## FORM MD-40

[See sub-rule (3) of rule 83]

## Certificate of registration to Medical Device Testing Laboratory for carry out Test or Evalution of a medical device on behalf of manufacturer

Registration No.: TL/MD/2025/000007

- 1. M/s, **MDR Laboratories Private Limited** situated at **No, 444 Gokulam Street, Mathur, Manali, , Ambattur, Tiruvallur, Tamil Nadu 600068** has been registered as a Medical Device Testing Laboratory for carry out Test or Evalution of medical device on behalf of manufacturer under the Medical Devices Rules, 2017.
- 2. Details of medical device(s) to be tested or evaluated.

S.No.	Generic name	Class of medical devices
1	External prostheses, Fixation tapes, Bandages (Biocompatibility as per ISO 10993-Parts 5,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)	Class A
2	Surgical gloves, Occlusive patches for ulcers (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)	Class B
3	Equipment covers, Probe covers, Bed cover, Fabrics (Biocompatibility as per ISO 10993-Parts 5,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)	Class A
4	Diagnostic kit/Devices, Examination devices (Biocompatibility as per ISO 10993-Parts 5,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)	Class A
5	Skin care devices, Electrodes (Biocompatibility as per ISO 10993-Parts 5,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)	Class A
6	Wound dressing or healing devices, Stimulator (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)	Class B
7	Wound care gels-cream-powders (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)	Class B

8	Surgical gowns, Gloves, Drapes, Wipes,	Class A
	Cream (Biocompatibility as per ISO 10993-	
	Parts 5,10,11,23, USP-87,88 and Chemical	
	Characterization as per ISO 10993-Part 18,	
	SOP ANA-011, ANA-012, ANA-013)	
9	Biological sample collection bag and	Class B
	container (Biocompatibility as per ISO	
	10993-Parts 3,5,6,10,11,23, USP-87,88 and	
	Chemical Characterization as per ISO	
	10993-Part 18, SOP ANA-011, ANA-012,	
	ANA-013)	
10	Extension sets, Transfer sets	Class B
	(Biocompatibility as per ISO 10993-Parts	
	3,4,5,6,10,11,23, USP-87,88, ASTM-F756	
	and Chemical Characterization as per ISO	
	10993-Part 18, SOP ANA-011, ANA-012,	
	ANA-013)	
11	Ophthalmic solutions, Contact lens	Class B
	solutions (Biocompatibility as per ISO	5.005
	10993-Parts 3,5,6,10,11,23,USP-87,88,151	
	and Chemical Characterization as per ISO	
	10993-Part 18,SOP ANA-011,ANA-012,	
	ANA-013)	
12	GGloves, Probe covers (Biocompatibility as	Class B
'-	per ISO 10993-Parts 3,5,6,10,11,23, USP-	Οίασο Β
	87,88,151 and Chemical Characterization	
		0.
	as per ISO 10993-Part 18, SOP ANA-011,	P
10	ANA-012, ANA-013)	Olasa D
13	Ocular devices, Surgical implements	Class B
	(Biocompatibility as per ISO 10993-Parts3,	5
	4,5,6,10,11,23,USP-87,88,151,ASTM-F756	4
	and Chemical Characterization as per ISO	0
	10993-Part18,SOP ANA-011,ANA-012,ANA-	7
	013)	
14	Dental resin, Dental filling materials	Class C
	(Biocompatibility as per ISO 10993-Parts	
	3,5,6,10,11,23, USP-87,88,151 and	7
	Chemical Characterization as per ISO	
	10993-Part 18, SOP ANA-011, ANA-012,	No.
	ANA-013)	4
15	Dental products, Dental implants	Class C
	(Biocompatibility as per ISO 10993-Parts	2
	3,5,6,10,11,23, USP-87,88,151 and	No. ""
	Chemical Characterization as per ISO	
	10993-Part 18, SOP ANA-011, ANA-012,	
	ANA-013)	
16	Internal drug delivery catheters	Class C
	(Biocompatibility as per ISO 10993-Parts	
	3,5,6,10,11,23,USP-87,88,151,ASTM-F756	
	and Chemical Characterization as per ISO	
	10993-Part 18,SOP ANA-011,ANA-012,	
	ANA-013)	
17	Packaging materials, Collagen	Class C
	(Biocompatibility as per ISO 10993-Parts	
	3,5,6,10,11,23,USP-87,88,151,ASTM-F756	
	and Chemical Characterization as per ISO	
	10993-Part 18,SOP ANA-011,ANA-012,	
	ANA-013)	
18	Polymers like nylon, Polystyrene	Class C
	(Biocompatibility as per ISO 10993-Parts	
	3,5,6,10,11,23,USP-87,88,151,ASTM-F756	
	and Chemical Characterization as per ISO	
1		
1	1 10993-Part 18,50P ANA-011.ANA-012.	
	10993-Part 18,SOP ANA-011,ANA-012, ANA-013)	

19		
	Polyethylene (linear), Polypropylene	Class C
	(Biocompatibility as per ISO 10993-Parts	
	3,5,6,10,11,23,USP-87,88,151,ASTM-F756	
	and Chemical Characterization as per ISO	
	10993-Part 18,SOP ANA-011,ANA-012,	
	ANA-013)	
20	Replacement joints, Bone prostheses	Class D
20		Class D
	(Biocompatibility as per ISO 10993-Parts	
	3,5,6,10,11,23,USP-87,88,151 and	
	Chemical Characterization as per ISO	
	10993-Part 18,SOP ANA-011,ANA-012,	
	ANA-013)	
21	Pacemakers, Artificial larynxes	Class D
	(Biocompatibility as per ISO 10993-Parts	
	3,5,6,10,11,23,USP-87,88,151 and	
	Chemical Characterization as per ISO	
	10993-Part 18,SOP ANA-011,ANA-012,	
	ANA-013)	
22	Dental implants (Biocompatibility as per	Class D
	ISO 10993-Parts 3,5,6,10,11,23,USP-	
1		
I	87,88,151 and Chemical Characterization	
I	as per ISO 10993-Part 18,SOP ANA-011,	
1	ANA-012,ANA-013)	
23	Pacemaker electrodes, Dialysers	Class C
23		Jiass U
I	(Biocompatibility as per ISO 10993-Parts	
	3,5,6,10,11,23, USP-87,88,151, ASTM-F756	
	and Chemical Characterization as per ISO	00
	10993-Part 18,SOP ANA-011,ANA-012,	70
		T.
- 04	ANA-013)	Olean O
24	Extracorporeal devices and accessories	Class C
	(Biocompatibility as per ISO 10993-Parts3,	7
	5,6,10,11,23,USP-87,88,151,ASTM-F756	
	and Chemical Characterization as per ISO	0
	10993-Part18,SOP ANA-011,ANA-012,ANA-	_
	013)	OL B
25	Surgical implements (Biocompatibility as	Class B
1 2		
25	per ISO 10993-Parts 3,5,6,10,11,23, USP-	_
25		X
	87,88 and Chemical Characterization as	VIQ
20	87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011,	NOIA
	87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)	WOW Starts
26	87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Solution administration sets	Class B
	87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Solution administration sets (Biocompatibility as per ISO 10993-Parts	Class B
	87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Solution administration sets (Biocompatibility as per ISO 10993-Parts	Class B
	87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Solution administration sets (Biocompatibility as per ISO 10993-Parts 3,4,5,6,10,11,23, USP-87,88, ASTM-F756	Class B
	87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Solution administration sets (Biocompatibility as per ISO 10993-Parts 3,4,5,6,10,11,23, USP-87,88, ASTM-F756 and Chemical Characterization as per ISO	Class B
	87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Solution administration sets (Biocompatibility as per ISO 10993-Parts 3,4,5,6,10,11,23, USP-87,88, ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012,	Class B
26	87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Solution administration sets (Biocompatibility as per ISO 10993-Parts 3,4,5,6,10,11,23, USP-87,88, ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)	
	87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Solution administration sets (Biocompatibility as per ISO 10993-Parts 3,4,5,6,10,11,23, USP-87,88, ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Adhesives and monitors of various types,	Class B
26	87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Solution administration sets (Biocompatibility as per ISO 10993-Parts 3,4,5,6,10,11,23, USP-87,88, ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)	
26	87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Solution administration sets (Biocompatibility as per ISO 10993-Parts 3,4,5,6,10,11,23, USP-87,88, ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Adhesives and monitors of various types, Mattress (Biocompatibility as per ISO	
26	87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Solution administration sets (Biocompatibility as per ISO 10993-Parts 3,4,5,6,10,11,23, USP-87,88, ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Adhesives and monitors of various types, Mattress (Biocompatibility as per ISO 10993-Parts 5,10,11,23, USP-87,88 and	
26	87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Solution administration sets (Biocompatibility as per ISO 10993-Parts 3,4,5,6,10,11,23, USP-87,88, ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Adhesives and monitors of various types, Mattress (Biocompatibility as per ISO 10993-Parts 5,10,11,23, USP-87,88 and Chemical Characterization as per ISO	
26	87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Solution administration sets (Biocompatibility as per ISO 10993-Parts 3,4,5,6,10,11,23, USP-87,88, ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Adhesives and monitors of various types, Mattress (Biocompatibility as per ISO 10993-Parts 5,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012,	
26	87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Solution administration sets (Biocompatibility as per ISO 10993-Parts 3,4,5,6,10,11,23, USP-87,88, ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Adhesives and monitors of various types, Mattress (Biocompatibility as per ISO 10993-Parts 5,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)	Class A
26	87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Solution administration sets (Biocompatibility as per ISO 10993-Parts 3,4,5,6,10,11,23, USP-87,88, ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Adhesives and monitors of various types, Mattress (Biocompatibility as per ISO 10993-Parts 5,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012,	
26	87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Solution administration sets (Biocompatibility as per ISO 10993-Parts 3,4,5,6,10,11,23, USP-87,88, ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Adhesives and monitors of various types, Mattress (Biocompatibility as per ISO 10993-Parts 5,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Monitoring devices, Transdermal patch,	Class A
26	87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Solution administration sets (Biocompatibility as per ISO 10993-Parts 3,4,5,6,10,11,23, USP-87,88, ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Adhesives and monitors of various types, Mattress (Biocompatibility as per ISO 10993-Parts 5,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Monitoring devices, Transdermal patch, Gel (Biocompatibility as per ISO 10993-	Class A
26	87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Solution administration sets (Biocompatibility as per ISO 10993-Parts 3,4,5,6,10,11,23, USP-87,88, ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Adhesives and monitors of various types, Mattress (Biocompatibility as per ISO 10993-Parts 5,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Monitoring devices, Transdermal patch, Gel (Biocompatibility as per ISO 10993-Parts 5,10,11,23, USP-87,88 and Chemical	Class A
26	87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Solution administration sets (Biocompatibility as per ISO 10993-Parts 3,4,5,6,10,11,23, USP-87,88, ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Adhesives and monitors of various types, Mattress (Biocompatibility as per ISO 10993-Parts 5,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Monitoring devices, Transdermal patch, Gel (Biocompatibility as per ISO 10993-Parts 5,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Parts 5,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Part 18,	Class A
26	87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Solution administration sets (Biocompatibility as per ISO 10993-Parts 3,4,5,6,10,11,23, USP-87,88, ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Adhesives and monitors of various types, Mattress (Biocompatibility as per ISO 10993-Parts 5,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Monitoring devices, Transdermal patch, Gel (Biocompatibility as per ISO 10993-Parts 5,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Parts 5,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)	Class A Class A
26	87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Solution administration sets (Biocompatibility as per ISO 10993-Parts 3,4,5,6,10,11,23, USP-87,88, ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Adhesives and monitors of various types, Mattress (Biocompatibility as per ISO 10993-Parts 5,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Monitoring devices, Transdermal patch, Gel (Biocompatibility as per ISO 10993-Parts 5,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Parts 5,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Part 18,	Class A
26	87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Solution administration sets (Biocompatibility as per ISO 10993-Parts 3,4,5,6,10,11,23, USP-87,88, ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Adhesives and monitors of various types, Mattress (Biocompatibility as per ISO 10993-Parts 5,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Monitoring devices, Transdermal patch, Gel (Biocompatibility as per ISO 10993-Parts 5,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Sensor, Personal protective equipment,	Class A Class A
26	87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Solution administration sets (Biocompatibility as per ISO 10993-Parts 3,4,5,6,10,11,23, USP-87,88, ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Adhesives and monitors of various types, Mattress (Biocompatibility as per ISO 10993-Parts 5,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Monitoring devices, Transdermal patch, Gel (Biocompatibility as per ISO 10993-Parts 5,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Sensor, Personal protective equipment, Masks (Biocompatibility as per ISO 10993-	Class A Class A
26	87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Solution administration sets (Biocompatibility as per ISO 10993-Parts 3,4,5,6,10,11,23, USP-87,88, ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Adhesives and monitors of various types, Mattress (Biocompatibility as per ISO 10993-Parts 5,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Monitoring devices, Transdermal patch, Gel (Biocompatibility as per ISO 10993-Parts 5,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Sensor, Personal protective equipment, Masks (Biocompatibility as per ISO 10993-Parts 5,10,11,23, USP-87,88 and Chemical	Class A Class A
26	87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Solution administration sets (Biocompatibility as per ISO 10993-Parts 3,4,5,6,10,11,23, USP-87,88, ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Adhesives and monitors of various types, Mattress (Biocompatibility as per ISO 10993-Parts 5,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Monitoring devices, Transdermal patch, Gel (Biocompatibility as per ISO 10993-Part 5,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Sensor, Personal protective equipment, Masks (Biocompatibility as per ISO 10993-Parts 5,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Parts 5,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Part 18,	Class A Class A
26 27 28 29	87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Solution administration sets (Biocompatibility as per ISO 10993-Parts 3,4,5,6,10,11,23, USP-87,88, ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Adhesives and monitors of various types, Mattress (Biocompatibility as per ISO 10993-Parts 5,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Monitoring devices, Transdermal patch, Gel (Biocompatibility as per ISO 10993-Parts 5,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Sensor, Personal protective equipment, Masks (Biocompatibility as per ISO 10993-Parts 5,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)	Class A  Class A
26	87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Solution administration sets (Biocompatibility as per ISO 10993-Parts 3,4,5,6,10,11,23, USP-87,88, ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Adhesives and monitors of various types, Mattress (Biocompatibility as per ISO 10993-Parts 5,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Monitoring devices, Transdermal patch, Gel (Biocompatibility as per ISO 10993-Parts 5,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Sensor, Personal protective equipment, Masks (Biocompatibility as per ISO 10993-Parts 5,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Parts 5,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Skin contacting devices, non-invasive	Class A Class A
26 27 28 29	87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Solution administration sets (Biocompatibility as per ISO 10993-Parts 3,4,5,6,10,11,23, USP-87,88, ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Adhesives and monitors of various types, Mattress (Biocompatibility as per ISO 10993-Parts 5,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Monitoring devices, Transdermal patch, Gel (Biocompatibility as per ISO 10993-Parts 5,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Sensor, Personal protective equipment, Masks (Biocompatibility as per ISO 10993-Parts 5,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Parts 5,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Skin contacting devices, non-invasive	Class A  Class A
26 27 28 29	87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Solution administration sets (Biocompatibility as per ISO 10993-Parts 3,4,5,6,10,11,23, USP-87,88, ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Adhesives and monitors of various types, Mattress (Biocompatibility as per ISO 10993-Parts 5,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Monitoring devices, Transdermal patch, Gel (Biocompatibility as per ISO 10993-Parts 5,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Sensor, Personal protective equipment, Masks (Biocompatibility as per ISO 10993-Parts 5,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Skin contacting devices, non-invasive electrodes (Biocompatibility as per ISO	Class A  Class A
26 27 28 29	87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Solution administration sets (Biocompatibility as per ISO 10993-Parts 3,4,5,6,10,11,23, USP-87,88, ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Adhesives and monitors of various types, Mattress (Biocompatibility as per ISO 10993-Parts 5,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Monitoring devices, Transdermal patch, Gel (Biocompatibility as per ISO 10993-Parts 5,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Sensor, Personal protective equipment, Masks (Biocompatibility as per ISO 10993-Parts 5,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Skin contacting devices, non-invasive electrodes (Biocompatibility as per ISO 10993-Parts 5,10,11,23, USP-87,88 and	Class A  Class A
26 27 28 29	87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Solution administration sets (Biocompatibility as per ISO 10993-Parts 3,4,5,6,10,11,23, USP-87,88, ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Adhesives and monitors of various types, Mattress (Biocompatibility as per ISO 10993-Parts 5,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Monitoring devices, Transdermal patch, Gel (Biocompatibility as per ISO 10993-Parts 5,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Sensor, Personal protective equipment, Masks (Biocompatibility as per ISO 10993-Parts 5,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Skin contacting devices, non-invasive electrodes (Biocompatibility as per ISO 10993-Parts 5,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Parts 5,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Parts 5,10,11,23, USP-87,88 and Chemical Characterization as per ISO	Class A  Class A
26 27 28 29	87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Solution administration sets (Biocompatibility as per ISO 10993-Parts 3,4,5,6,10,11,23, USP-87,88, ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Adhesives and monitors of various types, Mattress (Biocompatibility as per ISO 10993-Parts 5,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Monitoring devices, Transdermal patch, Gel (Biocompatibility as per ISO 10993-Parts 5,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Sensor, Personal protective equipment, Masks (Biocompatibility as per ISO 10993-Parts 5,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Skin contacting devices, non-invasive electrodes (Biocompatibility as per ISO 10993-Parts 5,10,11,23, USP-87,88 and	Class A  Class A  Class A
26 27 28 29	87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Solution administration sets (Biocompatibility as per ISO 10993-Parts 3,4,5,6,10,11,23, USP-87,88, ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Adhesives and monitors of various types, Mattress (Biocompatibility as per ISO 10993-Parts 5,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Monitoring devices, Transdermal patch, Gel (Biocompatibility as per ISO 10993-Parts 5,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Sensor, Personal protective equipment, Masks (Biocompatibility as per ISO 10993-Parts 5,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011, ANA-012, ANA-013)  Skin contacting devices, non-invasive electrodes (Biocompatibility as per ISO 10993-Parts 5,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Parts 5,10,11,23, USP-87,88 and Chemical Characterization as per ISO 10993-Parts 5,10,11,23, USP-87,88 and Chemical Characterization as per ISO	Class A  Class A  Class A

31	Burns and granulation tissue	Class B
	(Biocompatibility as per ISO 10993-Parts	
	3,5,6,10,11,23, USP-87,88 and Chemical	
	Characterization as per ISO 10993-Part 18,	
	SOP ANA-011, ANA-012, ANA-013)	
32	Laparoscopes, Arthroscopes, Endoscopes	Class B
32	(Biocompatibility as per ISO 10993-Parts	Class B
	3,5,6,10,11,23, USP-87,88,151 and	
	Chemical Characterization as per ISO	
	10993-Part 18, SOP ANA-011, ANA-012,	
	ANA-013)	
33	Blood administration sets, Filters	Class B
	(Biocompatibility as per ISO 10993-Parts	
	\$,4,5,6,10,11,23,USP-87,88,ASTM-F756 and	
	Chemical Characterization as per ISO	
	10993-Part 18, SOP ANA-011, ANA-012,	
	ANA-013)	
34	Irrigation set, Intravenous sets	Class B
"	(Biocompatibility as per ISO 10993-Parts	0.000 5
	8,4,5,6,10,11,23,USP-87,88,ASTM-F756 and	
	Chemical Characterization as per ISO	
	10993-Part 18, SOP ANA-011, ANA-012,	
L	ANA-013)	
35	Blood collections sets, Bags	Class B
	(Biocompatibility as per ISO 10993-Parts	
	8,4,5,6,10,11,23,USP-87,88,ASTM-F756 and	
	Chemical Characterization as per ISO	$O_{\wedge}$
	10993-Part 18, SOP ANA-011, ANA-012,	6
	ANA-013)	W. C. T.
36	Needles, Syringes (Biocompatibility as per	Class B
	ISO 10993-Parts 3,4,5,6,10,11,23, USP-	7. 51835 2
	87,88, ASTM-F756 and Chemical	=
		0
	Characterization as per ISO 10993-Part 18,	Z
07	SOP ANA-011, ANA-012, ANA-013)	Olara D
37	Surgical instruments, Urological devices	Class B
	(Biocompatibility as per ISO 10993-Parts	
	3,5,6,10,11,23, USP-87,88,151 and	~
	Chemical Characterization as per ISO	
	10993-Part 18, SOP ANA-011, ANA-012,	2
	ANA-013)	
38	Cardiovascular devices, Surgical	Class B
	accessories (Biocompatibility as per ISO	
	10993-Parts 3,5,6,10,11,23,USP-87,88,151	
	and Chemical Characterization as per ISO	
	10993-Part 18, SOP ANA-011,ANA-012,	
	ANA-013)	
39	Respiratory devices, Neurological devices	Class B
	(Biocompatibility as per ISO 10993-Parts	Olass D
	3,5,6,10,11,23, USP-87,88,151 and	
	Chemical Characterization as per ISO	
	10993-Part 18, SOP ANA-011, ANA-012,	
	ANA-013)	
40	Gynaecological devices (Biocompatibility	Class B
	as per ISO 10993-Parts 3,5,6,10,11,23,	
	USP-87,88,151 and Chemical	
	Characterization as per ISO 10993-Part 18,	
	SOP ANA-011, ANA-012, ANA-013)	
41	Skin staples, Dentistry devices	Class B
	(Biocompatibility as per ISO 10993-Parts	
	3,5,6,10,11,23, USP-87,88,151 and	
	Chemical Characterization as per ISO	
	· ·	
	10993-Part 18, SOP ANA-011, ANA-012,	
40	ANA-013)	Class P
42	Devices contacting mucosal membrane	Class B
	(Biocompatibility as per ISO 10993-Parts	
	3,5,6,10,11,23, USP-87,88,151 and	
	Chemical Characterization as per ISO	
	10993-Part 18, SOP ANA-011, ANA-012,	
<u></u>	ANA-013)	

43	Intravaginal devices, Vaginal pad	Class B
	(Biocompatibility as per ISO 10993-Parts	
	3,5,6,10,11,23, USP-87,88,151 and	
	Chemical Characterization as per ISO	
	10993-Part 18, SOP ANA-011, ANA-012,	
	ANA-013)	
44	Menstrual pad, Orthodontic devices	Class B
	(Biocompatibility as per ISO 10993-Parts	
	3,5,6,10,11,23, USP-87,88,151 and	
	Chemical Characterization as per ISO	
	10993-Part 18, SOP ANA-011, ANA-012,	
	ANA-013)	
45	Finger cot, Eye care device	Class B
	(Biocompatibility as per ISO 10993-Parts	
	3,5,6,10,11,23, USP-87,88,151 and	
	Chemical Characterization as per ISO	
	10993-Part 18, SOP ANA-011, ANA-012,	
	ANA-013)	
46	Catheters, Guide wire, Oxygenators	Class B
	(Biocompatibility as per ISO 10993-Parts	
	3,4,5,6,10,11,23,ÚSP-87,88,151,ASTM-F756	
	and Chemical Characterization as per ISO	
	10993-Part 18,SOP ANA-011,ANA-012,	
1	ANA-013)	
47	Blood tubing, Urological devices	Class B
1	(Biocompatibility as per ISO 10993-Parts	0.000 2
	3,4,5,6,10,11,23,USP-87,88,151,ASTM-F756	0,
	and Chemical Characterization as per ISO	70
	10993-Part 18,SOP ANA-011,ANA-012,	T <sub>2</sub>
	ANA-013)	4
48	Respiratory devices, Catheters,	Class B
70	(Biocompatibility as per ISO 10993-Parts3,	Olass B
	4,5,6,10,11,23,USP-87,88,151,ASTM-F756	0
	and Chemical Characterization as per ISO	Z
	10993-Part18,SOP ANA-011,ANA-012,ANA-	
	013)	
49	Gastrointestinal devices, Tubes	Class B
"	(Biocompatibility as per ISO 10993-Parts3,	Olass B
	4,5,6,10,11,23,USP-87,88,151,ASTM-F756	0
	and Chemical Characterization as per ISO	
	10993-Part18,SOP ANA-011,ANA-012,ANA-	all a
		× 0.
50	013)  Electrodes, Gynaecological devices	Class B
30	(Biocompatibility as per ISO 10993-Parts3,	Οίασο Β
1	4,5,6,10,11,23,USP-87,88,151,ASTM-F756	
1	and Chemical Characterization as per ISO	
1		
1	10993-Part18,SOP ANA-011,ANA-012,ANA-	
51	013) Haematological devices (Biocompatibility	Class B
] 51	` '	Class D
1	as per ISO 10993-Parts3,4,5,6,10,11,23,	
1	USP-87,88,151,ASTM-F756 and Chemical	
1	Characterization as per ISO 10993-Part18,	
<u></u>	SOP ANA-011,ANA-012,ANA-013)	Olara D
52	Health monitoring sensors	Class B
1	(Biocompatibility as per ISO 10993-Parts3,	
1	4,5,6,10,11,23,USP-87,88,151,ASTM-F756	
1	and Chemical Characterization as per ISO	
	10993-Part18,SOP ANA-011,ANA-012,ANA-	
	013)	
	Neuromuscular sensors and stimulators	Class B
53		
53	(Biocompatibility as per ISO10993-Parts3,	5.000 =
53	(Biocompatibility as per ISO10993-Parts3, 4,5,6,10,11,23,USP-87,88,151,ASTM-F756	5.000 =
53	(Biocompatibility as per ISO10993-Parts3, 4,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per	
53	(Biocompatibility as per ISO10993-Parts3, 4,5,6,10,11,23,USP-87,88,151,ASTM-F756	
53	(Biocompatibility as per ISO10993-Parts3, 4,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per	

-		
54	Devices contacting mucosal membrane	Class C
	(Biocompatibility as per ISO 10993-Parts	
	3,5,6,10,11,23, USP-87,88,151 and	
	Chemical Characterization as per ISO	
	10993-Part 18, SOP ANA-011, ANA-012,	
	ANA-013)	
55	Contraceptives, Personal lubricants	Class C
	(Biocompatibility as per ISO 10993-Parts	
	3,5,6,10,11,23, USP-87,88,151 and	
	Chemical Characterization as per ISO	
	10993-Part 18, SOP ANA-011, ANA-012,	
	ANA-013)	
56	Contact lenses, Urinary catheters	Class C
	(Biocompatibility as per ISO 10993-Parts	01000
	3,5,6,10,11,23, USP-87,88,151 and	
	Chemical Characterization as per ISO	
	10993-Part 18, SOP ANA-011, ANA-012,	
	ANA-013)	
57	Intra intestinal devices, Menstrual cups	Class C
	(Biocompatibility as per ISO 10993-Parts	
	3,5,6,10,11,23, USP-87,88,151 and	
	Chemical Characterization as per ISO	
	10993-Part 18, SOP ANA-011, ANA-012,	
	ANA-013)	
58	Endotracheal tubes, Bronchoscopes	Class C
30	(Biocompatibility as per ISO 10993-Parts	
		0.
	3,5,6,10,11,23, USP-87,88,151 and	P
	Chemical Characterization as per ISO	C.P.
	10993-Part 18, SOP ANA-011, ANA-012,	12
	ANA-013)	ORGANIS
59	Dental prostheses, Intrauterine device	Class C
	(Biocompatibility as per ISO 10993-Parts	
	3,5,6,10,11,23, USP-87,88,151 and	9
	Chemical Characterization as per ISO	_
	10993-Part 18, SOP ANA-011, ANA-012,	
	CD3 (ANA-013)	
60	Gastrointestinal devices (Biocompatibility	Class C
	as per ISO 10993-Parts 3,5,6,10,11,23,	X
	USP-87,88,151 and Chemical	9
	Characterization as per ISO 10993-Part 18,	
		4
	SOP ANA-011, ANA-012, ANA-013)	Olace O
61	Draining systems, Dental cements	Class C
	(Biocompatibility as per ISO 10993-Parts	
	3,5,6,10,11,23, USP-87,88,151 and	
	Chemical Characterization as per ISO	
	10993-Part 18, SOP ANA-011, ANA-012,	
<u></u>	ANA-013)	
62	Dialysis tubing and accessories	Class C
	(Biocompatibility as per ISO 10993-Parts	
	3,5,6,10,11,23, USP-87,88,151, ASTM-F756	
	and Chemical Characterization as per ISO	
	10993-Part 18,SOP ANA-011,ANA-012,	
	ANA-013)	
63	Hemoadsorbents, Immunoabsorbents	Class C
"		Class C
	(Biocompatibility as per ISO 10993-Parts3,	
	5,6,10,11,23,USP-87,88,151,ASTM-F756	
	and Chemical Characterization as per ISO	
	10993-Part18,SOP ANA-011,ANA-012,ANA-	
	013)	
64	Incubator, Neurological devices	Class C
	(Biocompatibility as per ISO 10993-Parts	
	3,5,6,10,11,23, USP-87,88,151, ASTM-F756	
	and Chemical Characterization as per ISO	
	10993-Part 18,SOP ANA-011,ANA-012,	
	ANA-013)	

65	Sutures, Intraocular lens(IOL), Ligation	Class C
	clips (Biocompatibility as per ISO 10993-	
	Parts 3,5,6,10,11,23,USP-87,88,151 and	
	Chemical Characterization as per ISO	
	10993-Part 18,SOP ANA-011,ANA-012,	
	ANA-013)	
66	Drug delivery devices, Replacement	Class C
00		01033 0
	tendons (Biocompatibility as per ISO	
	10993-Parts 3,5,6,10,11,23,USP-87,88,151	
	and Chemical Characterization as per ISO	
	10993-Part 18,SOP ANA-011,ANA-012,	
07	ANA-013)	010
67	Breast implants, Intrauterine devices	Class C
	(Biocompatibility as per ISO 10993-Parts	
	3,5,6,10,11,23,USP-87,88,151 and	
	Chemical Characterization as per ISO	
	10993-Part 18,SOP ANA-011,ANA-012,	
	ANA-013)	
68	Hearing aid and implant, cochlear implant	Class C
	(Biocompatibility as per ISO 10993-Parts	
	3,5,6,10,11,23,USP-87,88,151 and	
	Chemical Characterization as per ISO	
	10993-Part 18,SOP ANA-011,ANA-012,	
	ANA-013)	
69	Ventricular assist devices (Biocompatibility	Class C
	as per ISO 10993-Parts 3,5,6,10,11,23,USP-	
		0.
	87,88,151,ASTM-F756 and Chemical	YP_
	Characterization as per ISO 10993-Part 18,	(C)
	SOP ANA-011,ANA-012,ANA-013)	7/1.
70	Raw Ingredients, Container systems	Class C
I '		01033 0
	(Biocompatibility as per ISO 10993-Parts	4
	3,5,6,10,11,23,USP-87,88,151,ASTM-F756	0
	and Chemical Characterization as per ISO	$\rightarrow$
	10993-Part 18,SOP ANA-011,ANA-012,	
1		
	$\Delta m \Delta - 12131$	
71	ANA-013) Metals Plastics Rubber (Riccompatibility	Class C
71	Metals, Plastics, Rubber (Biocompatibility	Class C
71	Metals, Plastics, Rubber (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-	
71	Metals, Plastics, Rubber (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical	AW.
71	Metals, Plastics, Rubber (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-	AW.
71	Metals, Plastics, Rubber (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,	AW.
	Metals, Plastics, Rubber (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP- 87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011,ANA-012,ANA-013)	MOW
71	Metals, Plastics, Rubber (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011,ANA-012,ANA-013) Poly vinyl chloride, Polyesters	AW.
	Metals, Plastics, Rubber (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011,ANA-012,ANA-013)  Poly vinyl chloride, Polyesters (Biocompatibility as per ISO 10993-Parts	MOW
	Metals, Plastics, Rubber (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011,ANA-012,ANA-013) Poly vinyl chloride, Polyesters (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756	MOW
	Metals, Plastics, Rubber (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011,ANA-012,ANA-013)  Poly vinyl chloride, Polyesters (Biocompatibility as per ISO 10993-Parts	MOW
	Metals, Plastics, Rubber (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011,ANA-012,ANA-013) Poly vinyl chloride, Polyesters (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO	MOW
	Metals, Plastics, Rubber (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011,ANA-012,ANA-013)  Poly vinyl chloride, Polyesters (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012,	MOW
72	Metals, Plastics, Rubber (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011,ANA-012,ANA-013)  Poly vinyl chloride, Polyesters (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)	Class C
	Metals, Plastics, Rubber (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011,ANA-012,ANA-013)  Poly vinyl chloride, Polyesters (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)  Fluorocarbon Resins, Polyurethane	MOW
72	Metals, Plastics, Rubber (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011,ANA-012,ANA-013)  Poly vinyl chloride, Polyesters (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)  Fluorocarbon Resins, Polyurethane (Biocompatibility as per ISO 10993-Parts	Class C
72	Metals, Plastics, Rubber (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011,ANA-012,ANA-013)  Poly vinyl chloride, Polyesters (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)  Fluorocarbon Resins, Polyurethane (Biocompatibility as per ISO 10993-Parts	Class C
72	Metals, Plastics, Rubber (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011,ANA-012,ANA-013)  Poly vinyl chloride, Polyesters (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)  Fluorocarbon Resins, Polyurethane (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756	Class C
72	Metals, Plastics, Rubber (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011,ANA-012,ANA-013)  Poly vinyl chloride, Polyesters (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)  Fluorocarbon Resins, Polyurethane (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO	Class C
72	Metals, Plastics, Rubber (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011,ANA-012,ANA-013)  Poly vinyl chloride, Polyesters (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)  Fluorocarbon Resins, Polyurethane (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012,	Class C
72	Metals, Plastics, Rubber (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011,ANA-012,ANA-013)  Poly vinyl chloride, Polyesters (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)  Fluorocarbon Resins, Polyurethane (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)	Class C
72	Metals, Plastics, Rubber (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011,ANA-012,ANA-013)  Poly vinyl chloride, Polyesters (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)  Fluorocarbon Resins, Polyurethane (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)  Resins, Medical device extracts	Class C
72	Metals, Plastics, Rubber (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011,ANA-012,ANA-013)  Poly vinyl chloride, Polyesters (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)  Fluorocarbon Resins, Polyurethane (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)	Class C
72	Metals, Plastics, Rubber (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011,ANA-012,ANA-013)  Poly vinyl chloride, Polyesters (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)  Fluorocarbon Resins, Polyurethane (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)  Resins, Medical device extracts (Biocompatibility as per ISO 10993-Parts (Biocompatibility as per ISO 10	Class C
72	Metals, Plastics, Rubber (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011,ANA-012,ANA-013)  Poly vinyl chloride, Polyesters (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)  Fluorocarbon Resins, Polyurethane (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)  Resins, Medical device extracts (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756	Class C
72	Metals, Plastics, Rubber (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011,ANA-012,ANA-013)  Poly vinyl chloride, Polyesters (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)  Fluorocarbon Resins, Polyurethane (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)  Resins, Medical device extracts (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO	Class C
72	Metals, Plastics, Rubber (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011,ANA-012,ANA-013)  Poly vinyl chloride, Polyesters (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)  Fluorocarbon Resins, Polyurethane (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)  Resins, Medical device extracts (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012,	Class C
72 73	Metals, Plastics, Rubber (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011,ANA-012,ANA-013)  Poly vinyl chloride, Polyesters (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)  Fluorocarbon Resins, Polyurethane (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)  Resins, Medical device extracts (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)	Class C  Class C
72	Metals, Plastics, Rubber (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011,ANA-012,ANA-013)  Poly vinyl chloride, Polyesters (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)  Fluorocarbon Resins, Polyurethane (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)  Resins, Medical device extracts (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012,	Class C
72 73	Metals, Plastics, Rubber (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011,ANA-012,ANA-013)  Poly vinyl chloride, Polyesters (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)  Fluorocarbon Resins, Polyurethane (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)  Resins, Medical device extracts (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)  Cardiovascular devices (Biocompatibility	Class C  Class C  Class D
72 73	Metals, Plastics, Rubber (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011,ANA-012,ANA-013)  Poly vinyl chloride, Polyesters (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)  Fluorocarbon Resins, Polyurethane (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)  Resins, Medical device extracts (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)  Cardiovascular devices (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)  Cardiovascular devices (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-	Class C  Class C  Class D
72 73	Metals, Plastics, Rubber (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011,ANA-012,ANA-013)  Poly vinyl chloride, Polyesters (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)  Fluorocarbon Resins, Polyurethane (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)  Resins, Medical device extracts (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)  Cardiovascular devices (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical	Class C  Class C  Class D
72 73	Metals, Plastics, Rubber (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011,ANA-012,ANA-013)  Poly vinyl chloride, Polyesters (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)  Fluorocarbon Resins, Polyurethane (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)  Resins, Medical device extracts (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)  Cardiovascular devices (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,	Class C  Class C  Class D
72 73 74	Metals, Plastics, Rubber (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011,ANA-012,ANA-013)  Poly vinyl chloride, Polyesters (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)  Fluorocarbon Resins, Polyurethane (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)  Resins, Medical device extracts (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)  Cardiovascular devices (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical	Class C  Class C  Class C
72 73 74	Metals, Plastics, Rubber (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011,ANA-012,ANA-013)  Poly vinyl chloride, Polyesters (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)  Fluorocarbon Resins, Polyurethane (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)  Resins, Medical device extracts (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)  Cardiovascular devices (Biocompatibility as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)  Cardiovascular devices (Biocompatibility as per ISO 10993-Part 18, SOP ANA-011,ANA-012,ANA-013)	Class C  Class C  Class D
72 73 74	Metals, Plastics, Rubber (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011,ANA-012,ANA-013)  Poly vinyl chloride, Polyesters (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)  Fluorocarbon Resins, Polyurethane (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)  Resins, Medical device extracts (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)  Cardiovascular devices (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011,ANA-012,ANA-013)  Orthopedic pins, Plates, Screws	Class C  Class C  Class C
72 73 74	Metals, Plastics, Rubber (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011,ANA-012,ANA-013)  Poly vinyl chloride, Polyesters (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)  Fluorocarbon Resins, Polyurethane (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)  Resins, Medical device extracts (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)  Cardiovascular devices (Biocompatibility as per ISO 10993-Part 18, SOP ANA-011,ANA-012, ANA-013)  Cardiovascular devices (Biocompatibility as per ISO 10993-Part 18, SOP ANA-011,ANA-012,ANA-013)  Orthopedic pins, Plates, Screws (Biocompatibility as per ISO 10993-Parts	Class C  Class C  Class C
72 73 74	Metals, Plastics, Rubber (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011,ANA-012,ANA-013)  Poly vinyl chloride, Polyesters (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)  Fluorocarbon Resins, Polyurethane (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)  Resins, Medical device extracts (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)  Cardiovascular devices (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011,ANA-012,ANA-013)  Orthopedic pins, Plates, Screws (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151 and	Class C  Class C  Class C
72 73 74	Metals, Plastics, Rubber (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011,ANA-012,ANA-013)  Poly vinyl chloride, Polyesters (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)  Fluorocarbon Resins, Polyurethane (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)  Resins, Medical device extracts (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)  Cardiovascular devices (Biocompatibility as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)  Cardiovascular devices (Biocompatibility as per ISO 10993-Part 18, SOP ANA-011,ANA-012,ANA-013)  Orthopedic pins, Plates, Screws (Biocompatibility as per ISO 10993-Part 18, SOP ANA-011,ANA-012,ANA-013)  Orthopedic pins, Plates, Screws (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151 and Chemical Characterization as per ISO	Class C  Class C  Class C
72 73 74	Metals, Plastics, Rubber (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011,ANA-012,ANA-013)  Poly vinyl chloride, Polyesters (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)  Fluorocarbon Resins, Polyurethane (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)  Resins, Medical device extracts (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)  Cardiovascular devices (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011,ANA-012,ANA-013)  Orthopedic pins, Plates, Screws (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151 and	Class C  Class C  Class C
72 73 74	Metals, Plastics, Rubber (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18, SOP ANA-011,ANA-012,ANA-013)  Poly vinyl chloride, Polyesters (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)  Fluorocarbon Resins, Polyurethane (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)  Resins, Medical device extracts (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151,ASTM-F756 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)  Cardiovascular devices (Biocompatibility as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)  Cardiovascular devices (Biocompatibility as per ISO 10993-Part 18, SOP ANA-011,ANA-012,ANA-013)  Orthopedic pins, Plates, Screws (Biocompatibility as per ISO 10993-Part 18, SOP ANA-011,ANA-012,ANA-013)  Orthopedic pins, Plates, Screws (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151 and Chemical Characterization as per ISO	Class C  Class C  Class C

77	Bone cements and Intraosseous devices (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)	Class D
78	Subperiosteal implants, Implants (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)	Class D
79	Orthopaedic implants, Ocular implants (Biocompatibility as per ISO 10993-Parts 3,5,6,10,11,23,USP-87,88,151 and Chemical Characterization as per ISO 10993-Part 18,SOP ANA-011,ANA-012, ANA-013)	Class D



3. This Registration is subject to the conditions as specified in the Drugs and Cosmetics Act,1940(23 of 1940) and the Medical Devices Rules,2017.

Place: New Delhi Central Licensing Authority

Date: 16-Apr-2025

