker including accessories	Class D	An implantable pacemaker pulse generator is a device that generates a periodic electrical pulse to stimulate the heart.
341.	Implantable cardioverter defibrillator	Class D	An implantable cardioverter defibrillator (ICD) is used to treat irregular heartbeats called arrhythmias.
342.	Implantable cerebral stimulators	Class D	An implanted cerebellar stimulator is a device used to stimulate electrically a patient's cerebellar cortex related disorders.
343.	Implanted intracerebral/subcortical stimulator for pain relief	Class D	An implanted intracerebral/subcortical stimulator used to subsurface areas of a patient's brain to treat severe intractable pain.
344.	Implanted spinal cord stimulator for bladder evacuation	Class D	It is used to empty the bladder of a paraplegic patient who has a complete transection of the spinal cord and who is unable to empty his or her bladder by reflex means or by the intermittent use of catheters.
345.	Implanted neuromuscular stimulator	Class D	It provides electrical stimulation to a patient's nerve to cause muscles in the affecting area of the body to contract, thus improving condition of a patient with a paralyzed organ.
346.	Implantable Diaphragmatic stimulator	Class D	A device that provides electrical stimulation of a patient's phrenic nerve to contract the diaphragm rhythmically and produce breathing in patients who have hypoventilation caused by brain stem disease, high cervical spinal cord injury, or chronic lung disease.
347.	Implanted peripheral nerve stimulator for pain relief	Class D	It is used to stimulate electrically a peripheral nerve in a patient to relieve severe intractable pain.
348.	Implanted spinal cord stimulator	Class D	A device that is used to stimulate electrically a patient's spinal cord to relieve severe intractable pain.
349.	Permanent Pacemaker electrode	Class C	A device consisting of flexible insulated electrical conductors with one end connected to an implantable pacemaker pulse generator and the other end applied to the heart.

350.	A carotid sinus nerve stimulator	Class D	An implantable device used to decrease arterial pressure by stimulating Hering's nerve at the carotid sinus.
351.	Penile inflatable implant	Class C	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.
352.	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
353.	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.
354.	Implantable Infusion pump	Class D	An implantable infusion pump (IIP) is intended to provide long-term continuous or intermittent drug infusion
355.	Artificial Urinary Sphincters implants	Class C	It is used to prevent incontinence by occluding the urethra.
356.	Ureteral stent	Class C	An ureteral stent is a tube-like implanted device that is inserted into the ureter to provide ureteral rigidity and allow the passage of urine
357.	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.
358.	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.
359.	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.
360.	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.
361.	Implanted electrical urinary continence device	Class D	A device intended for treatment of urinary incontinence that consists of a receiver implanted in the abdomen with electrodes for pulsed-stimulation that are implanted either in the bladder wall or in the pelvic floor, and a battery-powered transmitter outside the body.

362.	Implantable transprostatic tissue retractor system	Class C	It is a prescription use device that consists of a delivery device and implant. The delivery device is inserted transurethrally and deploys the implant through the prostate
363.	External Infusion Pump	Class C	Intended for drug delivery to the patients body.
364.	Haemo-Dialyzer System	Class D	The dialyzer is intended for the treatment of chronic and acute renal failure by hemodialysis.
365.	Intraocular lens	Class C	Intraocular lens (IOL) are lens implanted in the eye used to treat cataracts or myopia
366.	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.
367.	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
368.	Breast implant	Class C	Breast implant is used to increase the breast size.
369.	Hernia Surgical mesh Implant	Class C	Hernia surgical mesh implant is a medical device that is used to provide additional support to weakened or damaged tissue
370.	Esophageal stent	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
371.	Biliary stents	Class C	Biliary stents provide bile drainage from the gallbladder, pancreas and bile ducts to the duodenum in conditions such as ascending cholangitis due to obstructing gallstones
372.	Glaucoma drainage stents	Class C	Glaucoma drainage stents are recent developments and are awaiting approval in some countries. They are used to reduce intraocular pressure by providing a drainage channel.
373.	Duodenal stents	Class C	Duodenal Stent is indicated for the palliative treatment of gastroduodenal obstructions
374.	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.
375.	Pancreatic stent	Class C	Pancreatic duct stents are often placed in patients who have chronic pancreatitis

376.	Bifurcation Stent	Class C	Intended for improving the side branch luminal diameter of arterial bifurcation liaisons.
377.	Carotid Stent System	Class C	Indicated for the treatment of patients at high risk for adverse events from carotid endarterectomy who require carotid revascularization.
378.	Peripheral Stent System	Class C	A Peripheral stent is a tube-shaped device placed in the peripheral arteries that supply blood into body organ.
379.	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
380.	Pedicle screw spinal system	Class C	It is used to intended to provide immobilization and stabilization of spinal segments
381.	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.
382.	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.
383.	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.
384.	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
385.	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.
386.	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
387.	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
388.	Finger joint metal/metal constrained uncemented prosthesis	Class C	A device intended to be implanted to replace a metacarpophalangeal or proximal interphalangeal (finger) joint

389.	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
390.	Finger joint polymer constrained prosthesis	Class C	A device intended to be implanted to replace a metacarpophalangeal or proximal interphalangeal (finger) joint
391.	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
392.	Hip joint metal/polymer constrained cemented or uncemented prosthesis	Class D	A hip joint metal/polymer constrained cemented or uncemented prosthesis is a device intended to be implanted to replace a hip joint
393.	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
394.	hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis	Class D	Intended to be implanted to replace a hip joint
395.	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
396.	Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis	Class C	Intended to be implanted to replace a hip joint
397.	Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis.	Class C	Intended to be implanted to replace a hip joint
398.	A knee joint femorotibial metallic constrained cemented prosthesis is a device intended to be implanted to replace part of a knee joint	Class C	Intended to be implanted to replace part of a knee joint
399.	Shoulder joint metal/metal or metal/polymer constrained cemented prosthesis	Class C	Intended to be implanted to replace a shoulder joint

400.	Wrist joint carpal lunate polymer prosthesis	Class C	Intended to be implanted to replace the carpal lunate bone of the wrist.
401.	Wrist joint metal/polymer semi-constrained cemented prosthesis	Class C	Intended to be implanted to replace a wrist joint.
402.	Wrist joint metal constrained cemented prosthesis	Class C	Intended to be implanted to replace a wrist joint
403.	Wrist joint polymer constrained prosthesis	Class C	Intended to be implanted to replace a wrist joint
404.	Wrist joint carpal trapezium polymer prosthesis	Class C	Intended to be implanted to replace the carpal trapezium bone of the wrist
405.	Wrist joint carpal scaphoid polymer prosthesis	Class C	Intended to be implanted to replace the carpal scaphoid bone of the wrist.
406.	Toe joint phalangeal (hemi-toe) polymer prosthesis	Class C	Intended to be implanted to replace the base of the proximal phalanx of the toe.
407.	Toe joint polymer constrained prosthesis	Class C	Intended to be implanted to replace the first metatarsophalangeal (big toe) joint
408.	Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis.	Class C	A shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis.
409.	Shoulder joint glenoid (hemi-shoulder) metallic cemented prosthesis	Class C	It is intended to be implanted to replace part of a shoulder joint
410.	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
411.	Shoulder joint metal/polymer semi-constrained cemented prosthesis	Class C	Intended to be implanted to replace a shoulder joint
412.	shoulder joint metal/polymer non-constrained cemented prosthesis	Class C	Intended to be implanted to replace a shoulder joint

413.	Knee joint tibial (hemi-knee) metallic resurfacing uncemented prosthesis	Class C	Intended to be implanted to replace part of a knee joint
414.	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
415.	knee joint femoral (hemi-knee) metallic uncemented prosthesis	Class C	Intended to be implanted to replace part of a knee joint.
416.	knee joint patellofemorotibial metal/polymer	Class C	Intended to be implanted to replace a knee joint
417.	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis.	Class C	Intended to be implanted to replace a knee joint
418.	Knee joint patellofemorotibial polymer/metal/metal constrained cemented prosthesis	Class C	Intended to be implanted to replace a knee joint
419.	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
420.	Knee joint femorotibial (uni-compartmental) metal/polymer porous-coated uncemented prosthesis	Class C	Intended to be implanted to replace part of a knee joint
421.	Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis	Class C	Intended to be implanted to replace part of a knee joint
422.	Knee joint femorotibial metal/polymer non-constrained cemented prosthesis	Class C	Intended to be implanted to replace part of a knee joint
423.	Knee joint femorotibial metal/polymer constrained cemented prosthesis	Class C	Knee joint femorotibial metal/polymer constrained cemented prosthesis
424.	Knee joint femorotibial metal/polymer constrained cemented prosthesis	Class C	Intended to be implanted to replace part of a knee joint

425.	Knee joint femorotibial metal/composite semi-constrained cemented prosthesis	Class C	Intended to be implanted to replace part of a knee joint.
426.	Knee joint femorotibial metal/composite non-constrained cemented prosthesis	Class C	Intended to be implanted to replace part of a knee joint
427.	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
428.	Hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis	Class D	Intended to be implanted to replace a hip joint
429.	hip joint metal constrained cemented or uncemented prosthesis	Class D	Intended to be implanted to replace a hip joint
430.	Hip joint metal/polymer constrained cemented or uncemented prosthesis	Class D	Intended to be implanted to replace a hip joint
431.	Hip joint femoral (hemi-hip) metallic resurfacing prosthesis	Class D	Intended to be implanted to replace a portion of the hip joint
432.	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
433.	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
434.	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
435.	A hip joint (hemi-hip) acetabular metal cemented prosthesis	Class D	Intended to be implanted to replace a portion of the hip joint
436.	Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis.	Class D	Intended to be implanted to replace a portion of the hip joint
437.	Orthodontic Bands/Braket	Class A	Band or belt intended to provide support.

438.	Orthopaedic Plates, clippersScrews	Class B	Cervical orthosis, cervical -thoracic, rigid, limb brace, lumbar, lumbo-sacral, rib fracture, sacroiliac, thoracic oethosis.
439.	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.
440.	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
441.	Resorbable calcium salt bone void filler device	Class C	A resorbable calcium salt bone void filler device is a resorbable implant intended to fill bony voids or gaps of the extremities, spine, and pelvis
442.	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.
443.	Intrastromal corneal ring	Class C	A small device implanted in the eye to correct vision.
444.	Injectable fillers	Class C	Injectable filler (injectable cosmetic filler, injectable facial filler) is a soft tissue filler injected into the skin to help fill in facial wrinkles, restoring a smoother appearance
445.	Tracheal prosthesis	Class C	It is intended to be implanted to restore the structure and/or function of the trachea or trachealbronchial tree
446.	Polytetrafluoroethylene with carbon fibers composite implant material	Class C	Intended to be implanted during surgery of the chin, jaw, nose, or bones or tissue near the eye or ear.
447.	Chin prosthesis	Class C	Intended to be implanted to augment or reconstruct the chin
448.	Ear prosthesis	Class C	Intended to be implanted to reconstruct the external ear
449.	Nose prosthesis	Class C	Intended to be implanted to augment or reconstruct the nasal dorsum.

450.	Esophageal prosthesis	Class C	Intended to be implanted to restore the structure and/or function of the esophagus
451.	Fixation, non-absorbable for pelvic use	Class C	Attaching suture or stapling ligaments of the pelvic floor.
452.	Sacroiliac joint fixation	Class C	The sacroiliac joints fixation may serve as protective mechanism for the lumbosacral region.
453.	Intra Ocular lenses (IOL)	Class D	Intended to be implanted to replace the natural lens of an eye.
454.	IOL multifocal		
455.	IOL toric optic		
456.	IOL accommodative		
457.	IOL iris reconstruction		
458.	Nebulizer	Class B	Intended to spray liquids in aerosol form into gases that are delivered directly to the patient for breathing includes heated, ultrasonic, gas, venturi, and refillable nebulizers.
459.	Adhesive	Class A	Adhesive strip for minor skin cut, adhesive gel used on measuring electrodes or any similar use which does not come with the body fluids.
460.	Tissue adhesive for the topical use	Class C	Intended for topical closure of surgical incisions including laparoscopic incisions and simple traumatic lacerations.
461.	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.
462.	Dental adhesive system	Class C	Used as dental cement, etchant, primer.

B - LIST OF IN VITRO DIAGNOSTIC MEDICAL DEVICES ALONG WITH THEIR RISK CLASS

S. N.	Category	<i>in vitro</i> diagnostic medical device	Class	Intended use
			A	
1.	Instruments, analyzers, receptacles etc used for an in vitro diagnostic procedure exemplified as :	Slides, Mixing sticks, Droppers etc.	A	If it is reagent or an article which possesses any specific characteristic that is intended by its product owner to make it suitable for an in vitro diagnostic procedure related to a specific examination
2.		Instruments/ Analyzers	A	an instrument intended specifically to be used for an in vitro diagnostic procedure
3.		Test tubes, Blood collection tubes, Petri dishes etc.	A	a specimen receptacle
			B	
4.	Clinical Chemistry Reagents/ Kits for estimation of various Parameters exemplified as:	Acid Phosphatase (total or prostatic) test reagents/kits	B	An acid phosphatase (total or prostatic) test reagent/kit is a medical device, intended for the estimation of acid phosphatase in serum/plasma.
5.		Albumin test reagents/kits	B	An albumin test reagent/kit is a medical device intended for the estimation of albumin in serum/plasma.
6.		Alkaline phosphatase or isoenzymes test reagents/kits	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.
7.		Ammonia test reagents/kits	B	An ammonia test reagent/kit is a medical device intended for the estimation of ammonia levels in blood, serum/plasma.
8.		Amylase test reagents/kits	B	An amylase test reagent/kit is a medical device intended for the estimation of the enzyme amylase in serum, saliva / urine.
9.		Bicarbonate / carbon dioxide test reagents/kits	B	A bicarbonate/carbon dioxide test reagent/kit s a medical device for the estimation of bicarbonate/carbon dioxide in plasma, serum/whole blood.

10.	bilirubin (total and direct) test reagents/kits	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.
11.	Calcium test reagents/kits	B	A calcium test reagent/kit is a medical device intended for the estimation of total calcium in serum.
12.	Chloride test reagents/kits	B	A chloride test reagent/kit is a medical device intended for the estimation of chloride in plasma, serum, sweat /urine.
13.	cholesterol (total) test reagents/kits	B	A cholesterol (total) test reagent/kit is a medical device intended for the estimation of cholesterol in serum or plasma.
14.	HDL cholesterol test reagents/kits	B	A HDL cholesterol test reagent/kit is a medical device intended for the estimation of HDL cholesterol in serum / plasma.
15.	LDL cholesterol test reagents/kits	B	A LDL cholesterol test reagent/kit is a medical device intended for the estimation of LDL cholesterol in serum/plasma.
16.	Lipoprotein test reagents/kits	B	A lipoprotein test reagent/kit is a medical device intended for the estimation of lipoproteins in serum / plasma.
17.	Cholinesterase test reagents/kits	B	A cholinesterase test reagent/kit is a medical device intended for the estimation of cholinesterase in serum /plasma. .
18.	Creatine Kinase and its isoenzyme test reagents/kits	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. .
19.	Copper test reagents/kits	B	Copper test reagent/kit is a medical device intended for the estimation of copper in plasma, serum / urine.
20.	Creatinine test reagents/kits	B	A creatinine test reagent/kit is a medical device intended for the estimation of creatinine in serum, plasma / urine.
21.	Gamma Glutamyl Transferase (GGT) and isoenzymes test reagents/kits	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.
22.		Glucose test reagents/kits	B	A Glucose test reagent/kit is a medical device intended for the estimation of glucose in blood/plasma/ body fluids.
23.		Glucose-6-Phosphate Dehydrogenase (G6PD) and its isoenzymes test reagents/kits	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. .
24.		Glycosylated Hemoglobin or its variants test reagents/kits	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.
25.		Hemoglobin test reagents/kits	B	A hemoglobin test reagent/kit is a medical device intended for the estimation of hemoglobin in blood.
26.		Iron test reagents/kits	B	An iron test reagent/kit is a medical device intended for the estimation of iron in serum /plasma.
27.		Ferritin test reagents/kits		An Ferritin test reagent/kit is a medical device intended for the estimation of ferritin in serum / plasma
28.		Iron-binding capacity test reagents/kits	B	Iron-binding capacity test reagents/kits are medical devices intended for the estimation of iron-binding capacity in serum / plasma.
29.		Lactate Dehydrogenase and its isoenzymes test reagents/kits	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.
30.		Lipase test reagents/kits	B	A lipase test reagent/kit is a medical device intended for the estimation of lipase in serum / plasma.
31.		Magnesium test reagents/kits	B	A magnesium test reagent/kit is a medical device intended for the estimation of magnesium levels in serum / plasma.
32.		Phosphorus (inorganic) test reagents/kits	B	A phosphorus (inorganic) test reagent/kit is a medical device intended for the estimation of inorganic phosphorus in serum,

				plasma / urine.
33.		Potassium test reagents/kits	B	A potassium test reagent/kit is a medical device intended for the estimation of potassium in serum, plasma / urine.
34.		Aspartate Amino Transferase (AST/SGOT) test reagents/kits	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.
35.		Alanine Amino Transferase (ALT/SGPT) test reagents/kits	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.
36.		Sodium test reagents/kits	B	A Sodium test reagent/kit is a medical device intended for the estimation of sodium in serum/ plasma / urine.
37.		Total protein test reagents/kits	B	A Total Protein test reagent/kit is a medical device intended for the estimation of total protein(s) in serum / plasma.
38.		Protein (fractionation) test reagents/kits	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.
39.		Protein-bound iodine test reagents/kits	B	A Protein-bound iodine test reagent/kit is a medical device intended for the estimation of protein-bound iodine in serum / plasma.
40.		Triglycerides test reagents/kits	B	A Triglyceride test reagent/kit is a medical device intended for the estimation of triglycerides in serum / plasma.
41.		Urea (BUN) test reagents/kits	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.
42.		Uric Acid test reagents/kits	B	A Uric Acid test reagent/kit is a medical device intended for the estimation of uric acid in serum/ plasma / urine.

43.		Micro-Protein test reagents/kits	B	A Micro-protein test reagent/kit is a medical device intended for the estimation of micro-proteins including micro-albumin in urine.
44.		Zinc test reagents/kits	B	A Zinc test reagent/kit is a medical device intended for the estimation of zinc in serum / plasma.
45.		Other clinical chemistry test reagents/kits	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 estimation of Complete Blood Counts , exemplified as:		B	
46.		Blood cell Diluents	B	A blood cell Diluent is a medical device used to dilute blood for further testing, such as Complete Blood Count(CBC) .
47.		Lyse reagents/kits for differential counts	B	A Lyse reagent/kit is a medical device used for lysing of cells for the estimation of Complete Blood Count(CBC).
48.		Rinse/Detergent/Cleaners reagents/kits	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:		B	
49.		Ascorbic Acid/ Bilirubin /Blood Cells/Glucose/ Ketone / Leukocyte peroxidase / Specific gravity/Urobilinogen Nitrite / pH / Protein / Albumin & other urinary analytes test reagents /Strips/kits	B	Ascorbic Acid/ Bilirubin /Blood Cells/Glucose/ Ketone / Leukocyte peroxidase / Specific gravity/Urobilinogen Nitrite / pH / Protein / Albumin & other urinary analytes test reagents /Strips/kits, are medical devices intended for the preliminary estimation of diagnostic markers in urine.
	In - vitro Diagnostic Medical		B	

50.	Devices for Self -Testing	Glucose test reagents/kits	B	A glucose test reagent/kit is a medical device intended for the preliminary self testing of glucose levels in blood/body fluids.
51.		Human Chorionic Gonadotropin (hCG) test reagents/kits	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.
52.		Luteinizing Hormone (LH) test reagents/kits	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.
53.		Glycosylated hemoglobin or its variants Test reagents/kits	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.
54.		Cholesterol test reagents/kits	B	A Cholesterol test reagent/kit is a medical device intended for preliminary self testing of cholesterol in blood /body fluids.
55.		Follicle Stimulating Hormone (FSH) test reagents/kits	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
56.	In - vitro Diagnostic Medical Device for near patient testing	Other In - vitro Diagnostic Medical Devices for Self - Testing	B*	
57.			C	
58.		Blood Gas Analysis test reagents/kits	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.
59.		Anticoagulant monitoring test reagents/kits	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.

60.		Diabetes management test reagents/kits	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.
61.		C- Reactive Protein (CRP) test reagents/kits	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
62.		H. pylori test reagents/kits	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.
63.		Troponin test reagents/kits	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
64.		Other in vitro Diagnostic Medical Devices for near patient test reagents/kits	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 parameters of ToRCH& other infectious agents exemplified as under:		C	
65.		Toxoplasma gondii test reagents/kits	C	A Toxoplasma gondii test reagent/kit is a medical device intended for the detection of Toxoplasma gondii in serum/body fluids.
66.		Rubella virus I test reagents/kits	C	A Rubella virus test reagent/kit is a medical device intended for the detection of Rubella virus in serum/body fluids.
67.		Cytomegalovirus test reagents/kits	C	A Cytomegalovirus test reagent/kit is a medical device intended for the detection of Cytomegalovirus in serum/body fluids.
68.		Herpes simplex virus reagents/kits	C	A Herpes simplex virus test reagent/kit is a medical device intended for the detection of Herpes simplex virus in serum/body fluids.
69.		Chlamydia pneumoniae test reagents/kits	C	A Chlamydia pneumoniae test reagent/kit is a medical device intended for the detection of Chlamydia pneumonia in serum/body fluids.

70.		Methicillin-Resistant Staphylococcus aureus test reagents/kits	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
71.		Enterovirus test reagents/kits	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 :		C	
72.		Alpha-fetoprotein test reagents/kits	C	An Alpha-fetoprotein test reagent/kit is a medical device intended for the detection of Alpha-fetoprotein in serum/body fluids.
73.		Beta-2 microglobulin test reagents/kits	C	A Beta-2 microglobulin test reagent/kit is a medical device intended for the detection of Beta-2 microglobulin in serum/body fluids
74.		Bladder tumour antigen (BTA) test reagents/kits	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
75.		CA15-3 test reagents/kits	C	A CA15-3 antigen (BTA) test reagent/kit is a medical device intended for the detection of CA15-3 in serum/body fluids
76.		CA27.29 test reagents/kits	C	A CA27.29 test reagent/kit is a medical device intended for the detection of CA27.29 in serum/body fluids
77.		CA125 test reagents/kits	C	A CA125test reagent/kit is a medical device intended for the detection of CA125 in serum/body fluids
78.		CA72-4 test reagents/kits	C	A CA72-4 test reagent/kit is a medical device intended for the detection of CA72-4 in serum/body fluids
79.		CA19-9 test reagents/kits	C	A CA19-9 test reagent/kit is a medical device intended for the detection of CA19-9 in serum/body fluids
80.		Calcitonin test reagents/kits	C	A Calcitonin test reagent/kit is a medical device intended for the detection of Calcitonin in serum/body fluids

81.	Carcinoembryonic antigen (CEA) test reagents/kits	C	A Carcinoembryonic antigen (CEA) test reagent/kit is a medical device intended for the detection of Carcinoembryonic antigen (CEA) in serum/body fluids
82.	Chromogranin A test reagents/kits	C	A Chromogranin A test reagent/kit is a medical device intended for the detection of Chromogranin A in serum/body fluids
83.	Estrogen / Progesterone receptors test reagents/kits	C	A Estrogen / Progesterone test reagent/kit is a medical device intended for the detection of Estrogen / Progesterone in serum/body fluids
84.	HER2 (Human Epidermal Growth Factor receptor, test reagents/kits	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
85.	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
86.	Lipid associated sialic acid test reagents/kits	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
87.	Neuron -Specific Enolase (NSE) test reagents/kits	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
88.	NMP22 test reagents/kits	C	A NMP22 test reagent/kit is a medical device intended for the detection of NMP22 in serum/body fluids
89.	Prostate-Specific Antigen (PSA) test reagents/kits	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
90.	Prostatic Acid Phosphatase (PAP) test reagents/kits	C	A Prostatic Acid Phosphatase (PAP) test reagents/kits test reagent/kit is a medical device intended for the detection of Prostatic Acid Phosphatase (PAP) test reagents/kits in serum/body fluids

91.		Prostate Cancer Antigen 3 gene (PCA 3) test reagents/kits	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
92.		Prostate-Specific Membrane Antigen (PSMA) test reagents/kits	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
93.		S-100 test reagents/kits	C	A S-100 test reagent/kit is a medical device intended for the detection of S-100 in serum/body fluids
94.		TA-90 test reagents/kits	C	A TA-90 test reagent/kit is a medical device intended for the detection of TA-90 in serum/body fluids
95.		Thyroglobulin test reagents/kits	C	A Thyroglobulin test reagent/kit is a medical device intended for the detection of Thyroglobulin in serum/body fluids
96.		Tissue Polypeptide Antigen (TPA) test reagents/kits	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
97.		Other Reagents/ Kits for detection of Cancer Markers	C*	
	Reagents/ Kits for estimation of Coagulation parameters exemplified as:		C	
98.		PT (Prothrombin Time) test reagents/kits	C	A Prothrombin Time (PT)test reagent/kit is a medical device intended for the estimation of prothrombin time in plasma/body fluids.
99.		TT (Thrombin Time) test reagents/kits	C	A Thrombin Time(TT)test reagent/kit is a medical device intended for the estimation of Thrombin Time in plasma/body fluids
100.		Activated Partial Thromboplastin Time(APTT) testsreagents/kits	C	A Activated Partial ThromboplastinTime (APTT) test reagent/kit is a medical device intended for the estimation of Activated Partial ThromboplastinTime in plasma/body fluids

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

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

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

			specimens.
134.	Anti Ganglioside Antibodies test reagents/kits	B	Anti Ganglioside Antibodies test reagent/kit is a medical device for the screening of auto-antibodies to Ganglioside in human specimens
135.	Anti-Cyclic Citrullinated Peptide (CCP) Antibodies test reagents/kits	B	Anti CyclicCitrullinated Peptide (CCP) Antibodies test reagent/kit is a medical device for the screening of CCP auto-antibodies in human specimens.
136.	Rheumatoid Factor (RF) immunological test reagents/kits	B	Rheumatoid Factor (RF) immunological test reagent/kit is a medical device for the screening of Rheumatoid Factor in human specimens.
137.	Anti Smooth Muscle Antibody test reagents/kits	B	Anti Smooth Muscle Antibody test reagent/kit is a medical device for the screening of auto-antibodies to smooth muscles in human specimens.
138.	Glutamic Acid Decarboxylase (GAD) Antibody test reagents/kits	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
139.	Anti ovary antibodies test reagents/kits	B	Anti ovary antibodies test reagent/kit is a medical device for the screening of auto-antibodies to ovarian antigens in human specimens
140.	Anti sperm Antibodies test reagents/kits	B	Anti sperm antibodies test reagent/kit is a medical device for the screening of auto-antibodies to spermatozoa in human specimens.
141.	Anti-IA2 test reagents/kits	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
142.	Anti-Acetylcholine Receptor test reagents/kits	B	Anti-Acetylcholine Receptor test reagent/kit is a medical device for the screening of auto-antibodies to Acetylcholine Receptor in human specimens
143.	Anti Thyroid gland antibody test reagents/kits	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
144.		ANCA test reagents/kits	B	The ANCA test reagent/kit is a medical device for the screening of Anti-Neutrophil Cytoplasmic Antibodies (ANCA) in human specimens .
145.		Anti-double stranded DNA (anti-dsDNA)test reagents/kits	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
146.		Anti-Extractable Nuclear Antigen(Anti-ENA)test reagents/kits	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.
147.		Anti-Intrinsic Factor test reagents/kits	B	The Anti-Intrinsic Factor test reagent/kit is a medical device for the screening of antibodies against intrinsic factor in human specimens.
148.		Anti- <i>Saccharomyces Cerevisiae</i> Antibodies (ASCA) test reagents/kits	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.
149.		Other Reagents/ Kits for detection of autoimmune disorders	B*	
150.	Reagents/ Kits for detection of markers for Congenital disorders exemplified as under		C	
151.		Triple Screen Test reagents/kits for Down's Syndrome	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.
152.		Quadruple Screen Test reagents/kits for Down's Syndrome	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
153.		Chorionic Villus Sample Test reagents/kits for Down's Syndrome	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.

154.		Maternal Serum Alpha-Fetoprotein (MSAFP) test reagents/kits for spina bifida	C	Maternal Serum Alpha-Fetoprotein (MSAFP) Test reagents/kits for is a medical device intended for the screening of spina bifida in serum.
155.		Others Reagents/ Kits for detection of Congenital disorders	C*	
	Reagents/ Kits for detection of Cardiac Markers exemplified as under		B or C	
156.		Creatine Kinase (CK) and CKMB test reagents/kits	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.
157.		Myoglobin test reagents/kits	B	Myoglobin Test reagent/kit for is a medical device intended for the estimation of myoglobin in blood /body fluids.
158.		Troponin test reagents/kits	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
159.		BNP &NT pro BNP test reagents/kits	C	BNP &NT pro BNP Test reagent/kit for is a medical device intended for the estimation of BNP &NT pro BNP in blood / body fluids
		Reagents/ Kits for human Genetic testing exemplified as:		C
160.	Genetic test reagents/kits for Cystic Fibrosis		C	Genetic test reagent/kit for Cystic Fibrosis is a medical device intended for the detection of Cystic Fibrosis in human specimens.
161.	Genetic test for Huntington's chorea		C	Genetic test reagent/kit for Huntington's chorea is a medical device intended for the detection of Huntington's chorea in human specimens.
162.	Other Reagents/ Kits for human Genetic testing		C*	
	Reagents/ Kits for the management		C	

163.	of life threatening infections exemplified as under:	HIV Viral Load test reagents/kits	C	HIV Viral Load test reagent/kit is a medical device intended for the estimation of HIV Viral Load in blood/body fluids.
164.		HBV Viral Load test reagents/kits	C	HBV Viral Load test reagent/kit is a medical device intended for the estimation of HBV Viral Load in blood/body fluids.
165.		HCV Viral Load test reagents/kits	C	HCV Viral Load test reagent/kit is a medical device intended for the estimation of HCV Viral Load in blood/body fluids.
166.		CD4 Count & % test reagents/kits	C	CD4 Count & % test reagent/kit is a medical device intended for the estimation of CD4 Count & % in blood/body fluids.
167.		CD8 Count & % test reagents/kits	C	CD8 Count & % test reagent/kit is a medical device intended for the estimation of CD8 Count & % in blood/body fluids.
168.		CD4/CD8 Ratio test reagents/kits	C	CD4/CD8 Ratio test reagent/kit are a medical device intended for the estimation of CD4/CD8 Ratio in blood/body fluids.
169.		Other Reagents/ Kits for the management of life threatening infections	C*	
	Reagents/ Kits for the detection of sexually transmitted agent exemplified as under:		C	
170.		Treponema pallidum test reagents and kits	C	Treponema pallidum test reagent/kit is a medical device intended for the detection of Treponema pallidum in blood/body fluids.
171.		Neisseria gonorrhoeae test reagents and kits	C	Neisseria gonorrhoeae test reagent/kit is a medical device intended for the detection of Neisseria gonorrhoeae in blood/body fluids
172.		Human Papilloma Virus (HPV) test reagents and kits	C	Human Papilloma Virus (HPV) test reagent/kit is a medical device intended for the detection of Human Papilloma Virus in blood/body fluids
173.		Chlamydia test reagents and kits	C	Chlamydia test reagent/kit is a medical device intended for the detection of Chlamydia in blood/body fluids
174.		Herpes Virus test reagents and kits	C	Herpes Virus test reagent/kit is a medical device intended for the detection of Herpes Virus in

				blood/body fluids
175.		Other Reagents/ Kits for the detection of sexually transmitted agent	C*	
176.	Reagents/ Kits for the Antigen detection of infectious agents with a risk of limited propagation exemplified as:		C	
177.		Malaria Antigen test reagents and kits	C	Malaria Antigen test reagent/kit is a medical device intended for the detection of Malaria Antigen in blood/body fluids
178.		Dengue virus Antigen test reagents and kits	C	Dengue virus Antigen test reagent/kit is a medical device intended for the detection of Dengue virus Antigen in blood/body fluids
179.		Chikungunya Antigen test reagents and kits	C	Chikungunya Antigen test reagent/kit is a medical device intended for the detection of Chikungunya Antigen in blood/body fluids
180.		Leptospira Antigen test reagents and kits	C	Leptospira Antigen test reagent/kit is a medical device intended for the detection of Leptospira Antigen in blood/body fluids
181.		Japanese Encephalitis Antigen test reagents and kits	C	Japanese Encephalitis Antigen test reagent/kit is a medical device intended for the detection of Japanese Encephalitis Antigen in blood/body fluids
182.		Typhoid Antigens test reagents and kits	C	Typhoid Antigens Test reagent/kit is a medical device intended for the detection of Typhoid Antigens in blood/body fluids
183.		Influenza A Antigen test reagents and kits	C	Influenza A Antigen test reagent/kit is a medical device intended for the detection of Influenza A Antigen in blood/body fluids
184.		Influenza B Antigen test reagents and kits	C	Influenza B Antigen test reagent/kit is a medical device intended for the detection of Influenza B Antigen in blood/body fluids
185.		Strep A Antigen test reagents and kits	C	Strep A Antigen test reagent/kit is a medical device intended for the detection of Strep A Antigen in blood/body fluids

186.		Strep B Antigen test reagents and kits	C	Strep B test Antigen reagent/kit is a medical device intended for the detection of Strep B Antigen in blood/body fluids
187.		Chagas Antigen test reagents and kits	C	Chagas disease Antigen test reagent/kit is a medical device intended for the detection of Chagas disease Antigen in blood/body fluids
188.		Filariasis Antigen test reagents and kits	C	Filariasis test Antigen reagent/kit is a medical device intended for the detection of Filariasis Antigen in blood/body fluids
189.		Kala Azar Antigen test reagents and kits gen	C	Kala Azar Antigen test reagent/kit is a medical device intended for the detection of Kala Azar Antigen in blood/body fluids
190.		Rotavirus Antigen test reagents and kits	C	Rotavirus Antigen test reagent/kit is a medical device intended for the detection of Rotavirus Antigen in blood/body fluids
191.		S. pneumonia Antigen test reagents and kits	C	S. pneumonia Antigen test reagent/kit is a medical device intended for the detection of S. pneumonia Antigen in blood/body fluids
192.		H. pylori Antigen Antigen test reagents and kits Antigen	C	H. pylori Antigen test reagent/kit is a medical device intended for the detection of H. pylori Antigen in blood/body fluids
193.		Other Reagents/ Kits for the detection of infectious agents with a risk of limited propagation	C*	Reagents/ Kits, other than above, for the Antigen detection of infectious agents with a risk of limited propagation
194.	Reagents/ Kits for the detection of Antibodies to infectious agents with a risk of limited propagation exemplified as under		B	
195.		Malaria Antibody test reagents and kits	B	Malaria Antibody test reagent/kit is a medical device intended for the detection of Malaria Antibody in blood/body fluids

196.		Dengue Antibody test reagents and kits	B	Dengue Antibody test reagent/kit is a medical device intended for the detection of Dengue Antibody in blood/body fluids
197.		Chikungunya Antibody test reagents and kits	B	Chikungunya Antibody test reagent/kit is a medical device intended for the detection of Chikungunya Antibody in blood/body fluids
198.		Leptospira Antibody test reagents and kits	B	Leptospira Antibody test reagent/kit is a medical device intended for the detection of Leptospira Antibody in blood/body fluids
199.		Japanese Encephalitis Antibody test reagents and kits	B	Japanese Encephalitis Antibody test reagent/kit is a medical device intended for the detection of Japanese Encephalitis Antibody in blood/body fluids
200.		Typhoid Antibody test reagents and kits	B	Typhoid Antibody test reagent/kit is a medical device intended for the detection of Typhoid Antibody in blood/body fluids
201.		Cryptococcus neoformans Antibody test reagents and kits	B	Cryptococcus neoformans Antibody test reagent/kit is a medical device intended for the detection of Cryptococcus neoformans Antibody in blood/body fluids
202.		Neisseria meningitides Antibody test reagents and kits	B	Neisseria meningitides Antibody test reagent/kit is a medical device intended for the detection of Neisseria meningitides Antibody in blood/body fluids
203.		Vibrio cholera Antibody test reagents and kits	B	Vibrio cholera Antibody test reagent/kit is a medical device intended for the detection of Vibrio cholera Antibody in blood/body fluids
204.		Influenza A Antibody test reagents and kits	B	Influenza A Antibody test reagent/kit is a medical device intended for the detection of Influenza A Antibody in blood/body fluids
205.		Influenza B Antibody test reagents and kits	B	Influenza B Antibody test reagent/kit is a medical device intended for the detection of Influenza B Antibody in blood/body fluids
206.		Strep A Antibody test reagents and kits	B	Strep A Antibody test reagent/kit is a medical device intended for the detection of Strep A Antibody in blood/body fluids

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

			D	
216.	in vitro Diagnostic Medical Devices for Blood Grouping or Tissue Typing	ABO System test reagents/kits	D	Intended for blood grouping or tissue typing.
217.		Rhesus (D) System test reagents/kits	D	
218.		The Duffy system test reagents/kits	D	
219.		The Kell system test reagents/kits	D	
220.		The Kidd system test reagents/kits	D	
221.		HLA test reagents/kits	D	
			D	
222.	Reagents/ Kits for the detection of transmissible agents - screening & confirmatory	HIV test reagents/kits	D	HIV test reagents/kits is a medical device intended for the detection of HIV in blood/body fluids.
223.		HBV test reagents/kits	D	HBV test reagents/kits is a medical device intended for the detection of HBV in blood/body fluids
224.		HCV test reagents/kits	D	HCV test reagents/kits is a medical device intended for the detection of HCV in blood/body fluids
225.		Syphilis screening reagents/kits	D	Syphilis test reagents/kits is a medical device intended for the screening of Syphilis in blood/body fluids
226.		Malaria screening reagents/kits	D	Malaria test reagents/kits is a medical device intended for the screening of Malaria in blood/body fluids
	Other in vitro Medical		B	

227.	Devices	TSH test reagents/kits	B	TSH test reagent/kit is a medical device intended for the estimation TSH in blood/body fluids.
228.		Total /Free triiodothyronine (T3) test reagents/kits	B	Total /Free triiodothyronine (T3) test reagent/kit is a medical device intended for the estimation Total /Free triiodothyronine (T3) in blood/body fluids
229.		Total / Free thyroxine (T4) test reagents/kits	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
230.		Dehydroepiandrosterone (DHEA-S) (free and sulfate) test reagents/kits	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
231.		Estrogen test reagents/kits	B	Estrogen test reagent/kit is a medical device intended for the estimation of Estrogen in blood/body fluids
232.		Progesterone test reagents/kits	B	Progesterone test reagent/kit is a medical device intended for the estimation of Progesterone in blood/body fluids
233.		Testosterone (Free and Total) test reagents/kits	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
234.		Sex Hormone Binding Globulin (SHBG) test reagents/kits	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
235.		Cortisol test reagents/kits	B	Cortisol test reagent/kit is a medical device intended for the estimation of Cortisol in blood/body fluids
236.		Insulin test reagents/kits	B	Insulin test reagent/kit is a medical device intended for the estimation of Insulin in blood/body fluids
237.		Luteinizing Hormone(LH) test reagents/kits	B	Luteinizing Hormones (LH)test reagent/kit is a medical device intended for the estimation of Luteinizing Hormone (LH) in blood/body fluids
238.		Follicle Stimulating Hormone(FSH) test reagents/kits	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
239.		Prolactin test reagents/kits	B	Prolactin test reagent/kit is a medical device intended for the estimation of Prolactin in blood/body fluids
240.		Other test reagents/kits for hormones	B	Test reagents/kits for the estimation of other than above hormones in blood/body fluids
241.		Vitamin B test reagents/kits	B	Vitamin B test reagent/kit is a medical device intended for the estimation of Vitamin B in blood/body fluids
242.		Vitamin D test reagents/kits	B	Vitamin D test reagent/kit is a medical device intended for the estimation of Vitamin B in blood/body fluids
243.		Vitamin A test reagents/kits	B	Vitamin A test reagent/kit is a medical device intended for the estimation of Vitamin A in blood/body fluids
244.		Vitamin E test reagents/kits	B	Vitamin E test reagent/kit is a medical device intended for the estimation of Vitamin E in blood/body fluids
245.		Vitamin K test reagents/kits	B	Vitamin K test reagent/kit is a medical device intended for the estimation of Vitamin K in blood/body fluids
246.		Other test reagents/kits for vitamins	B	Test reagents/kits for the estimation of other than above vitamins in blood/body fluids
247.		Homocystein test reagents/kits	B	Homocystein test reagent/kit is a medical device intended for the estimation of Homocystein in blood/body fluids
248.		allergens test reagents/kits	B	Test reagents/kits intended for the estimation of allergens in blood/body fluids
249.	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.
250.	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