## 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: 07/07/224

## **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.

SI. No.	NAME & ADDRESS OF MEDICAL DEVICE TESTING LABORATORY	REGISTRATION NO.	SCOPE OF TESTING
19 6 Good US 2 8	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	<ol> <li>Copper -T</li> <li>Condoms</li> <li>Sterile Hypodermic Needles</li> <li>Tubal Rings</li> <li>Hypodermic Syringes</li> <li>Blood Bags</li> </ol>
2	M/s Star Imaging & Path Lab Pvt. Ltd. Address: 4B/4, Tilak Nagar , West Delhi, Delhi (India) - 110018	TL/MD/2019/000002	<ol> <li>Bilirubin (Total and Direct) Test Reagents / Kits</li> <li>Creatinine test reagent / kit</li> <li>Aspartate Amino Transferase (AST / SGOT) test</li> <li>Alanine Amino Transferase (ALT/SGPT) test</li> <li>Uric Acid Test reagents / kits</li> <li>Total Protein test reagents / kits</li> <li>Activated partial thromboplastin time (APTT) test</li> <li>PT (Prothrombin Time) Test reagents / Kits</li> </ol>

3	M/s Alcatec Research Laboratories India Pvt. Ltd. Address: 1652 MIE Part B, Bahadurgarh, Haryana – 124507	TL/MD/2019/000003	Sterilized Surgical Ligatures     Sterilized Disposable Device     Sterilized Surgical Sutures
4	M/s Sree Chitra Tirunal Institute For Medical Sciences & Technology Address: Medical College, Thiruvananthapuram, Kerala - 695011	TL/MD/2019/000004	<ol> <li>Cardio Vascular Devices         <ul> <li>(Biological Evaluation as per ISO 10993)</li> </ul> </li> <li>Neuroprosthesis (Biological Evaluation as per ISO 10993)</li> <li>Orthopedic Implants (Biological Evaluation as per ISO 10993)</li> <li>All medical devices and Materials (Biological Evaluation as per ISO 10993)</li> <li>Dental Implants (Biological Evaluation Evaluation as per ISO 10993)</li> </ol>
5	M/s, GLR Laboratories Private Limited Address: GOKULAM STREET, Mathur, MATHUR, Chennai, Tamil Nadu - 600068	TL/MD/2019/000005	<ol> <li>Cardiovascular devices         (Biological evaluation as per ISO 10993)</li> <li>Orthopaedic devices         (Biological evaluation as per ISO 10993)</li> <li>Ocular devices (Biological evaluation as per ISO 10993)</li> <li>Surgical devices and sutures         (Biological evaluation as per ISO 10993)</li> <li>Respiratory devices (Biological evaluation as per ISO 10993)</li> <li>Gastrointestinal devices         (Biological evaluation as per ISO 10993)</li> <li>Urological devices (Biological evaluation as per ISO 10993)</li> <li>Haematological devices and IV sets (Biological evaluation as per ISO 10993)</li> <li>Dental devices (Biological evaluation as per ISO 10993)</li> <li>Personal care products and family planning (Biological evaluation as per ISO 10993)</li> <li>Neurological devices         (Biological evaluation as per ISO 10993)</li> <li>All medical devices and Materials (Biological evaluation as per ISO 10993)</li> </ol>

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> <li>Catheters (Biological Toxicity)</li> <li>Disposable Hypodermic needles (Biological Toxicity)</li> <li>Surgical dressings (Biological Toxicity)</li> <li>Orthopaedic Implants (Biological Toxicity)</li> <li>Blood Bags (Biological Toxicity)</li> <li>Brug eluting stent (Biological Toxicity)</li> <li>Intra Ocular Lenses (Biological Toxicity)</li> <li>Sutures (Biological Toxicity)</li> <li>Condoms (Biological Toxicity)</li> <li>Heart Valves (Biological Toxicity)</li> <li>Disposable perfusion sets (Biological Toxicity)</li> <li>Cardiac stent (Biological Toxicity)</li> <li>Cardiac stent (Biological Toxicity)</li> <li>Copper- T (Biological Toxicity)</li> <li>Scalp Vein Set (Biological Toxicity)</li> </ol>
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> <li>Disposable Perfusion Sets</li> <li>Cardiac Stents</li> <li>Drug Eluting Stents</li> <li>Blood Bags</li> <li>Catheters (Class D)</li> <li>Catheters (Class B)</li> <li>Catheters (Class C)</li> <li>Heart valves</li> <li>Intra Ocular Lenses</li> <li>I.V. Cannula</li> <li>Bone Cements</li> <li>Internal Prosthetic         <ul> <li>Replacements</li> </ul> </li> <li>Peritoneal dialysis sets</li> <li>Condoms</li> <li>Intra-uterine devices</li> <li>Surgical dressing</li> <li>Scalp Vein Set</li> <li>Ligatures and sutures</li> </ol>
8	M/s, TRUSTIN ANALYTICAL SOLUTIONS PRIVATE LIMITED Address: Plot no- 303/b, Block-B, RK Complex, 1 <sup>st</sup>	TL/MD/2020/000002	<ol> <li>Disinfectant ( Sterility and Antimicrobial activities as per ISO 11737-1 and 2, USP 42, EP 9.0, IP 2018, BP 2018)</li> <li>Catheters (Sterility, Bioburden and BET as per ISO 11737-1 and 2, USP 42, EP 9.0, IP</li> </ol>

(DQX	Floor, Thiruneermalai	2018, BP 2018) - Class A
	road, Parvathy puram,	3. Surgical Sutures (Physical
(with	Chrompet, ,	parameters, Sterility and BET
		as per ISO 11737-2, USP
	Chennai,	42, EP 9.0, IP 2018, BP 2018)
	Kanchipuram, Tamil	
	Nadu - 600044	- Class B
	activities 中国进行的时间	4. Surgical Dressings (Sterility,
	Hara Bille (Bill book)	Bioburden, BET as per IS 758,
	Entraine T	IS 1954, ISO 11737-1and 2, IP
	on Scale Children and I	2018, USP 42, BP 2018 and
		EN9.0) - Class A
	Market School St.	
	POT SESSION STATE	5. Surgical Dressings (Sterility,
	Toxicity Interest	Bioburden, BET as per IS 758,
	CONTROL SERVICE TO	IS 1954, ISO 11737-1and 2, IP
-	Condoms (Biological )	2018, USP 42, BP 2018 and
		EN9.0) - Class B
	Kendle - Distalled - Landing	6. Surgical Dressings (Sterility,
	A STATE OF THE STA	Bioburden, BET as per IS 758,
	The source of th	Diopuldell, DE1 as per 13 730,
	(Auditor estimate)	IS 1954, ISO 11737-1and 2, IP
	L Cardiac stent (Elulogici	2018, USP 42, BP 2018 and
	Toxicity	EN9.0) - Class C
Eggen	Connected Townson	7. Surgical Dressings (Sterility,
7	A Cash Company of the Cash	Bioburden, BET as per IS 758,
	Entertainment tenter	IS 1954, ISO 11737-1and 2, IP
	Carrier - (Albixo)	
	Chicago GOMA ART	2018, USP 42, BP 2018 and
	Disposition For Majora	EN9.0) - Class D
	Cardiac Steple	8. Blood bags with and without
	Constitution States	anticoagulant solutions
	Pioces Had	(Mechanical, Sterility and BET
	YT at I'll anatomical	as per ISO 3826, IS 15102,
		ISO 11737-2, USP42, EP 9.0,
	TO SERVICE STREET, STREET, ST.	
	(Disassu) sistential	IP 2018, BP 2018)
	seviny fiself	9. Contraceptives (Condoms -
	lates Ocular Lanses	Male/Female Condoms)
	DIV Cannula	(Mechanical parameters,
	atmatria Transacti	Bioburden and Pathogens as
		per ISO 4074-2015,
	OHE WAS IN THE TENT IN THE	WHOUNAIDS2010,
	A MARINE OSIGEM	
	11年11月1日1日1日1日日日日日日日日日日日日日日日日日日日日日日日日日日	ISO25841-2017,
	e. Condoma	WHOUNAIDS2012,Schedule
	Tights-elence devices	R, ISO11737-1, IP 2018,
	Spinore desente	USP42
	The Country of the Co	10. Catheters (Sterility, Bioburden
		and BET as per ISO 11737-1
	solution of the solution of	
		and 2, USP 42, EP 9.0, IP
	CHARLE CHESCHOLD	2018, BP 2018) - Class B
	ESSENTIAL SELECTOR DE LA CONTRACTOR DE L	11. Catheters (Sterility, Bioburden
	ELS DESTATEMENTS LOS	and BET as per ISO 11737-1
	0 8100 St 0 0 SH CE	and 2, USP 42, EP 9.0, IP
-	Charles and altern	2018, BP 2018) - Class C
		12. Disposable Hypodermic
	10 CT	
	THE THE WAY NOW A DOING	Needles (Sterility, Bioburden

and 2, USP 42, EP 9,0, IP 2018, BP 2018) - Class C 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 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 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) 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 17. Orthopaedic Implants ( (Sterility, Bioburden and BET as per ISO 11737-1 and 2, USP 42, EP 90, IP 2018, BP 2018) - Class C 17. Orthopaedic Implants ( (Sterility, Bioburden and BET as per ISO 11737-2, USP 42, EP 90, IP 2018, BP 2018) Class C 18. Cardiac Stents ( Sterility test as per ISO 11737-2, USP 42, EP 90, IP 2018, BP2018) Class C 19. Cardiac Stents ( Sterility test as per ISO 11737-2, USP 42, EP 90, IP 2018, BP2018) Class D 20. Contraceptives (CuT) (Mechanical parameters, Sterility, Bioburden as per WHO UNFPA 2016, ISO 7439, ISO 11737-1 and 2, IP 2018, USP 42, BP 9018, EP 90) 21. Disposable Hypodermic Syringes (Sterility and BET as per ISO 11737-2, USP 42, EP 90, IP 2018, BP 90)	and 2, USP 42, EP 9,0, IP 2018, BP 2018) - Class C 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 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 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) 16. Orthopaedic Implants (Sterility, Bioburden and BET as per ISO 11737-1 and 2, USP 42, EP 9.0, IP 2018, BP 2018) 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 17. Orthopaedic Implants ( (Sterility, Bioburden and BET as per ISO 11737-1 and 2, USP 42, EP 9.0, IP 2018, BP 2018) - Class C 19. Cardiac Stents ( Sterility test as per ISO 11737-2, USP 42, EP 9.0, IP 2018, BP 2018) - Class C 19. Cardiac Stents ( Sterility test as per ISO 11737-2, USP 42, EP 9.0, IP 2018, BP2018) - Class C 19. Cardiac Stents ( Sterility test as per ISO 11737-2, USP 42, EP 9.0, IP 2018, BP2018) - Class D 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) 12 Disposable Hypodermic Syringes (Sterility and BET as per ISO 11737-2, USP 42, EP 9.0, IP 2018, EF 9.0) 21 Disposable Hypodermic Syringes (Sterility and BET as per ISO 11737-2, USP 42, EP 9.0 117			100 1100
2018, BP 2018) - Class C 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 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 15. Intraocular Lenses (Sterility, Bioburden, BET and Pathogen identification as per ISO 11737-1 and 2, USP 42, EP 9.0, IP 2018, BP 2018) - Class C 15. Intraocular Lenses (Sterility, Bioburden, BET and Pathogen identification as per ISO 11737-1 - Part 1 and 2, USP 42, EP 9.0, IP 2018, BP 2018) 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 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 18. Cardiac Stents (Sterility test as per ISO 11737-2, USP 42, EP 9.0, IP 2018, BP2018) - Class C 19. Cardiac Stents (Sterility test as per ISO 11737-2, USP 42, EP 9.0, IP 2018, BP2018) - Class D 20. Contraceptives (CuT) (Mechanical parameters, Sterility, Bioburden as per WHO UNFPA 2016, ISO 7439, ISO 11737-1 and 2, IP 2018, USP 42, BP 9.0, IP 2018, EP 9.0, IP 2018, EP 9.0, IP 2018, EP 9.0, IP 2018, EP 9.0, IP 2018, USP 42, EP 9.0, IP 2018, EP 9.0, IP 20	2018, BP 2018) - Class C 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 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 215. 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) 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 17. Orthopaedic Implants (Sterility, Bioburden and BET as per ISO 11737-1 and 2, USP 42, EP 9.0, IP 2018, BP 2018) - Class C 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 18. Cardiac Stents ( Sterility test as per ISO 11737-2, USP 42, EP 9.0, IP 2018, BP2018) - Class C 219. Cardiac Stents ( Sterility test as per ISO 11737-2, USP 42, EP 9.0, IP 2018, BP2018) - Class D 20. Contraceptives (CuT) (Mechanical parameters, Sterility, Bioburden as per WHO UNIFPA 2016, ISO 7439, ISO 11737-1 and 2, IP 2018, USP 42, BP 2018, EP 9.0, 21. Disposable Hypodermic Syringes (Sterility and BET as per ISO 11737-2, USP 42, EP 9.0, IP 2018, BP 2018) - Class D 21. Disposable Hypodermic Syringes (Sterility and BET as per ISO 11737-2, USP 42, EP 9.0, IP 2018, BP 2018) - Class D		221	and BET as per ISO 11737-1
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  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  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) 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  17. Orthopaedic Implants ( (Sterility, Bioburden and BET as per ISO 11737-1 and 2, USP 42, EP 9.0, IP 2018, BP 2018) - Class C  18. Cardiac Stents (Sterility test as per ISO 11737-2, USP 42, EP 9.0, IP 2018, BP2018) Class C  19. Cardiac Stents (Sterility test as per ISO 11737-2, USP 42, EP 9.0, IP 2018, BP2018) Class D  20. Contraceptives (CuT) (Mechanical parameters, Sterility, Bioburden as per WHO UNFPA 2016, ISO 7439, ISO 11737-1 and 2, IP 2018, USP 42, BP 9.0, IP 2018, EP 9.0) 21. Disposable Hypodermic Syringes (Sterility, BP 2018) - Class per ISO 11737-2, USP 42, EP 9.0, IP 2018, BP 9.0)	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  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  15. Intraccular Lenses (Sterility, Bioburden, BET and Pathogen identification as per ISO 11737 - Part 1 and 2, USP 42, EP 9.0, IP 2018, BP 2018) 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  17. Orthopaedic Implants ( (Sterility, Bioburden and BET as per ISO 11737-1 and 2, USP 42, EP 9.0, IP 2018, BP 2018) - Class C  18. Cardiac Stents (Sterility test as per ISO 11737-2, USP 42, EP 9.0, IP 2018, BP2018) Class C  19. Cardiac Stents (Sterility test as per ISO 11737-2, USP 42, EP 9.0, IP 2018, BP2018) Class C  19. Cardiac Stents (Sterility test as per ISO 11737-2, USP 42, EP 9.0, IP 2018, BP2018) Class C  19. Cardiac Stents (Sterility test as per ISO 11737-2, USP 42, EP 9.0, IP 2018, BP2018) Class D  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) 21. Disposable Hypodermic Syringes (Sterility and BET as per ISO 11737-2, USP 42, EP 9.0, IP 2018, BP 2018) - Class B	910000000000000000000000000000000000000		
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Manual Ma		(Physical testing, Sterlity,		

-15 Et Like 1917 at Jakilanis	22. Catheters (Sterility, Bioburden
9 CE 99 CARSULLIAN	and BET as per ISO 11737-1
AND STREET STREET	and 2, USP 42, EP 9.0, IP
a le constitue de la constitue	2018, BP 2018) - Class D
Waste protect to the CT	23. Disposable Hypodermic
Pippurdenance Tuesday	Needles (Sterility, Bioburden
ISO 1435-Part A 15 90/A 3.	and BET as per ISO 11737-1
180 18974 and 2 USP 42	and 2, USP 42, EP 9.0, IP
- (8 P 9 to 19 20 to 2 P 20 8) -	2018, BP 2018) - Class B
Class 8	24. Disposable Perfusion sets
Tel Disposable Perfusion of Is	(Physical testing, Sterility,
to Unit's childed lepisyrigh	Bioburden and BET as per
and an TBB beeingmisdeliB	ISO 1135-Part 4, IS 9824-3,
190 1135 Plan 4 15 981 4-5	ISO 11737-1 and 2, USP 42,
150 1737-1 and 2, USP 42	EP 9.0, IP 2018, BP 2018) -
- (8102 98 B 2018) - (812 90 18) -	Class A
Classic	25. Disposable Perfusion sets
11 Intraocular Lensos (Stepulor	(Physical testing, Sterility,
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1 b Orthogaedic Implants (Steni	Class C
es at 138 bas nebaudol9	26. Intraocular Lenses (Sterility,
ISD 14737-1 and	Bioburden, BET and Pathogen
310 H 0 6 93 25 70U 5	identification as per ISO 11737
8F 2018 - Class C	- Part 1 and 2, USP 42, EP9.0,
I atmoorani olassoonino Thi	IP 2018, BP 2018)
28 the monudofff volher?	27. Internal Prosthetic
es per (SO 11 37-1 ar d 2	Replacements (Sterility test as
USP 42, EP 9.0, IP 20 8, B	per ISO 11737-2, USP 42,
2015) - Class D	EP 9.0, IP 2018, BP 2018)
18. Cardiac Stants / Stantily fee	28. Heart Valves (Sterility test as
as per ISO14737 2. AS P 42	per ISO 11737-2, USP 42, EP
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Class C	29. Surgical Sutures (Physical
9 9. Cardiao Stento y Stenley Isra	parameters, Sterility and BET
as per ISO 11/87-2, USP 4	as per ISO 11737-2, USP 42,
18 95 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9	EP 9.0, IP 2018, BP 2018) -
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8105 91 6 hast-1611 081 1	31. Contraceptives (Tubal
The Ask 42 Bb 2018 6F and	Ring)(Mechanical parameters
mscogyH sidsaggglQ	and Sterility as per IS 13009-
Sympas (Stanley and July	2000, ISO 11737-2, USP 42,
LA BUSTOTH OBLIGO	EP 9.0, IP2018, BP 2018)
10 - 10 0 18 2018 BP 2018 I - 0 1	32. Disposable Perfusion sets (Physical testing, Sterility,

A e doing	Scotting of the second of the		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  33. Internal Prosthetic Replacements (Sterility test as per ISO 11737-2, USP 42, EP 9.0, IP 2018, BP 2018)  34. IV Cannulae (Sterility, Bioburden, Pathogen identification as per ISO 11737-1 and 2, USP 42, EP 9.0, IP 2018, BP 2018)  35. Disposable Hypodermic Syringes (Sterility and BET as per ISO 11737-2, USP 42, EP9.0, IP 2018, BP 2018)
9		TL/MD/2020/000003	<ol> <li>Catheters – Class A</li> <li>Catheters (Excluding Biocompatibility testing) - Class B</li> <li>Catheters (Excluding Biocompatibility testing) - Class C</li> <li>Disposable Perfusion Sets (Excluding Biocompatibility testing) - Class C</li> <li>Disposable Hypodermic Needles (Excluding Biocompatibility testing) - Class C</li> <li>Disposable Hypodermic Needles (Excluding Biocompatibility testing) - Class D</li> <li>Disposable Hypodermic Syringes - Class A</li> <li>Disposable Hypodermic Syringes (Excluding Biocompatibility testing) - Class B</li> <li>Disposable Hypodermic Syringes (Excluding Biocompatibility testing) - Class C</li> <li>Disposable Hypodermic Syringes (Excluding Biocompatibility testing) - Class D</li> <li>I.V. Cannulae - Class A</li> <li>I.V. Cannulae (Excluding Biocompatibility testing) - Class B</li> <li>I.V. Cannulae (Excluding Biocompatibility testing) - Class C</li> <li>I.V. Cannulae (Excluding Biocompatibility testing) - Class C</li> <li>I.V. Cannulae (Excluding Biocompatibility testing) - Class C</li> <li>I.V. Cannulae (Excluding Biocompatibility testing) - Class D</li> <li>Scalp Vein Set - Class A</li> </ol>

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CACRO OL LING TON COL		Biocompatibility testing) -
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internal Prostretto		Class C
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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	<ol> <li>Catheters (Test as per IS/ISO 10555) - Class A</li> <li>Disinfectants (As per IP, BP, USP) - Class B</li> <li>Disposable Hypodermic Needles (Test as per IS 10654) - Class B</li> <li>Disposable Perfusion Sets (Test as per IS 12655) - Class A</li> <li>Disposable Perfusion Sets (Test as per IS 12655) - Class B</li> <li>Catheters (Test as per IS/ISO 10555) - Class B</li> <li>I.V. Cannulae (Test as per IS/ISO 10555) - Class B</li> <li>Disposable Hypodermic Syringes (Test as per IS10258) - Class B</li> <li>Scalp vein set (Test as per IS 16097) - Class B</li> <li>Surgical Dressings (Cotton and Gauze, Bandage)-Class B</li> <li>Surgical Dressings (Cotton and Gauze, Bandage)-Class A</li> </ol>
	ITL LABS PVT LTD B-283-284, Mangolpuri Industrial Area, Phase I, North West Delhi, Delhi - 110083	TL/MD/2021/000001	<ol> <li>Catheters (Excluding Biocompatibility testing) Class D</li> <li>Surgical Dressings (Excluding Biocompatibility testing) Class D</li> <li>Disposable Hypodermic Syringes Class D</li> <li>Disposable Hypodermic Syringes (Excluding Biocompatibility testing) Class D</li> <li>Surgical Dressings Class D</li> <li>Disposable Hypodermic Needles (Excluding Biocompatibility testing) Class C</li> <li>Contraceptives Class D</li> <li>I.V. Cannulae (Excluding Biocompatibility testing) Class C</li> <li>Surgical Dressings (Excluding Biocompatibility testing) Class D</li> <li>Scalp Vein Set (Excluding Biocompatibility testing) Class B</li> <li>Disposable Hypodermic Needles Class C</li> <li>I.V. Cannulae Class C</li> <li>I.V. Cannulae (Excluding Biocompatibility testing) Class C</li> <li>I.V. Cannulae (Excluding Biocompatibility testing) Class C</li> <li>I.V. Cannulae (Excluding Biocompatibility testing) Class C</li> <li>Scalp Vein Set Class B</li> <li>Contraceptives (Excluding</li> </ol>

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	G Schild - F161		10.	Disposable Perfusion Sets	
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125GU	ci 180 28 1861) 861560/			testing) Class C	
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	orre emoguiki aldezanari			compatibility testing) Class D	
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	Si section			Urine collecting bag Class B	
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	C 4-40 Mile Individual		25.	Sterile) Class D	
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	constitues and registro	V15		Endotracheal (ET) tube Class B	
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fici	Surgical Breasings (Co.			Syringes Class C	
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				Double Blood Bag, Triple	
10	Catheters (Exclusing 6	AMD/2021/000001 II		Blood Bag, Quad Blood Bag)	
II een	Ocmpatibility testing) C		10	Class C	
gnibula	Surgices Dressmos (Exc		29.	Disinfectant (Excluding Bio-	
Perio	Signature and American			compatibility testing)	
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12	Accuprec Research	TL/MD/2021/000002	1.	Vascular devices and IV sets;	
12	Labs Private Limited	TENNIS/202 I/ 00 00 0		Class D	
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13	M/s, Conformity Testing Labs Pvt Ltd WH-52, Mayapuri Industrial Area, Phase 1, New Delhi, West Delhi, Delhi - 110064	TL/MD/2021/000003	1.NIBP; Class B 2.IBP; Class C 3.Nebulizer; Class C 4.Thermometer; Class B 5.Glucometer; Class B
14	Brothers Laboratories Pvt. Ltd 103, D-3, Industrial Area Jhotwara, Jaipur, Rajasthan - 302012	TL/MD/2021/000004	1. Disposable Hypodermic Needles; Class B 2. Surgical Dressings; Class A 3. Disposable perfusion set; Class B 4. Catheters; Class B 5. Surgical Dressings; Class B 6. Disinfectants; Class B 7. Disposable Hypodermic Syringe; Class B 8. IV Canulae; Class B 9. Scalp Vein Set; Class B

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

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