

**No. 29/Misc/03/2019-DC (211)**  
**Government of India**  
**Directorate General of Health Services**  
**Central Drugs Standard Control Organisation**  
**(Medical Devices and Diagnostics Division)**

17 AUG 2022

**Subject: List of the certified Medical Device Testing Laboratory (MDTL) under MDR, 2017- regarding**

This office had registered a Medical Device Testing Laboratory (MDTL) to carry out test or evaluation of a medical device on behalf of the manufacturer (Form MD-40 of MDR, 2017). There are 18 MDTLs have been registered with CDSCO till dated 07.12.2021 under the provisions of the Medical Device Rules, 2017 (Form MD-40 enclosed).

The updated list of medical devices testing laboratories registered with CDSCO under the provisions of Medical Devices Rules, 2017 to carry out test or evaluation of a medical device on behalf of manufacturer is given below:

SI. No.	NAME & ADDRESS OF MEDICAL DEVICE TESTING LABORATORY	REGISTRATION NO.	SCOPE OF TESTING
1	<b>M/s SIPRA LABS LIMITED</b> Address: 7-2-1813/5/A, Adj. To Post Office, Industrial Estate, Sanathnagar, Telangana, Hyderabad- 500018	TL/MD/2019/000001	1. Copper -T 2. Condoms 3. Sterile Hypodermic Needles 4. Tubal Rings 5. Hypodermic Syringes 6. Blood Bags
2	<b>M/s Star Imaging &amp; Path Lab Pvt. Ltd.</b> Address: 4B/4, Tilak Nagar , West Delhi, Delhi (India) - 110018	TL/MD/2019/000002	1. Bilirubin (Total and Direct) Test Reagents / Kits 2. Creatinine test reagent / kit 3. Aspartate Amino Transferase (AST / SGOT) test 4. Alanine Amino Transferase (ALT/SGPT) test 5. Uric Acid Test reagents / kits 6. Total Protein test reagents / kits 7. Activated partial thromboplastin time (APTT) test 8. PT (Prothrombin Time) Test reagents / Kits
3	<b>M/s Alcatel Research Laboratories India Pvt. Ltd.</b>	TL/MD/2019/000003	1. Sterilized Surgical Ligatures 2. Sterilized Disposable Device 3. Sterilized Surgical Sutures

	Address: 1652 MIE Part B, Bahadurgarh, Haryana – 124507		
4	<b>M/s Sree Chitra Tirunal Institute For Medical Sciences &amp; Technology</b> Address: Medical College, Thiruvananthapuram, Kerala - 695011	TL/MD/2019/000004	<ol style="list-style-type: none"> <li>1. Cardio Vascular Devices (Biological Evaluation as per ISO 10993)</li> <li>2. Neuroprosthesis (Biological Evaluation as per ISO 10993)</li> <li>3. Orthopedic Implants (Biological Evaluation as per ISO 10993)</li> <li>4. All medical devices and Materials (Biological Evaluation as per ISO 10993)</li> <li>5. Dental Implants (Biological Evaluation as per ISO 10993)</li> </ol>
5	<b>M/s, GLR Laboratories Private Limited</b> Address: GOKULAM STREET, Mathur, MATHUR, Chennai, Tamil Nadu - 600068	TL/MD/2019/000005	<ol style="list-style-type: none"> <li>1. Cardiovascular devices (Biological evaluation as per ISO 10993)</li> <li>2. Orthopaedic devices (Biological evaluation as per ISO 10993)</li> <li>3. Ocular devices (Biological evaluation as per ISO 10993)</li> <li>4. Surgical devices and sutures (Biological evaluation as per ISO 10993)</li> <li>5. Respiratory devices (Biological evaluation as per ISO 10993)</li> <li>6. Gastrointestinal devices (Biological evaluation as per ISO 10993)</li> <li>7. Urological devices (Biological evaluation as per ISO 10993)</li> <li>8. Haematological devices and IV sets (Biological evaluation as per ISO 10993)</li> <li>9. Dental devices (Biological evaluation as per ISO 10993)</li> <li>10. Personal care products and family planning (Biological evaluation as per ISO 10993)</li> <li>11. Neurological devices (Biological evaluation as per ISO 10993)</li> <li>12. All medical devices and Materials (Biological evaluation as per ISO 10993)</li> </ol>
6	<b>M/s, PALAMUR BIOSCIENCES PRIVATE LIMITED</b> Address: 401 Aikya, 4th Floor, H.No-10-3- 32/9/23, Opp.Faust High School,East	TL/MD/2019/000006	<ol style="list-style-type: none"> <li>1. Catheters (Biological Toxicity)</li> <li>2. Disposable Hypodermic needles (Biological Toxicity)</li> <li>3. Surgical dressings (Biological Toxicity)</li> <li>4. Orthopaedic Implants (Biological Toxicity)</li> </ol>

	Marredpally, Secunderabad, Hyderabad, Telangana - 500026		<ol style="list-style-type: none"> <li>5. Blood Bags (Biological Toxicity)</li> <li>6. Drug eluting stent (Biological Toxicity)</li> <li>7. Intra Ocular Lenses (Biological Toxicity)</li> <li>8. Sutures (Biological Toxicity)</li> <li>9. Condoms (Biological Toxicity)</li> <li>10. Heart Valves (Biological Toxicity)</li> <li>11. Disposable perfusion sets (Biological Toxicity)</li> <li>12. Cardiac stent (Biological Toxicity)</li> <li>13. Copper- T (Biological Toxicity)</li> <li>14. Scalp Vein Set (Biological Toxicity)</li> </ol>
7	<b>M/s, Eurofins Advinus Limited</b> Address: 21 & 22, Phase II, Peenya Industrial Area, Bengaluru Pincode 560 058, INDIA, Bangalore, Bengaluru (Bangalore) Urban, Karnataka - 560058	TL/MD/2020/000001	<ol style="list-style-type: none"> <li>1. Disposable Perfusion Sets</li> <li>2. Cardiac Stents</li> <li>3. Drug Eluting Stents</li> <li>4. Blood Bags</li> <li>5. Catheters (Class D)</li> <li>6. Catheters (Class B)</li> <li>7. Catheters (Class C)</li> <li>8. Heart valves</li> <li>9. Intra Ocular Lenses</li> <li>10. I.V. Cannula</li> <li>11. Bone Cements</li> <li>12. Internal Prosthetic Replacements</li> <li>13. Peritoneal dialysis sets</li> <li>14. Condoms</li> <li>15. Intra-uterine devices</li> <li>16. Surgical dressing</li> <li>17. Scalp Vein Set</li> <li>18. Ligatures and sutures</li> </ol>
8	<b>M/s, TRUSTIN ANALYTICAL SOLUTIONS PRIVATE LIMITED</b> Address: Plot no- 303/b, Block-B, RK Complex, 1 <sup>st</sup> Floor, Thiruneermalai road, Parvathy puram, Chrompet, , Chennai, Kanchipuram, Tamil Nadu - 600044	TL/MD/2020/000002	<ol style="list-style-type: none"> <li>1. Disinfectant ( Sterility and Antimicrobial activities as per ISO 11737-1 and 2, USP 42, EP 9.0, IP 2018, BP 2018)</li> <li>2. Catheters (Sterility, Bioburden and BET as per ISO 11737-1 and 2, USP 42, EP 9.0, IP 2018, BP 2018) - Class A</li> <li>3. Surgical Sutures (Physical parameters, Sterility and BET as per ISO 11737-2, USP 42, EP 9.0, IP 2018, BP 2018) - Class B</li> <li>4. Surgical Dressings ( Sterility , Bioburden, BET as per IS 758, IS 1954, ISO 11737-1and 2, IP 2018, USP 42, BP 2018 and EN9.0) - Class A</li> </ol>

		<ol style="list-style-type: none"> <li>5. Surgical Dressings ( Sterility , Bioburden, BET as per IS 758, IS 1954, ISO 11737-1and 2, IP 2018, USP 42, BP 2018 and EN9.0) - Class B</li> <li>6. Surgical Dressings ( Sterility , Bioburden, BET as per IS 758, IS 1954, ISO 11737-1and 2, IP 2018, USP 42, BP 2018 and EN9.0) - Class C</li> <li>7. Surgical Dressings ( Sterility , Bioburden, BET as per IS 758, IS 1954, ISO 11737-1and 2, IP 2018, USP 42, BP 2018 and EN9.0) - Class D</li> <li>8. Blood bags with and without anticoagulant solutions (Mechanical, Sterility and BET as per ISO 3826, IS 15102, ISO 11737-2, USP42, EP 9.0, IP 2018, BP 2018)</li> <li>9. Contraceptives (Condoms - Male/Female Condoms) (Mechanical parameters, Bioburden and Pathogens as per ISO 4074-2015, WHOUNAIDS2010, ISO25841-2017, WHOUNAIDS2012, Schedule R, ISO11737-1, IP 2018, USP42</li> <li>10. Catheters (Sterility, Bioburden and BET as per ISO 11737-1 and 2, USP 42, EP 9.0, IP 2018, BP 2018) - Class B</li> <li>11. Catheters (Sterility, Bioburden and BET as per ISO 11737-1 and 2, USP 42, EP 9.0, IP 2018, BP 2018) - Class C</li> <li>12. Disposable Hypodermic Needles (Sterility, Bioburden and BET as per ISO 11737-1 and 2, USP 42, EP 9.0, IP 2018, BP 2018) - Class C</li> <li>13. Disposable Perfusion sets (Physical testing, Sterility, Bioburden and BET as per ISO 1135-Part 4, IS 9824-3, ISO 11737-1 and 2, USP 42, EP 9.0, IP 2018, BP 2018) - Class B</li> <li>14. Disposable Perfusion sets (Physical testing , Sterility, Bioburden and BET as per ISO 1135-Part 4, IS 9824-3, ISO 11737-1 and 2, USP 42, EP 9.0, IP 2018, BP 2018) - Class C</li> <li>15. Intraocular Lenses (Sterility,</li> </ol>
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			<p>Bioburden, BET and Pathogen identification as per ISO 11737 - Part 1 and 2, USP 42, EP 9.0, IP 2018, BP 2018)</p> <p>16. Orthopaedic Implants (Sterility, Bioburden and BET as per ISO 11737-1 and 2, USP 42, EP 9.0, IP 2018, BP 2018) - Class C</p> <p>17. Orthopaedic Implants ( (Sterility, Bioburden and BET as per ISO 11737-1 and 2, USP 42, EP 9.0, IP 2018, BP 2018) - Class D</p> <p>18. Cardiac Stents ( Sterility test as per ISO11737-2, USP 42, EP 9.0, IP 2018, BP2018)- Class C</p> <p>19. Cardiac Stents ( Sterility test as per ISO 11737-2, USP 42, EP 9.0, IP 2018, BP2018) - Class D</p> <p>20. Contraceptives (CuT) (Mechanical parameters, Sterility, Bioburden as per WHO UNFPA 2016, ISO 7439, ISO 11737-1and 2, IP 2018, USP 42, BP 2018, EP 9.0)</p> <p>21. Disposable Hypodermic Syringes (Sterility and BET as per ISO 11737-2, USP 42, EP 9.0, IP 2018, BP 2018) - Class B</p> <p>22. Catheters (Sterility, Bioburden and BET as per ISO 11737-1 and 2, USP 42, EP 9.0, IP 2018, BP 2018) - Class D</p> <p>23. Disposable Hypodermic Needles (Sterility, Bioburden and BET as per ISO 11737-1 and 2, USP 42, EP 9.0, IP 2018, BP 2018) - Class B</p> <p>24. Disposable Perfusion sets (Physical testing, Sterility, Bioburden and BET as per ISO 1135-Part 4, IS 9824-3, ISO 11737-1 and 2, USP 42, EP 9.0, IP 2018, BP 2018) - Class A</p> <p>25. Disposable Perfusion sets (Physical testing, Sterility, Bioburden and BET as per ISO 1135-Part 4, IS 9824-3, ISO 11737-1 and 2, USP 42, EP 9.0, IP 2018, BP 2018) - Class C</p> <p>26. Intraocular Lenses (Sterility, Bioburden, BET and Pathogen identification as per ISO 11737 - Part 1 and 2, USP 42, EP9.0,</p>
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			<p>IP 2018, BP 2018)</p> <p>27. Internal Prosthetic Replacements (Sterility test as per ISO 11737-2, USP 42, EP 9.0, IP 2018, BP 2018)</p> <p>28. Heart Valves (Sterility test as per ISO 11737-2, USP 42, EP 9.0, IP 2018, BP 2018)</p> <p>29. Surgical Sutures (Physical parameters, Sterility and BET as per ISO 11737-2, USP 42, EP 9.0, IP 2018, BP 2018) - Class A</p> <p>30. Surgical Sutures (Physical parameters, Sterility and BET as per ISO 11737-2, USP 42, EP 9.0, IP 2018, BP 2018) - Class C</p> <p>31. Contraceptives (Tubal Ring)(Mechanical parameters and Sterility as per IS 13009-2000, ISO 11737-2, USP 42, EP 9.0, IP2018, BP 2018)</p> <p>32. Disposable Perfusion sets (Physical testing, Sterility, Bioburden and BET as per ISO 1135-Part 4, IS 9824-3, ISO 11737-1 and 2, USP 42, EP 9.0, IP 2018, BP 2018)- Class B</p> <p>33. Internal Prosthetic Replacements (Sterility test as per ISO 11737-2, USP 42, EP 9.0, IP 2018, BP 2018)</p> <p>34. IV Cannulae (Sterility, Bioburden, Pathogen identification as per ISO 11737-1and 2, USP 42, EP 9.0, IP 2018 , BP 2018)</p> <p>35. Disposable Hypodermic Syringes (Sterility and BET as per ISO 11737-2, USP 42, EP9.0, IP 2018, BP 2018)</p>
9	<p><b>M/s, Devansh Testing &amp; Research Laboratory Pvt. Ltd.</b>  Address: RZ-21A/331, Madanpuri, Gali No.- 10, West Sagar Pur, Delhi, West Delhi, Delhi - 110046</p>	TL/MD/2020/000003	<p>1. Catheters – Class A</p> <p>2. Catheters (Excluding Bio-compatibility testing) - Class B</p> <p>3. Catheters (Excluding Bio-compatibility testing)- Class C</p> <p>4. Disposable Perfusion Sets (Excluding Biocompatibility testing) - Class C</p> <p>5. Disposable Hypodermic Needles (Excluding Bio-compatibility testing) - Class C</p> <p>6. Disposable Hypodermic Needles</p>

			(Excluding Bio-compatibility testing) - Class D
			7. Disposable Hypodermic Syringes - Class A
			8. Disposable Hypodermic Syringes (Excluding Bio-compatibility testing) - Class B
			9. Disposable Hypodermic Syringes (Excluding Bio-compatibility testing) - Class C
			10. Disposable Hypodermic Syringes (Excluding Bio-compatibility testing) - Class D
			11. I.V. Cannulae - Class A
			12. I.V. Cannulae (Excluding Bio- compatibility testing) - Class B
			13. I.V. Cannulae (Excluding Bio- compatibility testing) - Class C
			14. I.V. Cannulae (Excluding Bio- compatibility testing) - Class D
			15. Scalp Vein Set - Class A
			16. Scalp Vein Set (Excluding Biocompatibility testing) - Class B
			17. Scalp Vein Set (Excluding Biocompatibility testing) - Class C
			18. Scalp Vein Set (Excluding Biocompatibility testing) - Class D
			19. Surgical Dressings - Class A
			20. Surgical Dressings (Excluding Biocompatibility testing) - Class B
			21. Surgical Dressings (Excluding Biocompatibility testing) - Class C
			22. Surgical Dressings (Excluding Biocompatibility testing) - Class D
			23. Contraceptives - Class A
			24. Contraceptives (Excluding Biocompatibility testing) - Class B
			25. Contraceptives (Excluding Biocompatibility testing) - Class C
			26. Contraceptives (Excluding Biocompatibility testing) - Class D
			27. Disinfectant - Class A
			28. Catheters (Excluding Bio- compatibility testing) - Class D
			29. Disposable Hypodermic Needles - Class A
			30. Disposable Hypodermic Needles (Excluding Bio-compatibility testing) - Class B
			31. Disinfectant (Excluding Bio- compatibility testing) - Class B

			<p>32. Disinfectant (Excluding Bio-compatibility testing) - Class C</p> <p>33. Disinfectant (Excluding Bio-compatibility testing) - Class D</p> <p>34. Disposable Perfusion Sets - Class A</p> <p>35. Disposable Perfusion Sets (Excluding Biocompatibility testing) - Class B</p> <p>36. Disposable Perfusion Sets (Excluding Biocompatibility testing)</p>
10	<p><b>M/s, JAGDAMBA LABORATORIES</b> Address: 119, Solitaire Industrial Park, Phase-1, Dahmikallan, Bagru, Jaipur, Rajasthan- 303007</p>	TL/MD/2020/000004	<p>1. Catheters (Test as per IS/ISO 10555) - Class A</p> <p>2. Disinfectants (As per IP, BP, USP) - Class B</p> <p>3. Disposable Hypodermic Needles (Test as per IS 10654) - Class B</p> <p>4. Disposable Perfusion Sets (Test as per IS 12655) - Class A</p> <p>5. Disposable Perfusion Sets (Test as per IS 12655) - Class B</p> <p>6. Catheters (Test as per IS/ISO 10555) - Class B</p> <p>7. I.V. Cannulae (Test as per IS/ISO 10555) - Class B</p> <p>8. Disposable Hypodermic Syringes (Test as per IS10258) - Class B</p> <p>9. Scalp vein set (Test as per IS 16097) - Class B</p> <p>10. Surgical Dressings (Cotton and Gauze, Bandage)-Class B</p> <p>11. Surgical Dressings (Cotton and Gauze, Bandage)-Class A</p>
11	<p><b>ITL LABS PVT LTD</b> B-283-284, Mangolpuri Industrial Area, Phase I, North West Delhi, Delhi - 110083</p>	TL/MD/2021/000001	<p>1. Catheters (Excluding Bio-compatibility testing) Class D</p> <p>2. Surgical Dressings (Excluding Biocompatibility testing) Class D</p> <p>3. Disposable Hypodermic Syringes Class D</p> <p>4. Disposable Hypodermic Syringes (Excluding Bio-compatibility testing) Class D</p> <p>5. Surgical Dressings Class D</p> <p>6. Disposable Hypodermic Needles (Excluding Bio-compatibility testing) Class C</p> <p>7. Contraceptives Class D</p> <p>8. I.V. Cannulae (Excluding Bio-compatibility testing) Class C</p> <p>9. Surgical Dressings (Excluding</p>



			<p>Biocompatibility testing) Class D</p> <p>10. Scalp Vein Set (Excluding Biocompatibility testing) Class B</p> <p>11. Disposable Hypodermic Needles Class C</p> <p>12. I.V. Cannulae Class C</p> <p>13. I.V. Cannulae (Excluding Biocompatibility testing) Class C</p> <p>14. Scalp Vein Set Class B</p> <p>15. Contraceptives (Excluding Biocompatibility testing) Class D</p> <p>16. Catheters Class D</p> <p>17. Disinfectant Class B</p> <p>18. Disposable Perfusion Sets (Excluding Biocompatibility testing) Class C</p> <p>19. Disinfectant (Excluding Biocompatibility testing) Class B</p> <p>20. Disposable Perfusion Sets Class C</p> <p>21. Disposable Perfusion Sets (Excluding Biocompatibility testing) Class C</p> <p>22. Disposable Hypodermic Needles (Excluding Bio-compatibility testing) Class D</p> <p>23. Surgical Suture Class D</p> <p>24. Urine collecting bag Class B</p> <p>25. Surgical Gloves ( Sterile/Non Sterile) Class D</p> <p>26. Endotracheal (ET) tube Class B</p> <p>27. Disposable Hypodermic Syringes Class C</p> <p>28. Blood Bag (Single Blood Bag, Double Blood Bag, Triple Blood Bag, Quad Blood Bag) Class C</p> <p>29. Disinfectant (Excluding Bio-compatibility testing)</p>
12	<p><b>Accuprec Research Labs Private Limited</b> Opp. Zydus Pharmez, Changodar- Bavla Highway, Vill-Matoda,, Sanand, Ahmedabad, Gujarat - 382213</p>	TL/MD/2021/000002	<p>1. Vascular devices and IV sets; Class D</p> <p>2. Tubal rings; Class C</p> <p>3. Copper T; Class C</p> <p>4. Sutures; Class C</p> <p>5. Disposable Hypodermic needles; Class C</p> <p>6. Catheters; Class D</p> <p>7. Disposable Hypodermic Syringes; Class B</p> <p>8. Blood bags; Class B</p> <p>9. Condoms; Class C</p> <p>10. Coronary stents; Class D</p>

			<ul style="list-style-type: none"> <li>11. Intra Ocular Lenses Implants; Class D</li> <li>12. Orthopaedic Implants and Devices; Class D</li> <li>13. Drug eluting stents; Class D</li> <li>14. Internal Prosthetic replacements; Class D</li> <li>15. Ablation devices; Class D</li> </ul>
13	<b>M/s, Conformity Testing Labs Pvt Ltd</b> WH-52, Mayapuri Industrial Area, Phase 1, New Delhi, West Delhi, Delhi - 110064	TL/MD/2021/000003	<ul style="list-style-type: none"> <li>1. NIBP; Class B</li> <li>2. IBP; Class C</li> <li>3. Nebulizer; Class C</li> <li>4. Thermometer; Class B</li> <li>5. Glucometer; Class B</li> </ul>
14	<b>Brothers Laboratories Pvt. Ltd</b> 103, D-3, Industrial Area Jhotwara, Jaipur, Rajasthan - 302012	TL/MD/2021/000004	<ul style="list-style-type: none"> <li>1. Disposable Hypodermic Needles; Class B</li> <li>2. Surgical Dressings; Class A</li> <li>3. Disposable perfusion set; Class B</li> <li>4. Catheters; Class B</li> <li>5. Surgical Dressings; Class B</li> <li>6. Disinfectants; Class B</li> <li>7. Disposable Hypodermic Syringe; Class B</li> <li>8. IV Canulae; Class B</li> <li>9. Scalp Vein Set; Class B</li> </ul>
15	<b>M/s, Shiva Analyticals (India) Private Limited</b> situated at Plot Nos. 24D (P) & 34D, KIADB Industrial Area, Hoskote, Bangalore, Hoskote, Bengaluru (Bangalore) Rural, Karnataka - 562114	TL/MD/2021/000005	<ul style="list-style-type: none"> <li>1. Cardiac Stents (Test- Ethylene Oxide residue, Standard/Specification-ISO 10993-7-2008) Class C, Class D</li> <li>2. Catheters (Test- Ethylene Oxide residue, Standard/Specification-ISO 10993-7-2008) – Class A, B, C, D</li> <li>3. Disposable Perfusion Sets (Test- Ethylene Oxide residue, Standard/Specification-ISO 10993-7-2008) Class A, Class B, Class C</li> <li>4. Drug Eluting Stents (Test- Ethylene Oxide residue, Standard/Specification-ISO-10993-7-2008) Class D</li> <li>5. Heart Valves (Test- Ethylene Oxide residue, Standard/Specification-ISO 10993-7-2008) Class D</li> <li>6. Intra Ocular Lenses (Test- Ethylene Oxide residue, Standard/Specification-ISO 10993-7-2008) Class C</li> <li>7. IV Cannula (Test- Ethylene Oxide residue, Standard/Specification-ISO</li> </ul>

			<p>10993-7-2008) Class B, Class C</p> <p>8. Orthopaedic Implants (Test- Ethylene Oxide residue, Standard/Specification-ISO 10993-7-2008) Class B, Class C, Class D.</p> <p>9. Scalp Vein Set (Test- Ethylene Oxide residue, standard/Specification-ISO10993-7-2008) Class B</p> <p>10. Surgical Dressings (Test- Ethylene Oxide residue, tandard/Specification-ISO 10993-7-2008) Class A, Class B, Class C, Class D</p> <p>11. Disposable Hypodermic Needles (Test-Ethylene Oxide residue, Standard/Specification-ISO 10993-7-2008) Class B</p> <p>12. Disposable Hypodermic Syringes (Test-Ethylene Oxide residue, Standard/Specification-ISO 10993-7-2008) Class B, Class C</p> <p>13. Ablation Device (Test- Ethylene Oxide residue, Standard/Specification-ISO-10993-7-2008)</p>
16	<p><b>M/s, APEX QUALITY CERTIFICATION SERVICES PVT. LTD.</b> situated at 161, KASTURBA NAGAR, NIRMAN NAGAR, Jaipur, Jaipur, Rajasthan - 302019</p>	TL/MD/2021/000006	<p>1. Infusion/Syringe Pump ( Flow Rate, Volume, Occlusion Pressure, Electrical Safety) (Reference Standard IEC 60601-2-24, IS13450(Part2 Sec24)and IEC 60601-1). Class C.</p> <p>2. Aspirator ( Vacuum Testing, Electrical Safety) (Reference Standard ISO 10079-1 and IEC 60601-1) – Class C.</p> <p>3. Glucometer (Glucose Concentration Testing) (Reference Standard IS/ISO 15197.2013) – Class C</p> <p>4. Blood Pressure Monitoring Devices (Leak Test, NIBP Pressure Accuracy) (Reference Standard IEC60601-2-30. 2009) – Class B.</p> <p>5. Nebulizer (Flow Rate, Aerosol Output, Aerosol Output Rate, Electrical Safety) (Reference</p>

			<p>Standard ISO27427.2013 and IEC 60601-1) Class C.</p> <p>6. Digital Thermometer, (Temperature Testing) (Reference Standard - IS/ISO 80601-2-56. 2017 and IS 3055 Part 1 and Part 2 and IS 6274)</p>
17	<p><b>M/s, Shri Ram Scientific And Industrial Research Foundation</b></p> <p>Address: 8E, Diamond Press Building, Jhandewalan Extension, Rani Jhansi Road,, Delhi, New Delhi, Delhi - 110055</p>	TL/MD/2021/000007	<ol style="list-style-type: none"> <li>1. Tubal Rings/Fallopian Rings (Shape, Dimensions, Fracture Test, Memory Test, Friction Force Test, Fatigue Test, Radio Opacity, Sterility, Identification of polymer)</li> <li>2. Male Latex Condoms (Dimensions, Burst volume and pressure test, Water Leakage test, Quantity of lubricant, Colour Fastness, Integrity of individual package seal, Labeling packaging and storage)</li> <li>3. COPPER-T 380A (Physical Parameters and Dimensions, Pouch burst strength, Amt of copper wire, Strength of the Tie, Copper collar pull force, Sterility)</li> <li>4. Implantable Medical Devices (Physical Parameters and Dimensions, Sterility Test, BET Test, Bio-Burden Test)</li> <li>5. Implantable Medical Devices (Physical Parameters and Dimensions, Sterility Test, BET Test, Bio-Burden Test)</li> <li>6. IUCD-375 (Visual Inspection, Sealed Pouch peel strength, Frame dimensions, Copper wire weight, Insertion Tube dimension, Thread, Flange displacement force, Sterility)</li> <li>7. Disposable Hypodermic Needles (Acidity or Alkalinity, Extractable Metals, Physical Parameters and Dimensions, Performance Bond - Hub and Needle tube, Patency of lumen, Sterility, Bacterial Endotoxin)</li> <li>8. Disposable syringe (Extraneous matter, Acidity or Alkalinity, Extractable Metals Lubricant, Physical Parameters and Dimensions, Sterility Test, Bacterial Endotoxin)</li> </ol>

			<ol style="list-style-type: none"> <li>9. Disposable syringe (Extraneous matter, Acidity or Alkalinity, Extractable Metals Lubricant, Physical Parameters and Dimensions, Sterility Test, Bacterial Endotoxin)</li> <li>10. Surgical dressings (Threads, weight, Length and width, foreign matter, fluorescence, packaging, labelling and storage)</li> <li>11. Surgical dressings (Threads, weight, Length and width, foreign matter, fluorescence, packaging, labelling and storage)</li> <li>12. Surgical dressings (Threads, weight, Length and width, foreign matter, fluorescence, packaging, labelling and storage)</li> <li>13. Sterile Hypodermic Syringe for Single use (Sterility Test, Bacterial Endotoxin Test)</li> <li>14. Cardiac Stent (Sterility Test)</li> <li>15. Cardiac Stent (Sterility Test)</li> <li>16. Catheters (Dimensions, Sterility Test)</li> <li>17. Catheters (Dimensions, Sterility Test)</li> <li>18. Blood Bags (Sterility Test, BET, Chemical Analysis, Physical Dimensions)</li> <li>19. Blood Bags (Sterility Test, BET, Chemical Analysis, Physical Dimensions)</li> <li>20. Disposable Hypodermic Needles (Acidity or Alkalinity, Extractable Metals, Physical Parameters and Dimensions, Performance Bond - Hub and Needle tube, Patency of lumen, Sterility, Bacterial Endotoxin)</li> <li>21. Surgical dressings (Threads, weight, Length and width, foreign matter, fluorescence, packaging, labelling and storage)</li> <li>22. Umbilical Tapes (Physical Test, Adhesive, Strength, Length dia)</li> <li>23. Umbilical Tapes (Physical Test, Adhesive, Strength, Length dia)</li> <li>24. IV Cannula (Dimensions, Sterility)</li> <li>25. IV Cannula (Dimensions, Sterility)</li> <li>26. Copper-T (Sterility Test, Membrane)</li> </ol>
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			Filtration Method) 27. Suture absorbable / Suture non-absorbable Synthetic (Sterility Test, Direct Inoculation Method) 28. Tubal Ring (Sterility Test, Membrane Filtration Method)
18.	<b>M/s, VIVO BIO TECH LTD</b> Address: 3 Floor, Ilyas Mohammed Khan Estate, D. No. 8-2-672/ 5 & 6, Road No.1, Banjara Hills, Hyderabad, Hyderabad, Telangana - 500034	TL/MD/2021/000008	1. Infusion Set Class B 2. Sutures Class 3. Transcatheter Aortic Valve Class D 4. Tubal Ring Class C 5. Blood Collection Sets Class D 6. Blood Bags Class 7. Intraocular Lens Class C 8. Orthopedic Implants Class
19	<b>M/s, Conformity Testing Labs Pvt Ltd</b> Address: WH-52, Mayapuri Industrial Area, Phase 1, New Delhi, West Delhi, Delhi - 110064	TL/MD/2021/000009	1. CT scan Equipment 2. MRI Equipment 3. Defibrillators 4. Bone Marrow cell separator 5. PET Equipment 6. X-Ray Equipment 7. Dialysis Machine
20	M/s, Oasis Test House Limited situated at SP-2, 22 Godam Industrial Estate, Jaipur-302006. , Jaipur, Jaipur, Rajasthan - 302006	TL/MD/2022/000001	1. Orthopaedic Implants 2. Intraocular lens 3. Catheter class A 4. Bone cement 5. Blood bags 6. Catheter Class B 7. Disposable Hypodermic Needles 8. Disposable Perfusion Sets 9. Disposable Hypodermic Syringes 10. IV Cannulae 11. Scalp Ven Set 12. surgical dressings 13. Sutures and Ligatures 14. Intrauterine Device
21	M/s, Oasis Test House situated at 24 A - B, Sardar Patel Industrial Estate, Narol, Ahmedabad, Gujarat - 382405	TL/MD/2022/000003	1. Catheters - Class A 2. Intra Ocular Lenses - Class C 3. Orthopedic Implants -Class C 4. Surgical Dressings - Class B 5. Orthopedic Implants - Class D 6. Scalp vein set - Class B 7. Disinfectants - Class B 8. Infusion sets - Class B 9. Blood bags - Class C 10. Catheters - Class B 11. Disp Hypodermic Needles-Class B 12. Disposable Perfusion Sets-Class

			<p>B</p> <p>13. Disp Hypodermic Syringes-Class B</p> <p>14. Disposable Perfusion Sets- class A</p> <p>15. IV Cannulae - Class B</p>
22	<p><b>M/s Astute Labs Pvt. Ltd.,</b></p> <p>Sr. No. 82/1, Bajirao Dhawade Patil Industrial Estate, NDA Road, Shivane, Pune, Maharashtra - 411023</p>	TL/MD/2022/000004	<ol style="list-style-type: none"> <li>1. X-ray Equipment for Radiography and Radioscopy – Class C</li> <li>2. Cardiac Defibrillators – Class C</li> <li>3. Invasive Blood Pressure Monitoring Equipment - Class C</li> <li>4. Mammographic X-ray Equipment and Mammographic Stereotactic Devices - Class C</li> <li>5. Peritoneal Dialysis Equipment - Class C</li> <li>6. Ultrasonic Medical Diagnostic and Monitoring Equipment - Class B</li> <li>7. X-ray Equipment for Interventional Procedures - Class C</li> </ol>
23	<p><b>M/s INSTITUTE FOR INDUSTRIAL RESEARCH &amp; TOXICOLOGY</b></p> <p>F209, PHASE 1, UPSIDC, M.G. ROAD, Ghaziabad, Uttar Pradesh, 201001 Ghaziabad (India) - 245101</p>	TL/MD/2022/000005	<ol style="list-style-type: none"> <li>1. Foley Catheter Two way (Test Parameter BET and Sterility) - Class D</li> <li>2. DISPOSABLE ELECTRODE RECORDING CATHETER (Test Parameter-BET and Sterility) - Class D</li> <li>3. INTRODUCER SHEATH CATHETER (Test Parameter-BET and Sterility) - Class D</li> <li>4. DOUBLE LUMEN CATHETER SET (Test Parameter-BET and Sterility) - Class D</li> <li>5. DISPOSABLE CENTRAL VENOUS CATHETER (Test Parameter-BET and Sterility) - Class D</li> <li>6. DOLPHIN SUTURES (Test parameter Sterility) - Class C</li> <li>7. DISPOSABLE EMBOLECTOMY CATHETER (Test Parameter-BET and Sterility) - Class D</li> <li>8. DISPOSABLE THERMODILUTION CATHETER (Test Parameter-BET and Sterility) - Class D</li> <li>9. Foley Catheter Two way (Test Parameter BET and Sterility) - Class B</li> <li>10. Male Catheter (Test Parameter-BET and Sterility) - Class B</li> </ol>

			<ul style="list-style-type: none"> <li>11. Ryles Tube 14FG (Test Parameter-BET, Bioburden and Sterility) - Class B</li> <li>12. Endotracheal tube (Test Parameter-BET, Bioburden and Sterility) - Class B</li> <li>13. Coronary Artery Cannula (Test Parameter-BET and Sterility) - Class B</li> <li>14. Natural rubber latex condom (Test Parameter-BET ) - Class B</li> <li>15. Urethral Catheter (Test Parameter-BET and Sterility) - Class D</li> <li>16. Multiple Lumen Catheter (Test Parameter-BET and Sterility) - Class B</li> </ul>
24	<p><b>M/s Vorick Analytical Research Pvt. Ltd.</b></p> <p>Plot No. 252, Sector – K, Bhorganh Industrial Area, Bawana – II, Narela, North Delhi, Delhi (India) - 110040</p>	TL/MD/2022/000006	<ul style="list-style-type: none"> <li>1. Lint Bandage - Dimensions, pH Value, Scouring Loss, Freedom from optical Witness Class A</li> <li>2. Heart Valves - Heavy toxic metals as Arsenic, lead, Cadmium, Mercury Particulate Contamination, Sterility Class D</li> <li>3. Disposable Perfusion set - Particulate contamination, Tubing length, Flow rate, Heavy Metals, Acidity or alkalinity, Residue on evaporation, UV absorption of extract solution, Sterility Class B</li> <li>4. Heavy toxic metals as Arsenic, lead, Cadmium, Mercury, Particulate Contamination, Mercury Class D</li> <li>5. Ablation Devices -Heavy toxic metals as Arsenic, lead, Cadmium, Mercury, Particulate Contamination, Sterility Class C</li> <li>6. Ablation Devices- Heavy toxic metals as Arsenic, lead, Cadmium, Mercury, Particulate Contamination, Sterility Class D</li> <li>7. Cardiac Stents - Heavy toxic metals as Arsenic, lead, Cadmium, Mercury, Particulate Contamination, Sterility Class D</li> <li>8. Disposable Hypodermic Syringe - Capacity, Fiducial Line, Limits for acidity or alkalinity, Metal, Lubricant, Scale, Barrel, Piston, Nozzle, Performance, Reducing</li> </ul>



			<p>substances, Sterility Class B</p> <p>9. Bone Cements-Heavy toxic metals as Arsenic, lead, Cadmium, Mercury, Sterility Class C</p> <p>10. Contraceptives- Heavy toxic metals as Arsenic, lead, Cadmium, Mercury, Water Leakage test, Bursting volume and pressure test, dimension, Sterility Class C</p> <p>11. Contraceptives- Heavy toxic metals as Arsenic, lead, Cadmium, Mercury, Water Leakage test, Bursting volume and pressure test, dimension, Sterility Class D</p> <p>12. Disinfectant-Efficacy Test Class B</p> <p>13. Disposable Hypodermic Needles - Limits for acidity or alkalinity, Limits for extractable metals, Size designation, Colour coding, Needle hub, tube, point, Sheath, Performance, Sterility Class B</p> <p>14. IVD Kits - Sterility Class B</p> <p>15. IVD Kits - Sterility Class C</p> <p>16. IVD Kits - Sterility Class D</p> <p>17. Blood Bags - Length, Width, Diameter, Leakage test, Limit of acidity or alkalinity, Heavy toxic metals as Arsenic, lead, Cadmium, Mercury, Sterility Class C</p> <p>18. Disposable Hypodermic Needles - Limits for acidity or alkalinity, Limits for extractable metals, Size designation, Colour coding, Needle hub, tube, point, Sheath, Performance, Sterility Class C</p> <p>19. Internal Prosthesis - Heavy toxic metals as Arsenic, lead, Cadmium, Mercury Particulate Contamination, Sterility Class D</p> <p>20. IV Cannula - Limits for acidity or alkalinity, Intravascular Catheter, Distal end, Hub, Effective length, Outside Diameter, Corrosion Test, Peak tensile force, Freedom from leakage, Sterility Class C</p> <p>21. Surgical Dressing-Bleached Gauze, Length, Width, Weight in</p>
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			<p>gm/m<sup>2</sup>, Scouring loss/Foreign matter, Absorbency, Freedom from optical Whiteness, pH value of aqueous extract, Sterility Class A</p> <p>22. Orthopedic Implants- Heavy toxic metals as Arsenic, lead, Cadmium, Mercury, Particulate Contamination, Sterility Class D</p> <p>23. Surgical Dressing IHS/ As per manufacturer specifications Class D</p> <p>24. Internal Prosthesis - Heavy toxic metals as Arsenic, lead, Cadmium, Mercury Particulate Contamination, Sterility Class C</p> <p>25. Disposable Perfusion set - Particulate contamination, Tubing length, Flow rate, Heavy Metals, Acidity or alkalinity, Residue on evaporation, UV absorption of extract solution, Sterility Class A</p> <p>26. Surgical Dressing - Bleached Gauze, Length, Width, Weight in gm/m<sup>2</sup>, Scouring loss/Foreign matter, Absorbency, Freedom from optical Whiteness, pH value of aqueous extract, Sterility Class C</p> <p>27. IV Cannula - Limits for acidity or alkalinity, Intravascular Catheter, Distal end, Hub, Effective length, Outside Diameter, Corrosion Test, Peak tensile force, Freedom from leakage, Sterility Class B</p> <p>28. Crepe Bandages - Dimensions, Weight per unit area, Stretchability, breaking load, Chemical Neutrality. Class A</p> <p>29. POP Bandages - Setting Time, Tensile Strength, Compressive strength Class A</p> <p>30. Disposable Perfusion set - Particulate contamination, Tubing length, Flow rate, Heavy Metals, Acidity or alkalinity, Residue on evaporation, UV absorption of extract solution, Sterility Class C</p> <p>31. Catheters- Length, Diameter, Heavy toxic metals as Arsenic, lead, Cadmium, Mercury, Particulate Contamination, Sterility Class A</p>
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**(Dr V G Somani)**  
**Drugs Controller General (I)**

To,  
IT Cell for uploading the information on the CDSCO website.

