

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

NOTICE

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

Date: 01 NOV 2017

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

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

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

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

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



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

To,

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

## Annexure-1

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

**(A) List of Medical Devices under provisions of sub-rule (1) rule 4 of the medical devices rules 2017**

| #  | Notified Device<br>Category/Drug | Device Name                                   | Risk<br>Class | General<br>Intended Use   |
|----|----------------------------------|---|---------------|---|
| 1. | Ablation Device                  | Vein Ablation<br>Device                       | Class C       | It is a non-thermal, minimally-invasive choice for treating the source of varicose veins, providing patients with immediate recovery and a return to normal daily routines  |
| 2. | Ablation Device                  | Thermal Ablation<br>Device                    | Class C       | Destruction of tissue by application of heat. Ablation of the endometrium as a treatment for menorrhagia is performed by placing a balloon filled with hot water in the uterine cavity.   |
| 3. | Ablation Device                  | Radiofrequency<br>Ablation Device             | Class D       | A medical procedure in which part of the electrical conduction system of the heart, tumour or other dysfunctional tissue is ablated using the heat generated from high frequency alternating current  |
| 4. | Ablation Device                  | Percutaneous<br>Conduction Tissue<br>Ablation | Class D       | Clinical applications using hollow needles (cryoprobes) through which cooled, thermally conductive, fluids are circulated.  |
| 5. | Ablation Device                  | Suction Ablation<br>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. |

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

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

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

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

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

| | | simultaneous administration of |

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

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

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

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

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

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

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

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

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

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

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| 154. |  | Biliary stents | Class C | the duodenum in conditions such as ascending cholangitis due to obstructing gallstones |
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| 155. | Catheters                     | Duodenal stents                 | Class C | Duodenal Stent is indicated for the palliative treatment of gastroduodenal obstructions  |
| 156. | Catheters                     | Colonic stent                   | Class C | A colonic stent is a flexible, hollow tube designed to keep a segment of the colon (large bowel) open when it has become blocked(obstructed). This blockage is commonly caused by a tumour inside the bowel or by outside pressure on the bowel wall.                                  |
| 157. | Catheters                     | Pancreatic stent                | Class C | Pancreatic duct stents are often placed in patients who have chronic pancreatitis  |
| 158. | Catheters                     | Carotid Stent System            | Class D | Indicated for the treatment of patients at high risk for adverse events from carotid endarterectomy who require carotid revascularization.   |
| 159. | Catheters                     | Peripheral Stent System         | Class C | A Peripheral stent is a tube-shaped device placed in the peripheral arteries that supply blood into body organ.  |
| 160. | Contraceptives                | Tubal Rings/<br>Fallopian Rings | Class C | Contraception devices for female sterilization   |
| 161. | Contraceptives                | Male / Female<br>Condoms        | Class C | Condom with nonoxynol-9, micro-condom, prophylactic (condom) – latex sheath, non-latex, condoms with natural membrane, intra vaginal condoms etc.  |
| 162. | Contraceptives                | Cu-T                            | Class D | Indicated for intrauterine contraception for up to 10 years.   |
| 163. | Disinfectants                 | Disinfectants                   | Class B | An agent that destroys pathogenic and other kinds of microorganisms by chemical or physical means. A disinfectant destroys most recognized pathogenic microorganisms, but not necessarily all microbial forms, such as bacterial spores. It is intended to disinfect a medical device. |
| 164. | Disposable Hypodermic Needles | Aspiration Needle               | Class B | Used for either laparoscopic aspiration or injection   |

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



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

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| <b>189.</b> | Disposable Hypodermic Syringes | Insulin Syringes  | Class B | Used to inject insulin for the treatment of diabetes.  |
| <b>190.</b> | Disposable Hypodermic Syringes | Auto Disable Syringe for single use   | Class B | Intend to inject fluids into or withdraw fluids from the body.   |
| <b>191.</b> | Disposable Hypodermic Syringes | Traditional single use syringe without safety feature (Sterile hypodermic syringes for single use)    | Class B | Intend to inject fluids into or withdraw fluids from the body.   |
| <b>192.</b> | Disposable Hypodermic Syringes | Auto-disable (AD) syringes for immunization   | Class B | Intend to inject fluids into or withdraw fluids from the body.   |
| <b>193.</b> | Disposable Hypodermic Syringes | Re use Prevention (RUP) syringes for therapeutic injections (Syringes with re-use prevention feature) | Class B | Intend to inject fluids into or withdraw fluids from the body.   |
| <b>194.</b> | Disposable Hypodermic Syringes | Sharps Injury Protection (SIP) - Plastic needle shield to be added to a syringe                       | Class B | Intend to inject fluids into or withdraw fluids from the body.   |
| <b>195.</b> | Disposable Perfusion Sets      | Sharps Injury Blood Administration kits   | Class B | It is used to administer blood from a container to a patient's vascular system through a needle or catheter inserted |

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

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

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

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

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

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| 244. | Internal Prosthetic Replacements | A testicular prosthesis                   | Class D | A testicular prosthesis is an implanted device that consists of a solid or gel-filled silicone rubber prosthesis that is implanted surgically to resemble a testicle.                          |
| 245. | Internal Prosthetic Replacements | Aneurysm Implant (detachable coils/clips) | Class D | It is intended for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae.               |
| 246. | Intra Ocular Lenses              | Intraocular lens                          | Class C | Intraocular lens (IOL) are lens implanted in the eye used to treat cataracts or myopia   |
| 247. | IV Cannulae                      | Intravenous Cannula                       | Class B | The IV Cannula is a passive device to provide for the infusion of fluids, drugs, and/or blood components, or to facilitate the placement of Vascular Access devices .                          |
| 248. | IV Cannulae                      | Arterial Cannula                          | Class B | Inserted into an artery, commonly the radial artery, and is used during major operations and in critical care areas to measure beat-to-beat blood pressure and to draw repeated blood samples. |
| 249. | IV Cannulae                      | Coronary Artery Cannula                   | Class B | Cannulation technique for left-sided coronary artery surgery.  |
| 250. | IV Cannulae                      | Hemodialysis Cannula                      | Class B | Allowing the arterial blood to flow to the dialyzer and the dialyzed blood to return from the dialyzer to the circulation through the cannula in the vein.                                     |
| 251. | IV Cannulae                      | Vena Cava Cannula                         | Class B | Inserted into Vena Cava, taking deoxygenated blood to heart.   |
| 252. | IV Cannulae                      | Venous Cannula                            | Class B | It is intended for use as a single cannula for both venous drainage and reinfusion of blood via an internal jugular vein during extracorporeal life support procedures.                        |
| 253. | IV Cannulae                      | Ventricular Cannula                       | Class B | For use in neurosurgical procedures. It is specially designed to penetrate delicate brain tissue and give continued access to brain's ventricular system.                                      |
| 254. | IV Cannulae                      | A-V Cannula Shunt                         | Class C | It is inserted into one of the client's blood vessels to facilitator repeated hemodialysis.  |

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

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

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

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

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

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

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

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

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| <b>323.</b> | Orthopaedic Implants | Spinal interlaminar fixation orthosis              | Class C | A device intended to be implanted made of an alloy, that consists of various hooks and a posteriorly placed compression or distraction rod. The device is used primarily in the treatment of scoliosis                                     |
| <b>324.</b> | Orthopaedic Implants | 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  |
| <b>325.</b> | Orthopaedic Implants | Smooth or threaded metallic bone fixation fastener | Class C | It may be used for fixation of bone fractures, for bone reconstructions, as a guide pin for insertion of other implants, or it may be implanted through the skin so that a pulling force (traction) may be applied to the skeletal system. |
| <b>326.</b> | Orthopaedic Implants | Sacroiliac joint fixation                          | Class C | The sacroiliac joints fixation may serve as protective mechanism for the lumbosacral region.   |
| <b>327.</b> | Orthopaedic Implants | Cervical Artificial Disc                           | Class D | Cervical Artificial Disc is indicated for reconstruction of the disc.  |
| <b>328.</b> | Scalp Vein Set       | Scalp Vein Set                                     | Class B | Intended to be used for insertion into the patient's vascular system (single use only) as an in-dwelling device to administer fluids intravenously or to sample blood.   |
| <b>329.</b> | Surgical Dressings   | Surgical Staples                                   | Class B | Surgical staples are specialized staples used in surgery in place of sutures to close skin wounds, connect or remove parts of body during surgery.   |
| <b>330.</b> | Surgical Dressings   | Surgical Dressings                                 | Class A | Dressing aerosol, non-adherent, dressing, periodontal, kit, dressing pad, dressing.  |
| <b>331.</b> | Surgical Dressings   | Surgical Dressings                                 | Class B | Dressing-gel, dressing- permeable, moisture dressing, tracheostomy tube dressing, wound and burn dressings, hydrogel dressing, wound and burn, occlusive.  |
| <b>332.</b> | Surgical Dressings   | Cotton Grudges and bandages                        | Class B | Adhesive bandages, Gauge bandages, Pressure bandages, Traction bandages, Medical Absorbent (fiber) bandages.   |
| <b>333.</b> | Surgical Dressings   | Sterile Drapes                                     | Class B | It is intended for use during various surgeries.   |

|      |                    |  |         |   |
|------|--------------------|--|---------|---|
| 334. | Surgical Dressings | Wound Dressings/Bacteriostatic Wound Dressings | Class C | Includes Beads, Hydrophilics For Wound Exudate Absorption for wound care.   |
| 335. | Surgical Dressings | Casting tapes/Splint Rolls                     | Class B | A prosthetic and orthotic accessory, intended for medical purposes to support, protect, or aid in the use of a cast, orthosis (brace), or prosthesis.       |
| 336. | Surgical Dressings | Haemostatic Gelatine Sponge /Haemostat         | Class C | Intended for the control of surface bleeding from vascular access sites and percutaneous catheters or tubes.  |
| 337. | Surgical Dressings | Surgical Dressings                             | Class C | Material dressing, surgical, polylactic acid dressings.   |
| 338. | Surgical Dressings | Absorbable Hemostatic Based                    | Class D | An absorbable haemostatic agent or dressing is a device intended to produce haemostasis by accelerating the clotting process of blood. It is absorbable.    |
| 339. | Surgical Dressings | Umbilical occlusion device                     | Class A | These devices may be a clip, tie, tape, or other article used to close the blood vessels in the umbilical cord of a newborn infant.                         |
| 340. | Surgical Dressings | Bolster Suture                                 | Class A | Non-latex plastic bolsters are used to hinder pressure of any temporary suture against the body during surgery.   |
| 341. | Surgical Dressings | Suture Non Absorbable Synthetic                | Class C | Non-absorbable suture is comprised of surgical steel as well as synthetic non-absorbable sutures for use in general soft tissue approximation and ligation. |
| 342. | Surgical Dressings | Suture Absorbable                              | Class C | The device is intended for use in general soft tissue approximation and ligation.   |
| 343. | Surgical Dressings | Endovascular suturing system                   | Class C | It is a medical device intended to provide fixation and sealing between an endovascular graft and the native artery.  |
| 344. | Surgical Dressings | Fixation, non-absorbable for pelvic use        | Class C | Attaching suture or stapling ligaments of the pelvic floor.   |
| 345. | Surgical Dressings | Tissue adhesive for the topical use            | Class C | Intended for topical closure of surgical incisions including laparoscopic incisions and simple traumatic lacerations.                                       |

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|------|--------------------|-------------------------------------|---------|--|
| 346. | Surgical Dressings | Tissue adhesive for non-topical use | Class D | Intended for use in adhesion of internal tissues and vessels, for example; adhesives used in the embolization of brain arteriovenous malformation or for use in ophthalmic surgery.  |
| 347. | Surgical Dressings | Alcohol Swabs                       | Class A | It is a single use, sterile device containing 70% Isopropyl alcohol used for scrubbing and allowing drying and will disinfect needless access sites prior to use..   |
| 348. | Surgical Dressings | Ligature Wire                       | Class B | offer a spot-welded auxiliary hook which may be added to any bracket by simply tying in the arch wire  |
| 349. | Surgical Dressings | Surgical Sealant                    | Class B | For use in vascular reconstructions to achieve adjunctive hemostasis by mechanically sealing areas of leakage.   |
| 350. | Surgical Dressings | Wound Closure Device                | Class B | Wound Closure Devices are indicated for soft tissue approximation.   |
| 351. | Surgical Dressings | Intracardiac patch                  | Class D | intracardiac patch or pledget made of polypropylene, polyethylene terephthalate, or polytetrafluoroethylene is a fabric device placed in the heart that is used to repair septal defects, for patch grafting, to repair tissue, and to buttress sutures. |

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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