

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)

Dated: 09 OCT 2020

NOTICE

Subject: List of medical devices testing laboratory (MDTL) for carry out test or evaluation of medical device on behalf of manufacturer registered with CDSCO under MDR 2017- reg.

As you are aware that Medical Devices Rules 2017 has already been published vide G.S.R. 78(E) dated 31.01.2017 under Drugs and Cosmetics Act to regulate the manufacture, import, sale and distribution of the medical devices and said rules are effective from 01.01.2018.

The updated list of medical devices testing laboratories registered with CDSCO up till under rule 81 in the provisions of Medical Devices Rules, 2017 to carry out test or evaluation of a medical device on behalf of manufacturer is given below & there are more applicants which are under evaluation.

Sl. No.	NAME & ADDRESS OF MEDICAL DEVICE TESTING LABORATORY	REGISTRATION NO.	SCOPE OF TESTING
1	M/s SIPRA LABS LIMITED 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	M/s Star Imaging & Path Lab Pvt. Ltd. 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	M/s Alcatec Research Laboratories India Pvt. Ltd. Address: 1652 MIE Part B, Bahadurgarh, Haryana – 124507	TL/MD/2019/000003	1. Sterilized Surgical Ligatures 2. Sterilized Disposable Device 3. Sterilized Surgical Sutures
4	M/s Sree Chitra Tirunal Institute For Medical Sciences & Technology 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	M/s, GLR Laboratories Private Limited 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	M/s, PALAMUR BIOSCIENCES PRIVATE LIMITED Address: 401 Aikya, 4th Floor, H.No-10-3-32/9/23, Opp.Faust High School, East Marredpally, Secunderabad, Hyderabad, Telangana - 500026	TL/MD/2019/000006	<ol style="list-style-type: none"> 1. Catheters (Biological Toxicity) 2. Disposable Hypodermic needles (Biological Toxicity) 3. Surgical dressings (Biological Toxicity) 4. Orthopaedic Implants (Biological Toxicity) 5. Blood Bags (Biological Toxicity) 6. Drug eluting stent (Biological Toxicity) 7. Intra Ocular Lenses (Biological Toxicity) 8. Sutures (Biological Toxicity) 9. Condoms (Biological Toxicity) 10. Heart Valves (Biological Toxicity) 11. Disposable perfusion sets (Biological Toxicity) 12. Cardiac stent (Biological Toxicity) 13. Copper- T (Biological Toxicity) 14. Scalp Vein Set (Biological Toxicity)
7	M/s, Eurofins Advinus Limited 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"> 1. Disposable Perfusion Sets 2. Cardiac Stents 3. Drug Eluting Stents 4. Blood Bags 5. Catheters (Class D) 6. Catheters (Class B) 7. Catheters (Class C) 8. Heart valves 9. Intra Ocular Lenses 10. I.V. Cannula 11. Bone Cements 12. Internal Prosthetic Replacements 13. Peritoneal dialysis sets 14. Condoms 15. Intra-uterine devices 16. Surgical dressing 17. Scalp Vein Set 18. Ligatures and sutures
8	M/s, TRUSTIN ANALYTICAL SOLUTIONS PRIVATE LIMITED Address: Plot no-303/b, Block-B, RK Complex, 1 st	TL/MD/2020/000002	<ol style="list-style-type: none"> 1. Disinfectant (Sterility and Antimicrobial activities as per ISO 11737-1 and 2, USP 42, EP 9.0, IP 2018, BP 2018) 2. Catheters (Sterility, Bioburden and BET as per ISO 11737-1 and 2, USP 42, EP 9.0, IP

<p>Floor, Thiruneermalai road, Parvathy puram, Chrompet, , Chennai, Kanchipuram, Tamil Nadu - 600044</p>	<p>2018, BP 2018) - Class A</p> <ol style="list-style-type: none"> 3. Surgical Sutures (Physical parameters, Sterility and BET as per ISO 11737-2, USP 42, EP 9.0, IP 2018, BP 2018) - Class B 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 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 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 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 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) 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 10. Catheters (Sterility, Bioburden and BET as per ISO 11737-1 and 2, USP 42, EP 9.0, IP 2018, BP 2018) - Class B 11. Catheters (Sterility, Bioburden and BET as per ISO 11737-1 and 2, USP 42, EP 9.0, IP 2018, BP 2018) - Class C 12. Disposable Hypodermic Needles (Sterility, Bioburden
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			<p>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 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 ISO 11737-2, USP 42, EP 9.0, IP 2018, BP 2018) - Class C</p> <p>19. Cardiac Stents (Sterility test as per ISO 11737-2, USP 42, EP 9.0, IP 2018, BP 2018) - Class D</p> <p>20. Contraceptives (CuT) (Mechanical parameters, Sterility, Bioburden as per WHO UNFPA 2016, ISO 7439, ISO 11737-1 and 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>
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| | | | <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, 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,</p> |
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			<p>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 11737-1 and 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, EP 9.0, IP 2018, BP 2018)</p>
9	<p>M/s, Devansh Testing & Research Laboratory Pvt. Ltd. Address: RZ-21A/331, Madanpuri, Gali No.- 10, West Sagar Pur, Delhi, West Delhi, Delhi - 110046</p>	TL/MD/2020/000003	<ol style="list-style-type: none"> 1. Catheters – Class A 2. Catheters (Excluding Bio-compatibility testing) - Class B 3. Catheters (Excluding Bio-compatibility testing)- Class C 4. Disposable Perfusion Sets (Excluding Biocompatibility testing) - Class C 5. Disposable Hypodermic Needles (Excluding Bio-compatibility testing) - Class C 6. Disposable Hypodermic Needles (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

			<ul style="list-style-type: none"> 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 Biocompatibility testing) - Class D 29. Disposable Hypodermic Needles - Class A 30. Disposable Hypodermic Needles (Excluding Biocompatibility testing) - Class B 31. Disinfectant (Excluding Biocompatibility testing) - Class B 32. Disinfectant (Excluding Biocompatibility testing) - Class C 33. Disinfectant (Excluding Biocompatibility testing) - Class D 34. Disposable Perfusion Sets - Class A 35. Disposable Perfusion Sets (Excluding Biocompatibility testing) - Class B 36. Disposable Perfusion Sets (Excluding Biocompatibility testing)
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10	M/s, JAGDAMBA LABORATORIES Address: 119, Solitaire Industrial Park, Phase-1, Dahmikallan, Bagru, Jaipur, Rajasthan- 303007	TL/MD/2020/000004	1. Catheters (Test as per IS/ISO 10555) - Class A 2. Disinfectants (As per IP, BP, USP) - Class B 3. Disposable Hypodermic Needles (Test as per IS 10654) - Class B 4. Disposable Perfusion Sets (Test as per IS 12655) - Class A 5. Disposable Perfusion Sets (Test as per IS 12655) - Class B 6. Catheters (Test as per IS/ISO 10555) - Class B 7. I.V. Cannulae (Test as per IS/ISO 10555) - Class B 8. Disposable Hypodermic Syringes (Test as per IS10258) - Class B 9. Scalp vein set (Test as per IS 16097) - Class B 10. Surgical Dressings (Cotton and Gauze, Bandage)-Class B 11. Surgical Dressings (Cotton and Gauze, Bandage)-Class A
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(Dr. V. G. Somani)
 Drugs Controller General (India)

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 IT Cell for uploading the information on the CDSCO website.

