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: 81312021

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
	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	 Copper -T Condoms Sterile Hypodermic Needles Tubal Rings Hypodermic Syringes 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	 Bilirubin (Total and Direct) Test Reagents / Kits Creatinine test reagent / kit Aspartate Amino Transferase (AST / SGOT) test Alanine Amino Transferase (ALT/SGPT) test Uric Acid Test reagents / kits Total Protein test reagents / kits Activated partial thromboplastin time (APTT) test 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	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	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	 Cardiovascular devices (Biological evaluation as per ISO 10993) Orthopaedic devices (Biological evaluation as per ISO 10993) Ocular devices (Biological evaluation as per ISO 10993) Surgical devices and sutures (Biological evaluation as per ISO 10993) Respiratory devices (Biological evaluation as per ISO 10993) Gastrointestinal devices (Biological evaluation as per ISO 10993) Urological devices (Biological evaluation as per ISO 10993) Haematological devices and IV sets (Biological evaluation as per ISO 10993) Dental devices (Biological evaluation as per ISO 10993) Personal care products and family planning (Biological evaluation as per ISO 10993) Neurological devices (Biological evaluation as per ISO 10993) 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	 Catheters (Biological Toxicity) Disposable Hypodermic needles (Biological Toxicity) Surgical dressings (Biological Toxicity) Orthopaedic Implants (Biological Toxicity) Blood Bags (Biological Toxicity) Brug eluting stent (Biological Toxicity) Intra Ocular Lenses (Biological Toxicity) Sutures (Biological Toxicity) Condoms (Biological Toxicity) Heart Valves (Biological Toxicity) Disposable perfusion sets (Biological Toxicity) Cardiac stent (Biological Toxicity) Copper- T (Biological Toxicity) Scalp Vein Set (Biological Toxicity) 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	 Disposable Perfusion Sets Cardiac Stents Drug Eluting Stents Blood Bags Catheters (Class D) Catheters (Class B) Catheters (Class C) Heart valves Intra Ocular Lenses I.V. Cannula Bone Cements Internal Prosthetic Replacements Peritoneal dialysis sets Condoms Intra-uterine devices Surgical dressing Scalp Vein Set Ligatures and sutures
8	M/s, TRUSTIN ANALYTICAL SOLUTIONS PRIVATE LIMITED Address: Plot no- 303/b, Block-B, RK Complex, 1st	TL/MD/2020/000002	 Disinfectant (Sterility and Antimicrobial activities as per ISO 11737-1 and 2, USP 42, EP 9.0, IP 2018, BP 2018) Catheters (Sterility, Bioburden and BET as per ISO 11737-1 and 2, USP 42, EP 9.0, IP

	Floor, Thiruneermalai		2018, BP 2018) - Class A
	road, Parvathy puram, Chrompet, ,	3.	Surgical Sutures (Physical parameters, Sterility and BET
	Chennai,	8	as per ISO 11737-2, USP
	Kanchipuram, Tamil		42, EP 9.0, IP 2018, BP 2018)
	Nadu - 600044	8	- Class B
	Nadu - 600044	4	. Surgical Dressings (Sterility ,
	Intro Ocular Lenses (8)		Bioburden, BET as per IS 758,
	Tordotty)		IS 1954, ISO 11737-1and 2, IP
	Sutures (Storagical Toxis	5	2018, USP 42, BP 2018 and
	Condoms (Biological T	9	EN9.0) - Class A
	Hospital savisy haek	5	5. Surgical Dressings (Sterility ,
	TOXICITY - CATCHER		Bioburden, BET as per IS 758,
	e noieuhso skissoosiid .		IS 1954, ISO 11737-1and 2, IP
	(viroko T isolnotosit)		2018, USP 42, BP 2018 and
	Cardiac stort (Biorogica		EN9.0) - Class B
	(Vilotoro T		S. Surgical Dressings (Sterility,
	Copped T (Biological	C	Bioburden, BET as per IS 758,
	scielly red niev gless a		IS 1954, ISO 11737-1and 2, IP
	Tours of T		2018, USP 42, BP 2018 and
			EN9.0) - Class C
	Disposable Perfusion I	r I topografience diene -	7. Surgical Dressings (Sterility,
	Cardiac Stenta	,	Bioburden, BET as per IS 758,
	Once Eleting Stents		IS 1954, ISO 11737-1and 2, IP
	anas modis		2018, USP 42, BP 2018 and
	Castetes (Class D)		EN9.0) - Class D
	Catherine (Class B)		8. Blood bags with and without
	Caldesters (Class C) •		anticoagulant solutions
	cavley meets		(Mechanical, Sterility and BET
	Intra Onder Lenses		as per ISO 3826, IS 15102,
	elunnati VII o		ISO 11737-2, USP42, EP 9.0,
	1. Boné Cements		IP 2018, BP 2018)
	2. Internal Prosthetic		9. Contraceptives (Condoms -
	Replacements		Male/Female Condoms)
	a Pentoneal distraction E		(Mechanical parameters,
	4 Condoms		Bioburden and Pathogens as
	recively somety-extra 3		per ISO 4074-2015,
	anisati skotom 2. 8		WHOUNAIDS2010,
	Fig. State Violet Set		ISO25841-2017,
	B Ugahinea and sutured		WHOUNAIDS2012,Schedule
		,	R, ISO11737-1, IP 2018,
-	Distriction (Sterring)	TUNBERGEORGE	USP42
1 3	Artimicrobial activities		10. Catheters (Sterility, Bioburden
. 0	150 11737-1 and 2 US		and BET as per ISO 11737-1
	42 67 8 9 10 30 13 45		and 2, USP 42, EP 9.0, IP
huc	Cathuren Spenits Biol		2018, BP 2018) - Class B
	and BITT as per ISO 11		11. Catheters (Sterility, Bioburden
91	end 2 USP 42 EP 90.		and BET as per ISO 11737-1
			and 2, USP 42, EP 9.0, IP
		DE la Cosas	2018, BP 2018) - Class C
			12. Disposable Hypodermic
1			Needles (Sterility, Bioburden

and BET as per ISO 11737-1 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 9.0, IP 2018, BP 2018) - Class D 18. Cardiac Stents (Sterility test as per ISO11737-2, 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 11737-1and 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

22. Catheters (Sterility, Bioburden and BET as per ISO 11737-1 and 2, USP 42, EP 9.0, IP 2018, BP 2018) - Class D 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 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 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
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) 27. Internal Prosthetic
Replacements (Sterility test as per ISO 11737-2, USP 42, EP 9.0, IP 2018, BP 2018)
28. Heart Valves (Sterility test as per ISO 11737-2, USP 42, EP 9.0, IP 2018, BP 2018)
29. Surgical Sutures (Physical parameters, Sterility and BET as per ISO 11737-2, USP 42, EP 9.0, IP 2018, BP 2018) - Class A
30. Surgical Sutures (Physical parameters, Sterility and BET as per ISO 11737-2, USP 42, EP 9.0, IP 2018, BP 2018) - Class C
31. Contraceptives (Tubal Ring)(Mechanical parameters and Sterility as per IS 13009-2000, ISO 11737-2, USP 42,
EP 9.0, IP2018, BP 2018) 32. Disposable Perfusion sets (Physical testing, Sterility,

er on	Scalp Vein Set (Exclud Secompatibility testing Sear Vein Set (Exclud Secompatibility testing Scalp vein Set (Exclud Scalp vein Set (Exclud Sear Vein Set (Exclud Class Dessings - Class Dessings (Exclud Surgical Dressings (Excludes Biocompatibility testing Surgical Dressings (Excludes Biocompatibility testing Surgical Dressings (Excludes Biocompatibility testing Excludes Biocompatibility testing		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 11737-1and 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	M/s, Devansh Testing & Research Laboratory Pvt. Ltd. Address: RZ-21A/331, Madanpuri, Gali No 10, West Sagar Pur, Delhi, West Delhi, Delhi - 110046	TL/MD/2020/0000003	 Catheters – Class A Catheters (Excluding Biocompatibility testing) - Class B Catheters (Excluding Biocompatibility testing)- Class C Disposable Perfusion Sets (Excluding Biocompatibility testing) - Class C Disposable Hypodermic Needles (Excluding Biocompatibility testing) - Class C Disposable Hypodermic Needles (Excluding Biocompatibility testing) - Class D Disposable Hypodermic Syringes - Class A Disposable Hypodermic Syringes (Excluding Biocompatibility testing) - Class B Disposable Hypodermic Syringes (Excluding Biocompatibility testing) - Class C Disposable Hypodermic Syringes (Excluding Biocompatibility testing) - Class D I.V. Cannulae - Class A I.V. Cannulae (Excluding Biocompatibility testing) - Class B I.V. Cannulae (Excluding Biocompatibility testing) - Class C I.V. Cannulae (Excluding Biocompatibility testing) - Class C I.V. Cannulae (Excluding Biocompatibility testing) - Class C I.V. Cannulae (Excluding Biocompatibility testing) - Class D Scalp Vein Set - Class A

Hattis He faithful all fine Hat		
Class D		16. Scalp Vein Set (Excluding
Sinkernal Prestinglic		Biocompatibility testing) -
Seningements (Statistics)		Class B
S PRODUCTOTOR SOLVE		17. Scalp Vein Set (Excluding
COLOR GO CLASS SHEET		
101112 40 21 02 41 03		Biocompatibility testing) -
Models) escures Ard		Class C
distantes, Painogen		18. Scalp Vein Set (Excluding
idensification as ner 130		Biocompatibility testing) -
1173R-fand 2, USP 42 EP		Class D
9 0 iP 2018 - 8P 2018		19. Surgical Dressings - Class A
a management and a second	pl l	20. Surgical Dressings (Excluding
A 1215 THE ARTERS CONTRACT		Biocompatibility testing) -
LA TOUR STREET VOLUME		Class B
EP900, IP 2016, BP 2018)		21. Surgical Dressings (Excluding
		Biocompatibility testing) -
Cathalan - Class A	IN ECCOCOCIOSACIMA	Class C
California (Evoluting Pin-	2	22. Surgical Dressings (Excluding
positive constant to the constant		Biocompatibility testing) -
	3	
rui s in uuocika) a (araalko		Class D
Countries Administration		23. Contraceptives - Class A
etalino.nune i etascoga:C	100	24. Contraceptives (Excluding
villating Biocompatibility		Biocompatibility testing) -
testing) - Class C		Class B
Deposition of the property of the content of the co		25. Contraceptives (Excluding
and remains in settings.		Biocompatibility testing) -
Sauth Control of Statement		
seed of the passing o		Class C
- Smeddayy eldwidday		26. Contraceptives (Excluding
Headles (Excinging pays		Biocompatibility testing) -
competibility testing) - Class		Class D
Disposable Hypodermic	N	27. Disinfectant - Class A
Sydnage - Class A		28. Catheters (Excluding Bio-
Disposable Hypogramic	8	compatibility testing) - Class D
Syranges (Europalised II o-		29. Disposable Hypodermic
specific desired of leavening		Needles - Class A
A March and A March and Co.		
Service of the service of		30. Disposable Hypodermic
-old Buildings sabinite		Needles (Excluding Bio-
SERVICE (DURBIE AMERICA)		compatibility testing) - Class B
Disposoble Pagedennie		31. Disinfectant (Excluding Bio-
S (all hands) Aspanya		compatibility testing) - Class B
competitivity testing) - Class		32 Disinfectant (Excluding Bio-
. V. Cannulae - Class A.	,	compatibility testing) - Class C
1 V. Cannulae (Eveluding Str.	dr.	33. Disinfectant (Excluding Bio-
esciff confest with tenner		compatibility testing) - Class D
ASI no le des St. selvane O. W.I.		34. Disposable Perfusion Sets -
Ale Burenant seminerary An		
Deleta - Ocultana Anno Andri da		Class A
des un oraxes, selumber, v.i		35. Disposable Perfusion Sets
Participant of the Company of the Co		(Excluding Biocompatibility
Scalp Veln Set - Class A		testing) - Class B
		36. Disposable Perfusion Sets
	Case 7 of 10	(Excluding Biocompatibility
		testing)

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

Characteristic and a state of the state of t	12.I.V. Cannulae - Class C
this of El sec as teath selbooks	13.I.V. Cannulae (Excluding Bio-
S age!	13.1.V. Carmulae (Excluding Bio
TANK SIND ASSOCIATION OF THE PARTY OF THE PA	compatibility testing) – Class C
Service Commence of the	14. Scalp Vein Set – Class B
10 10 10 10 10 10 10 10 10 10 10 10 10 1	15. Contraceptives (Excluding
Call Bac Hashing Bidesons II c	Biocompatibility testing) Class
G 46849 - 100071 01 184 49 -	D
Dicharted as 1881) assertia July	16. Catheters – Class D
8 8860 - (3660)	17. Disinfectant – Class B
se as leaf) esumed v.i. C	18. Disposable Perfusion Sets
S apailo - fedeet oether	(Excluding Biocompatibility
Simmiscophi plassoga (1. G	testing) – Class C
- Sydnges (Test as ports (1258))	19. Disinfectant (Excluding Bio-
- Class B	compatibility testing) - Class B
- If Sould voin set (Tost as per IS	20. Disposable Perfusion Sets –
COST) - Class B	Class C
no Surgical Dressings (Coffon	21. Disposable Perfusion Sets
and Gaute Bandage)-Classif	(Excluding Biocompatibility
11 Surgicel Dressings (Collon-	testing) – Class C
and Cause Bandage) Class	
	22. Disposable Hypodermic
All makes with a single of a single	Needles (Excluding Bio-
77 real? notified unfullmaneau	compatibility testing) – Class D
Complete Strates American Complete Comp	23. Surgical Suture – Class D
RECOUNTY CONTRACTOR INCIDENCE Y	24. Urine collecting bag – Class B
Elemen Augus durabore	25. Surgical Gloves (Sterile/Non
10 86910	Sterile) - Class D
a Disposable Hypopolinio	26. Endotracheal (ET) tube Class
Syringes Class D .	B - Bled interest Deliver
4. Disposable hypodermic	27. Disposable Hypodermic
Syringes	Syringes – Class C
Affiditsemes-pid pribator 3)	28. Blood Bag (Single Boold
testing)- Class D	Bag, Double Boold Bag, Triple
5 Surgical Dressings - Class D	Boold Bag.,Quad Blood Bag) -
Berosable Hypoderma	Class C
Needles (Excluding Se-	29. Disinfectant (Excluding Bio-
compatibility (suno) - Class	compatibility testing) – Class B
3	Compatibility teeting) Glace 2

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

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