

**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)**

**121 NOV 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 Medical Devices Rules, 2017).

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:

<b>Sl. No.</b>	<b>NAME &amp; ADDRESS OF MEDICAL DEVICE TESTING LABORATORY</b>	<b>REGISTRATION NO.</b>	<b>SCOPE OF TESTING</b>
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</b>	TL/MD/2019/000003	1. Sterilized Surgical Ligatures 2. Sterilized Disposable Device

	<b>Pvt. Ltd.</b> Address: 1652 MIE Part B, Bahadurgarh, Haryana – 124507		3. Sterilized Surgical Sutures
4	<b>M/s Sree Chitra Tirunal Institute For Medical Sciences &amp; Technology</b> Address: Medical College, Thiruvananthapuram, Kerala - 695011	TL/MD/2019/000004	1. Cardio Vascular Devices (Biological Evaluation as per ISO 10993) 2. Neuroprosthesis (Biological Evaluation as per ISO 10993) 3. Orthopedic Implants (Biological Evaluation as per ISO 10993) 4. All medical devices and Materials (Biological Evaluation as per ISO 10993) 5. Dental Implants (Biological Evaluation as per ISO 10993)
5	<b>M/s, GLR Laboratories Private Limited</b> Address: GOKULAM STREET, Mathur, MATHUR, Chennai, Tamil Nadu - 600068	TL/MD/2019/000005	1. Cardiovascular devices (Biological evaluation as per ISO 10993) 2. Orthopaedic devices (Biological evaluation as per ISO 10993) 3. Ocular devices (Biological evaluation as per ISO 10993) 4. Surgical devices and sutures (Biological evaluation as per ISO 10993) 5. Respiratory devices (Biological evaluation as per ISO 10993) 6. Gastrointestinal devices (Biological evaluation as per ISO 10993) 7. Urological devices (Biological evaluation as per ISO 10993) 8. Haematological devices and IV sets (Biological evaluation as per ISO 10993) 9. Dental devices (Biological evaluation as per ISO 10993) 10. Personal care products and family planning (Biological evaluation as per ISO 10993) 11. Neurological devices (Biological evaluation as per ISO 10993) 12. All medical devices and Materials (Biological evaluation as per ISO 10993)
6	<b>M/s, PALAMUR BIOSCIENCES PRIVATE LIMITED</b> Address: 401 Aikya, 4th Floor, H.No-10-3-	TL/MD/2019/000006	1. Catheters (Biological Toxicity) 2. Disposable Hypodermic needles (Biological Toxicity) 3. Surgical dressings (Biological Toxicity)

	32/9/23, Opp.Faust High School, East Marredpally, Secunderabad, Hyderabad, Telangana - 500026		<ol style="list-style-type: none"> <li>4. Orthopaedic Implants (Biological Toxicity)</li> <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</li> </ol>

			<p>1954, ISO 11737-1 and 2, IP 2018, USP 42, BP 2018 and EN9.0) - Class A</p> <p>5. Surgical Dressings ( Sterility , Bioburden, BET as per IS 758, IS 1954, ISO 11737-1 and 2, IP 2018, USP 42, BP 2018 and EN9.0) - Class B</p> <p>6. Surgical Dressings ( Sterility , Bioburden, BET as per IS 758, IS 1954, ISO 11737-1 and 2, IP 2018, USP 42, BP 2018 and EN9.0) - Class C</p> <p>7. Surgical Dressings ( Sterility , Bioburden, BET as per IS 758, IS 1954, ISO 11737-1 and 2, IP 2018, USP 42, BP 2018 and EN9.0) - Class D</p> <p>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)</p> <p>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</p> <p>10. Catheters (Sterility, Bioburden and BET as per ISO 11737-1 and 2, USP 42, EP 9.0, IP 2018, BP 2018) - Class B</p> <p>11. Catheters (Sterility, Bioburden and BET as per ISO 11737-1 and 2, USP 42, EP 9.0, IP 2018, BP 2018) - Class C</p> <p>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</p> <p>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</p> <p>14. Disposable Perfusion sets (Physical testing , Sterility, Bioburden and BET</p>
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			<p>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>15. Intraocular Lenses (Sterility, 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,</p>
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			<p>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, 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,</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</p>

	Delhi, West Delhi, Delhi - 110046		<p>(Excluding Biocompatibility testing) - Class C</p> <ol style="list-style-type: none"> <li>5. Disposable Hypodermic Needles (Excluding Bio-compatibility testing) - Class C</li> <li>6. Disposable Hypodermic Needles (Excluding Bio-compatibility testing) - Class D</li> <li>7. Disposable Hypodermic Syringes - Class A</li> <li>8. Disposable Hypodermic Syringes (Excluding Bio-compatibility testing) - Class B</li> <li>9. Disposable Hypodermic Syringes (Excluding Bio-compatibility testing) - Class C</li> <li>10. Disposable Hypodermic Syringes (Excluding Bio-compatibility testing) - Class D</li> <li>11. I.V. Cannulae - Class A</li> <li>12. I.V. Cannulae (Excluding Bio-compatibility testing) - Class B</li> <li>13. I.V. Cannulae (Excluding Bio-compatibility testing) - Class C</li> <li>14. I.V. Cannulae (Excluding Bio-compatibility testing) - Class D</li> <li>15. Scalp Vein Set - Class A</li> <li>16. Scalp Vein Set (Excluding Biocompatibility testing) - Class B</li> <li>17. Scalp Vein Set (Excluding Biocompatibility testing) - Class C</li> <li>18. Scalp Vein Set (Excluding Biocompatibility testing) - Class D</li> <li>19. Surgical Dressings - Class A</li> <li>20. Surgical Dressings (Excluding Biocompatibility testing) - Class B</li> <li>21. Surgical Dressings (Excluding Biocompatibility testing) - Class C</li> <li>22. Surgical Dressings (Excluding Biocompatibility testing) - Class D</li> <li>23. Contraceptives - Class A</li> <li>24. Contraceptives (Excluding Biocompatibility testing) - Class B</li> <li>25. Contraceptives (Excluding Biocompatibility testing) - Class C</li> <li>26. Contraceptives (Excluding Biocompatibility testing) - Class D</li> <li>27. Disinfectant - Class A</li> <li>28. Catheters (Excluding Bio-compatibility testing) - Class D</li> </ol>
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			<ul style="list-style-type: none"> <li>29. Disposable Hypodermic Needles - Class A</li> <li>30. Disposable Hypodermic Needles (Excluding Bio-compatibility testing) - Class B</li> <li>31. Disinfectant (Excluding Bio-compatibility testing) - Class B</li> <li>32. Disinfectant (Excluding Bio-compatibility testing) - Class C</li> <li>33. Disinfectant (Excluding Bio-compatibility testing) - Class D</li> <li>34. Disposable Perfusion Sets - Class A</li> <li>35. Disposable Perfusion Sets (Excluding Biocompatibility testing) - Class B</li> <li>36. Disposable Perfusion Sets (Excluding Biocompatibility testing)</li> </ul>
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	<ul style="list-style-type: none"> <li>1. Catheters (Test as per IS/ISO 10555) - Class A</li> <li>2. Disinfectants (As per IP, BP, USP) - Class B</li> <li>3. Disposable Hypodermic Needles (Test as per IS 10654) - Class B</li> <li>4. Disposable Perfusion Sets (Test as per IS 12655) - Class A</li> <li>5. Disposable Perfusion Sets (Test as per IS 12655) - Class B</li> <li>6. Catheters (Test as per IS/ISO 10555) - Class B</li> <li>7. I.V. Cannulae (Test as per IS/ISO 10555) - Class B</li> <li>8. Disposable Hypodermic Syringes (Test as per IS10258) - Class B</li> <li>9. Scalp vein set (Test as per IS 16097) - Class B</li> <li>10. Surgical Dressings (Cotton and Gauze, Bandage)-Class B</li> <li>11. Surgical Dressings (Cotton and Gauze, Bandage)-Class A</li> </ul>
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	<ul style="list-style-type: none"> <li>1. Catheters (Excluding Bio-compatibility testing) Class D</li> <li>2. Surgical Dressings (Excluding Biocompatibility testing) Class D</li> <li>3. Disposable Hypodermic Syringes Class D</li> <li>4. Disposable Hypodermic Syringes (Excluding Bio-compatibility testing) Class D</li> </ul>



			<ol style="list-style-type: none"> <li>5. Surgical Dressings Class D</li> <li>6. Disposable Hypodermic Needles (Excluding Bio-compatibility testing) Class C</li> <li>7. Contraceptives Class D</li> <li>8. I.V. Cannulae (Excluding Bio-compatibility testing) Class C</li> <li>9. Surgical Dressings (Excluding Biocompatibility testing) Class D</li> <li>10. Scalp Vein Set (Excluding Biocompatibility testing) Class B</li> <li>11. Disposable Hypodermic Needles Class C</li> <li>12. I.V. Cannulae Class C</li> <li>13. I.V. Cannulae (Excluding Bio-compatibility testing) Class C</li> <li>14. Scalp Vein Set Class B</li> <li>15. Contraceptives (Excluding Biocompatibility testing) Class D</li> <li>16. Catheters Class D</li> <li>17. Disinfectant Class B</li> <li>18. Disposable Perfusion Sets (Excluding Biocompatibility testing) Class C</li> <li>19. Disinfectant (Excluding Bio-compatibility testing) Class B</li> <li>20. Disposable Perfusion Sets Class C</li> <li>21. Disposable Perfusion Sets (Excluding Biocompatibility testing) Class C</li> <li>22. Disposable Hypodermic Needles (Excluding Bio-compatibility testing) Class D</li> <li>23. Surgical Suture Class D</li> <li>24. Urine collecting bag Class B</li> <li>25. Surgical Gloves ( Sterile/Non Sterile) Class D</li> <li>26. Endotracheal (ET) tube Class B</li> <li>27. Disposable Hypodermic Syringes Class C</li> <li>28. Blood Bag (Single Blood Bag, Double Blood Bag, Triple Blood Bag, Quad Blood Bag) Class C</li> <li>29. Disinfectant (Excluding Bio-compatibility testing)</li> </ol>
12	<b>Accuprec Research Labs Private Limited</b> Opp. Zydus Pharmez, Changodar- Bavla	TL/MD/2021/000002	<ol style="list-style-type: none"> <li>1. Vascular devices and IV sets; Class D</li> <li>2. Tubal rings; Class C</li> <li>3. Copper T; Class C</li> </ol>

	Highway, Vill-Matoda,, Sanand, Ahmedabad, Gujarat - 382213		<ol style="list-style-type: none"> <li>4. Sutures; Class C</li> <li>5. Disposable Hypodermic needles; Class C</li> <li>6. Catheters; Class D</li> <li>7. Disposable Hypodermic Syringes; Class B</li> <li>8. Blood bags; Class B</li> <li>9. Condoms; Class C</li> <li>10. Coronary stents; Class D</li> <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> </ol>
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	<ol 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> </ol>
14	<b>Brothers Laboratories Pvt. Ltd</b> 103, D-3, Industrial Area Jhotwara, Jaipur, Rajasthan - 302012	TL/MD/2021/000004	<ol 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> </ol>
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	<ol 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> </ol>

			<ol style="list-style-type: none"> <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 10993-7-2008) Class B, Class C</li> <li>8. Orthopaedic Implants (Test- Ethylene Oxide residue, Standard/Specification-ISO 10993-7-2008) Class B, Class C, Class D.</li> <li>9. Scalp Vein Set (Test- Ethylene Oxide residue, standard/Specification-ISO10993-7-2008) Class B</li> <li>10. Surgical Dressings (Test- Ethylene Oxide residue, tandard/Specification-ISO 10993-7-2008) Class A, Class B, Class C, Class D</li> <li>11. Disposable Hypodermic Needles (Test-Ethylene Oxide residue, Standard/Specification-ISO 10993-7-2008) Class B</li> <li>12. Disposable Hypodermic Syringes (Test-Ethylene Oxide residue, Standard/Specification-ISO 10993-7-2008) Class B, Class C</li> <li>13. Ablation Device (Test- Ethylene Oxide residue, Standard/Specification-ISO-10993-7-2008)</li> </ol>
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	<ol style="list-style-type: none"> <li>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.</li> <li>2. Aspirator ( Vacuum Testing, Electrical Safety) (Reference Standard ISO 10079-1 and IEC 60601-1) – Class C.</li> <li>3. Glucometer (Glucose Concentration Testing) (Reference Standard IS/ISO 15197.2013) – Class C</li> <li>4. Blood Pressure Monitoring Devices</li> </ol>

			<p>(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 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</li> </ol>

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

			<ul style="list-style-type: none"> <li>9. Blood bags - Class C</li> <li>10. Catheters - Class B</li> <li>11. Disp Hypodermic Needles-Class B</li> <li>12. Disposable Perfusion Sets-Class B</li> <li>13. Disp Hypodermic Syringes-Class B</li> <li>14. Disposable Perfusion Sets- class A</li> <li>15. IV Cannulae - Class B</li> </ul>
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	<ul 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> </ul>
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	<ul 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> </ul>

			<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, Bhorgarh 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,</li> </ul>



			<p>Nozzle, Performance, Reducing 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>
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			<p>21. 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 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,</p>
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			<p>lead, Cadmium, Mercury, Particulate Contamination, Sterility Class A</p> <p>32. Catheters- Length, Diameter, Heavy toxic metals as Arsenic, lead, Cadmium, Mercury, Particulate Contamination, Sterility Class B</p> <p>33. Catheters- Length, Diameter, Heavy toxic metals as Arsenic, lead, Cadmium, Mercury, Particulate Contamination, Sterility Class C</p> <p>34. Catheters- Length, Diameter, Heavy toxic metals as Arsenic, lead, Cadmium, Mercury, Particulate Contamination, Sterility Class D</p> <p>35. Orthopedic Implants- Heavy toxic metals as Arsenic, lead, Cadmium, Mercury, Particulate Contamination, Sterility Class C</p> <p>36. 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 B</p> <p>37. Disposable Hypodermic Syringe - Capacity, Fiducial Line, Limits for acidity or alkalinity, Metal, Lubricant, Scale, Barrel, Piston, Nozzle, Performance, Reducing substances, Sterility Class B</p> <p>38. Rolled Bandage - Dimensions, pH Value, Scouring Loss, Freedom from optical Witness Class A</p>
25.	<p><b>M/s, TUV Rheinland (India) Pvt. Ltd.,</b></p> <p>situated at Survey No 480/2, AMTZ Campus, Nadupuru Village, Pedagantyada, Pragati Maidan, Visakhapatnam, Andhra Pradesh - 530031</p>	TL/MD/2022/000007	<p>1. Medical Electrical Equipments- IEC/EN 60601-1/IS 13450 (Part 1) Class A</p> <p>2. Electrical Safety Testing - Pulse Oximeter, Oxygen Concentrator, Electrocardiograph Class C</p> <p>3. Electro Magnetic Interference and Electro Magnetic Compatibility (EMI/EMC) - Electro Medical Equipments Class C</p> <p>4. Personal Protectives (Coverall, Surgical Masks, Filter type Particulate Matter Respirator,</p>

			<p>Medical Textile, Face Mask, Surgical Gowns and Surgical Drapes) Class A</p> <p>5. Personal Protectives (Coverall, Surgical Masks, Filter type Particulate Matter Respirator, Medical Textile, Face Mask, Surgical Gowns and Surgical Drapes) Class B</p> <p>6. Bioburden Testing (Disposable Hypodermic Needles, Surgical Dressings, Medical Textile) Class A</p> <p>7. In - Vitro Cytotoxicity Test (Disposable Hypodermic Needles, Surgical Dressings, Medical Textile) Class A</p> <p>8. Electrical Safety Testing - Pulse Oximeter, Oxygen Concentrator, Electrocardiograph Class B</p> <p>9. Electro Magnetic Interference and Electro Magnetic Compatibility (EMI/EMC) - Electro Medical Equipments Class A</p> <p>10. Electrical Safety Testing - Pulse Oximeter, Oxygen Concentrator, Electrocardiograph Class A</p> <p>11. Electro Magnetic Interference and Electro Magnetic Compatibility (EMI/EMC) - Electro Medical Equipments Class B</p> <p>12. Bioburden Testing (Disposable Hypodermic Needles, Surgical Dressings, Medical Textile) Class B</p> <p>13. Medical Electrical Equipments- IEC/EN 60601-1/IS 13450 (Part 1) Class B</p> <p>14. Medical Electrical Equipments- IEC/EN 60601-1/IS 13450 (Part 1) Class C</p> <p>15. In-Vitro Cytotoxicity Test (Disposable Hypodermic Needles, Surgical Dressings, Medical Textile) Class B</p>
26.	<p><b>M/s, SHREE BALAJI TEST LAB PVT. LTD.</b></p> <p>situated at C-181, NARAINA INDUSTRIAL AREA PHASE-1 , New Delhi</p>	TL/MD/2022/000008	<p>1. Surgical Gloves (Physiochemical, BET and Sterility) Class A</p> <p>2. Disinfectant Class B</p> <p>3. Catheters (Physiochemical, BET and Sterility) Class C</p> <p>4. Cardiac Stents (BET and Sterility) Class D</p>

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27.	<p><b>M/s, INTERSTELLER TESTING CENTRE PVT. LTD.</b></p> <p>situated at 86, Industrial Area, Phase 1, Panchkula, Haryana - 134109</p>	TL/MD/2022/000009	<ol style="list-style-type: none"> <li>1. Suprapubic or non disposable cannula (Test parameter- Sterility and BET) Class B</li> <li>2. Disposable Hypodermic needles (Test parameter- Sterility and BET) Class B</li> <li>3. Nasogastric Tube/ Ryles Tube (Test parameter- Sterility and BET) Class B</li> <li>4. Disposable perfusion set (Test parameter Sterility and BET) Class B</li> <li>5. Feeding Tube (Test parameter- Sterility and BET) Class B</li> <li>6. Gastrointestinal Tube (Test parameter Sterility and BET) Class B</li> <li>7. Gastro-Enterostomy Tube (Test parameter- Sterility and BET) Class B</li> <li>8. Bolster Suture (Test parameter- Sterility and BET) Class A</li> <li>9. Blood Transfusion set (Test parameter Sterility and BET) Class B</li> </ol>

			<ul style="list-style-type: none"> <li>10. Urinary Drainage Unit (Test parameter Sterility and BET) Class B</li> <li>11. Upper Urinary tract catheter (Test parameter- Sterility and BET) Class B</li> <li>12. Foley Catheter (Test parameter- Sterility and BET) Class B</li> <li>13. Coude catheter (Test parameter- Sterility and BET) Class B</li> <li>14. Alcohol Swabs (Test parameter- Sterility and BET) Class A</li> <li>15. Surgical Dressing (Test parameter Sterility and BET) Class A</li> <li>16. Nasopharyngeal Catheter (Test parameter- Sterility and BET) Class A</li> <li>17. Disposable Hypodermic Syringe (Test parameter- Sterility and BET) Class B</li> <li>18. Contraceptives (Test parameter- Sterility and BET) Class C</li> <li>19. Intraocular lenses (Test parameter Sterility and BET) Class C</li> <li>20. Surgical stapler (Test parameter- Sterility and BET) Class B</li> <li>21. Orthopaedic implants (Test parameter Sterility and BET) Class B</li> <li>22. Internal Prosthetic placements (Test parameter- Sterility and BET) Class C</li> <li>23. Ablation device (Test parameter- Sterility and BET) Class C</li> <li>24. IV cannula (Test parameter- Sterility and BET) Class B</li> </ul>
28.	<p><b>M/s, Yadav Measurements Private Limited</b></p> <p>situated at Plot No 373-375, RIICO Bhamashah Industrial Area , Kaladwas, Udaipur , Rajasthan, India- 313003</p>	TL/MD/2022/000010	<ul style="list-style-type: none"> <li>1. Medical Electrical Equipments (EN/IEC 60601-1-2) Class A</li> <li>2. In Vitro Diagnostic (IVD) Medical Electrical equipments (IEC 61326-2-6) Class A</li> <li>3. In Vitro Diagnostic (IVD) Medical Electrical equipments (IEC 61326-2-6) Class C</li> <li>4. Electro Magnetic Interference and Electro Magnetic Compatibility (EMI/EMC)-Electro Medical and IVD Equipments (Basic Standard) Class A</li> <li>5. Electro Magnetic Interference and</li> </ul>

			<p>Electro Magnetic Compatibility (EMI/EMC)-Electro Medical and IVD Equipments (Basic Standard) Class C</p> <p>6. Medical Electrical Equipments (EN/IEC 60601-1-2) Class C</p> <p>7. In-Vitro Diagnostic (IVD) Medical Electrical equipments (IEC 61326-2-6) Class B</p> <p>8. Electro Magnetic Interference and Electro Magnetic Compatibility (EMI/EMC)-Electro Medical and IVD Equipments (Basic Standard) Class B</p> <p>9. Medical Electrical Equipments (EN/IEC 60601-1-2) Class B</p>
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**(Dr V G Somani)**  
**Drugs Controller General (I)**

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IT Cell for uploading the information on the CDSCO website.

