

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: **3 OCT 2019**

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 Alcatel 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)

V.G.S.

(Dr. V. G. Somani)
 Drugs Controller General (India)

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