

**Laboratory** Trustin Analytical Solutions Pvt. Ltd., R.K. Complex, First Floor, Plot No. 303/B, 'B' Block, Thiruneermalai Road, Parvathy Puram, Chrompet, Chennai, Tamil Nadu

**Accreditation Standard** ISO/IEC 17025: 2005

**Certificate Number** TC-5410

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**Validity** 31.03.2017 to 30.03.2019

Last Amended on --

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
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**MECHANICAL TESTING**

I.	Rubber & Rubber Products			
1	a) Condoms (Male and Female)	Length	ISO 4074/WHO UNAIDS /ISO 25841/WHO UNAIDS 2012/ Drugs & Cosmetics Act and Rules 1940 and Rule 1945 (Revised Schedule 'R' )	100 mm to 400 mm
		Width		20 mm to 200 mm
	b) Surgical/ Examination Gloves	Single Wall Thickness		0.001 mm to 1.00 mm
		Burst Volume (BA)		0.5 to 150Lits.
		Burst Volume (AA)		0.5 to 150Lits.
		Burst Pressure (BA)		0 to 10KPa
		Burst Pressure (AA)		0 to 10KPa
		Package seal Integrity		Visual
		Freedom from holes/Water Leakage Test		Visual
		Quantity of Lubricant		1 to 3500mg
		Visible Defects		Visual
		Packaging and Labeling		Visual
		Odour		Sensory inspection
		Colour Fastness Test		Revised Schedule 'R'
	<b>Dimensions</b>			
	Length	IS 13422 /IS 15354	100 mm to 500 mm	
	Width	ASTM D 3577	10 mm to 150 mm	
	Thickness	ASTM D 3578	0.01 mm to 2.0 mm	
	Finger Palm Cuff	EN 455 Part 1, 2	0.01 mm to 2.0 mm 0.01 mm to 2.0 mm	
	<b>Dimension (A to G)</b>	IS 4148		
	Position A		70mm to 170 mm	
	Position B		40 mm to 120 mm	
	Position C		40 mm to 150 mm	
	Position D		230 mm to 330 mm	
	Position E		40 mm to 130 mm	
	Position F		140 mm to 230 mm	
	Position G		50 to 150	

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		<b>Thickness</b> Finger Palm Cuff	IS 4148	0.01 mm to 2.0 mm 0.01 mm to 2.0 mm 0.01 mm to 2.0 mm
		pH	IS 4148	0 to 14.0
		<b>Tensile/Physical Properties (Before Accelerating and After Accelerating)</b>		
		Tensile Strength/ Force at break (MPa)/N/Median	IS 13422 IS 15354	1 to 50/ 1 to 45
		Elongation at break (%)	ASTM D 3577	1 to 2500
		Stress at 500% elongation (MPa)	ASTM D 3578 EN 455-2 IS 4148	0.01 to 20
		Water tightness/ Freedom from Holes	EN 455-1 IS 15354	Visual
		Powder content (g/glove)	ASTM D 6124 ISO 21171	Qualitative
<b>2</b>	<b>Plastics &amp; Plastics Products</b>	<b>Dimension</b>		
	<b>a) Blood bag</b>	Collection tube length	ISO 3826-1- Plastics collapsible containers for human blood and blood components	500 mm to 1500 mm
		Collection tube internal diameter		1.0 mm to 10 mm
		Collection tube Thickness		0.1 mm to 5.0 mm
		Transfer tube length		50 mm to 2000 mm
		Transfer tube internal diameter		1 mm to 10 mm
		Transfer tube Thickness		0.1 mm to 5.0 mm
		Blood taking needle Length		10 mm to 50 mm
		Blood taking needle outer Diameter		0.1 mm to 5.0 mm
		<b>Design</b>		
		Air Content (ml)		Qualitative
		Emptying under		Qualitative

Ramprasath.R  
Convenor

N. Venkateswaran  
Program Director

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		Pressure(Min.)		
		Rate of Collection		Qualitative
		Collection and transfer tube strength		Qualitative
		Blood taking needle Strength		Qualitative
		Suspension		Qualitative
		Outlet port		Qualitative
		<b>Physical Requirements</b>		
		Thermal stability		Qualitative
		Water vapour Transmission (%)		Qualitative
		Particulate contamination		Qualitative (Visual)
		Performance of Labeling	-	Qualitative
	<b>b) Intra Uterine Devices - Cu T 380A/ Copper T /Cu 375 Series</b>	<b>Dimensions – T Frame</b>	ISO 7439/Section 19(III) of Drugs & Cosmetics Act 1940 and Rules 1945as per Schedule R/MOHFW/WHO/ UNFPA 2010	
		Length of Horizontal arm		25 mm to 35.5 mm
		Length of Vertical stem		25 mm to 39.5 mm
		Diameter of Horizontal arms		0.5 mm to 10.0 mm
		Diameter of Vertical arm/stem		0.5 mm to 10.0 mm
		T piece ball diameter		1.0 mm to 10.0 mm
		<b>Thread</b>		
		Length of thread		50 mm to 200 mm
		Strength of thread		0.5 to 200 N
		Diameter of thread		0.05 mm to 2.00 mm
	<b>Copper Collars</b>			
	Length	1.00 mm to 10.00 mm		
	Sleeve position	0.5 mm to 10.0 mm		
	Internal Diameter	0.50 mm to 3.00 mm		
	External Diameter	0.50 mm to 5.00 mm		
	Weight	10.0 to 200 (mg)		
	Retention force(Kgf)		Qualitative	
	<b>Copper Wire</b>			

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		Diameter		0.05 mm to 2.00 mm
		Weight		50 to 300 (mg)
		Surface area ( copper wire + sleeves)		150 to 750 (mm <sup>2</sup> )
		<b>Insertion Tube</b>		
		Length		100 mm to 250 mm
		Inner diameter		1.5 mm to 8.0 mm
		Outer diameter		2.0 mm to 9.0 mm
		<b>Movable Flange</b>		
		Diameter of center hole		.0 mm to 8.0 mm
		Flange displacement force		.0 to 100 (N)
		<b>Displacement Rod</b>		
		Solid rod length		170 mm to 210 mm
		Diameter of Rod at tip		1.0 mm to 3.5 mm
		<b>Packaging and labeling</b>		
		Sealed pouch peel strength		Qualitative
		Sealed pouch integrity		Qualitative
		Printing		Qualitative
		Cleanliness		Qualitative
		Labeling and inserts		Qualitative
	<b>c) Tubal Ring</b>	<b>Dimension</b>		
		Inner Diameter	IS 13009	0.05 mm to 2.50 mm
		Outer Diameter		1.00 mm to 5.00 mm
		Thickness		1.00 mm to 5.00 mm
		Load at Fracture		Qualitative
		Elongation at Fracture		Qualitative
		Friction force test		Qualitative
		Memory test		Qualitative
		Stain Capacity		Qualitative
		Fatigue test		Qualitative
		Visual Inspection		Visual

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	<b>d) Surgical Suture (Absorbable/Non-absorbable)</b>	Length	USP 39/EP 9.0/IP 2014	1 mm to 800 mm
		Diameter		0.001 mm to 2.00 mm
		Knot-Pull Tensile Strength		0.5 to 100(N)
		Needle attachment		0.5 to 100 (N)
<b>3.</b>	<b>Miscellaneous - Sanitary Napkins</b>	Length	IS 5405	100 mm to 400 mm
		Width		30 mm to 100 mm
		Thickness (mm)		Qualitative
		Absorbency and Ability to withstand Pressure after Absorption		Qualitative
		Disposability		Qualitative
		pH		0 to 14
	Instructions		Qualitative (Visual)	

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