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Ref. F.02(89)/RMSCL/LAB EMPANELMENT(S&S)/NIB-01/2021/JUT

Dated: 23 04/2021

#### Corrigendum-I

Subject: - Amendment of Bid for the Empanelment of the Analytical Testing Laboratories for the test and analysis of Surgical & Suture

Ref: - NIB No. F.02(89)/RMSCL/LAB EMPANELMENT(S&S)/NIB-01/2021/86 Dated :23.03.2021 The following amendments are made:

List of the product which need to amend for parameters

Sr. No	Code No.	Item Description	Unit		Test proposed to be carried out (Standard)	Test parameters proposed to be carried out by bidder			
1	2	3	4		5	6			
1	S-1	Absorbable Gelatin Sponge IP 66, Size 80 +-	Piece	A	Physical				
		10 mm x 50 mm x 10 mm . Should be sterlised		1	Description				
		As per IP		В	Chemical				
				1	Water Absorbance				
				2	Density				
				3	Formaldehyde				
				4	Total Nitrogen				
					5	Digestibility			
						6	Solubility		
	-						7	Porosity	
						8	Ash		
1.		·		9	Water	Deleted			
				C	Biological Test				
				1	Sterility				
				2	Pyrogen / Bacterial Endotoxins Test				
	S-4	Blood Administration Set / Blood Transfusion	Unit	Α .	Physical				
		SetConforms to IS 9824- 3:1996 For needle			1	Tubing (Length, Internal Diameter., other properties- kink resistance, transparency)			
		IS:10654:2002		2	Closure -Piercing Device				
				3	Connection between male fiting, injection site and tubing	. ,			
				4	Air - inlet device	,			
			-	5	Filter				





		Zivoliana .
6	Drip chamber and drip tube	
7	Filter for Blood and Blood derivates	
8	Flow Regulator	
9	Test for injection Site	
	, v	
10	Test for Integrity	
11	Tensile Strength	5
11	Tensne Strength	
12	Particulate Contamination	
13	Protective Cap	
14	Blood Flow Rate	
15	Male Fitting	
16	Test for filter efficiency	
В	Chemical test	
1	Reducing (Oxidizable) Matter	
2	Heavy Metal Ions	
3	Acidity or Alkalinity	
4	Residue on evaporation	
5	UVAbsorbance	
С	Biological Test	
1	Sterility Test	
2	Pyrogen / Bacterial Endotoxins Test	
3	Toxicity Test	
Ď	For Needles	Needles Parameter Added IS:10654:2002
1	Description	
2	Cleanliness	
3	Limits of Acidity or Alkalinity	<u> </u>
4	Limits of Extractable Matels	1,000
5	Freedm from defects	
6	Tolerance of length	
7	Lubricant	
8	Needle Point	
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5		0.10	Cu to District			Calibration (Calibration)
3		S-13	Sterile Disposable Infusion Set with Microdip (I.V) IS 12655-4	A	Physical	
	-		Unit	1	Description	
			·	2	Tubing	
				3	Test of Integrity	
				4	Connection between components	
				5	Closure piercing device	
				6	Drip chamber and drip tube	
				7	Flow Rate	
				8	Flow Regulator	
				9	Injection site	
				10	Male Fitting	
				11	Test for efficiency of fluid filter	
				12	Protective Cap	
				13	Test of Injection site	
_				14	Particulate contamination	
				B	Chemical test	
				1	Acidity or Alkalinity	
				2	UV Absorbency of extract	
				3	Reducing (Oxidizable)Substance	
				4	Heavy Metal Ions	
				5	Residue on evaporation	
			· 	C	Biological Test	
				1	Sterility Test	
				2	Pyrogen / Bacterial Endotoxins Test	
				3	Toxicity Test	
				D	For Needles	Needles Parameter Added
						IS:10654:2002
					Description	
				1	Cleanliness	
					Limits of Acidity or Alkalinity	
					Limits of Extractable Matels	
.					Freedm from defects	
	•				Tolerance of length	
_					Lubricant	
	·			8 1	Needle Point	

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. 4	S-18	Paper Adhesive Plaster 1"	Unit	A	Physical	
		X 9.0 mts (with cutter) Non woven adhesive tape		1	Description	
		As per USP /BP		2	Dimension (Length, width)	
			•	3	Tensile strength	
				4	Adhesive strength	
5	S-19	Paper Adhesive Plaster 2"	Unit	A	Physical	
	X 9,0 mts (with cutter) Non woven adhesive tape		1	Description		
		As per USP /BP		2	Dimension (Length, width)	
		•		3	Tensile strength	
				4	Adhesive strength	
6	S-20	Paper Adhesive Plaster 3"	Unit	Α	Physical	
	-	X 9.0 mts (with cutter)		1	Description	
		Non woven adhesive tape As per USP /BP		2	Dimension (Length, width)	
				3	Tensile strength	
			4	Adhesive strength		
7	S-21	Plaster of Paris Bandages	Unit	A	Physical	
, .		15cm X 2.7mts / Roll		1	Description	<u> </u>
	As per BP	As per BP		2	Weight per unit area of Bandage & fabric	
				В	Chemical Test	
				1	Fiber Identification	
				2	Identification A (Cotton)	
				3	Identification B (Iodinated Zinc Chloride Solution Test)	
				4	Identification C (Solubilty in Sulphuric Acid)	
				5	Identification D (Zinc Chloride Solution Test)	
				6	Threads per unit area (warp, weft)	
				7	Setting time	
				8	Content of Calcium sulphate hemihydrate	
8	S-22	Plaster of Paris Bandages 10cm X 2.7mts / Roll	Unit	A	Physical	
		As per BP		1	Description	
				2	Weight per unit area of Bandage & fabric	
			!	В	Chemical Test	
				1	Fiber Identification	<u> </u>
!			2	Identification A (Cotton)		
		•	3	Identification B (Iodinated Zinc Chloride Solution Test)		
			4	Identification C (Solubilty in Sulphuric Acid)		
			5	Identification D (Zinc Chloride Solution Test)		
				6	Threads per unit area (warp, weft)	
				7	Setting time	



	1	I.	1			TICEO C
				8	Content of calcium sulphate Hemihydrate	
9	S-26	Sterile Hypodermic	Unit	A	Physical	
		Syringe with Needle attached, 24G, Single		1	Description	,
		2ml IS 10258; 2002		2	Components	
				3	Cleanliness	
				4	Lubrication	
				5	Tolerance on graduated Capacity	
				6	Graduated Scale	
				a	Overall length of scale to nominal capacity mark	
				b	Scale Interval	
				C	Increment betwween Graduation lines to be numbered	
				7	Barrel	
				a	Dimension	
				ь	Fingergrip	
ı				8	Pistan/plunger Assembly	
l				a	Fit of Piston in barrel	
			İ	b	Fiducial line	
				9	Leakage Test	
	-			a	Liquid leakage past the syringe piston and at the syringe needle union during compression	
				b	Air leakage past the syringe piston and at the syringe needle union during aspiration	
			i	10	Test for Needle assembly	
				a	Needle Attachment	
	į			ь	Needle dimensions	
				11	Bond between hub/ syringe barrel and needle tube	
ļ				12	Patency of lumen	
				13	Dead space	
				В	Chemical test	
			•	1	Acidity or Alkalinity (pH)	
	[			2	Extractable Metals	
				C	Biological test	
				1	Sterility	
			ļ <del>-</del>	2	Pyrogen / Bacterial Endotoxins Test	
				3	Toxicity	
				D	For Needles	Needles Parameter Added IS:10654:2002
				1	Description	
			<del> </del>	2	Cleanliness	
			<u> </u>	3	Limits of Acidity or Alkalinity	
			-		Limits of Extractable Matels	

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				5	Freedm from defects	
				6	Tolerance of length	
				7	Lubricant	
				8	Needle Point	
10	S-27	Sterile Hypodermic	Unit	A	Physical	
		Syringe with Needle attached, 24G Single Use		Ī	Description	
		- 5 ml IS 12050		2	Components	
				3	Cleanliness	
				4	Lubrication	
				5	Tolerance on graduated Capacity	
				6	Graduated Scale	
				a	Overall length of scale to nominal capacity mark	
				Ь	Scale Interval	
				С	Increment betwween Graduation lines to be numbered	
				7	Barrel	
		'		a	Dimension	
				b	Fingergrip	
			8	Pistan/plunger Assembly		
				a	Fit of Piston in barrel	
		i		ь	Fiducial line	
				9	Leakage Test	
				а	Liquid leakage past the syringe piston and at the syringe needle union during compression	
				b	Air leakage past the syringe piston and at the syringe needle union during aspiration	
				10	Test for Needle assembly	
	ı			a	Needle Attachment	
		•		b	Needle dimensions	
				11	Bond between hub/ syringe barrel and needle tube	
				12	Patency of lumen	
				13	Dead space	
	İ			В	Chemical test	
				1	Acidity or Alkalinity (pH)	
				2	Extractable Metals	·
				С	Biological test	
				1	Sterility	
				2	Pyrogen / Bacterial Endotoxins Test	
				3	Toxicity	
				D	For Needles	Needles Parameter Added IS:10654:2002
				1	Description	



	r						WINDER OF THE PROPERTY OF THE
		İ			2	Cleanliness	
		İ			3	Limits of Acidity or Alkalinity	
					4	Limits of Extractable Matels	
					5	Freedm from defects	V
	i				6	Tolerance of length	
					7	Lubricant	
					8	Needle Point	
ŀ	11	S-28	Sterile Hypodermic	Unit	A	Physical	
			Syringe with Needle attached, 22G, Single Use	i	1	Description	
			- 10 ml IS 12050		2	Components	
					3	Cleanliness	
					4	Lubrication	
-				!	5	Tolerance on graduated Capacity	
					6	Graduated Scale	
					a	Overall length of scale to nominal capacity mark	
		]		l	ь	Scale Interval	
					c	Increment betwween Graduation	
	i					lines to be numbered	
İ		i			7	Barrel	
					a	Dimension	
					b	Fingergrip	
					8	Pistan/plunger Assembly	
	ŀ	i			a	Fit of Piston in barrel	
				}	ь 9	Fiducial line	
						Leakage Test Liquid leakage past the syringe	
					a	piston and at the syringe needle	
				-	b i	union during compression  Air leakage past the syringe piston	
	i				D	and at the syringe needle union	
İ					10	during aspiration Test for Needle assembly	
		İ			a	Needle Attachment	
!				-	b	Needle dimensions	
l			į	!	11	Bond between hub/ syringe barrel	
						and needle tube	
					12	Patency of lumen	
					13	Dead space	
					В	Chemical test	
				_	1	Acidity or Alkalinity (pH)	
,					2	Extractable Metals	, , , , , , , , , , , , , , , , , , , ,
				-	C	Biological test	
					1	Sterility Description (Particle Folder)	
				.,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	2	Pyrogen / Bacterial Endotoxins Test	



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				3	Toxicity			
				D	For Needles	Needles Parameter Added IS:10654:2002		
				1	Description			
				2	Cleanliness			
				3	Limits of Acidity or Alkalinity			
			1	4	Limits of Extractable Matels			
				5	Freedm from defects			
				6	Tolerance of length			
				7	Lubricant	61. W.P		
				8	Needle Point			
12	S-29	Sterile Hypodermic	Unit	A	Physical			
		Syringe with Needle attached, 22G, Single Use		1	Description			
		- 20 ml IS 12050		2	Components			
				3	Cleanliness			
				4	Lubrication			
			5	Tolerance on graduated Capacity				
			6	Graduated Scale				
				a	Overall length of scale to nominal capacity mark			
				b	Scale Interval			
	i			С	Increment betwween Graduation lines to be numbered			
						7	Barrel	
					a	Dimension		
				b	Fingergrip			
				8	Pistan/plunger Assembly			
			ı	a	Fit of Piston in barrel			
						ь	Fiducial line	
				9	Leakage Test			
				a	Liquid leakage past the syringe piston and at the syringe needle			
			·	ь	union during compression  Air leakage past the syringe piston and at the syringe needle union during aspiration			
				10	Test for Needle assembly			
				a	Needle Attachment	<u> </u>		
				b	Needle dimensions			
				11	Bond between hub/ syringe barrel and needle tube			
				12	Patency of lumen			
				13	Dead space			
				В	Chemical test			
				l		<u> </u>		



			V	The state of the s	
			1	Acidity or Alkalinity (pH)	
			2	Extractable Metals	
			C	Biological test	
			1	Sterility	
			2	Pyrogen / Bacterial Endotoxins Test	
			3	Toxicity	,
			D	For Needles	Needles Parameter Added IS:10654:2002
			1	Description .	
			2	Cleanliness	
			3	Limits of Acidity or Alkalinity	, , , , , , , , , , , , , , , , , , ,
			4	Limits of Extractable Matels	
			5	Freedm from defects	
			6	Tolerance of length	
			7	Lubricant	
		ı	8	Needle Point	
13 S-13	66 Chemotherapy Port	Unit	i	Sterilization	
	&Non-coring needles(Adult) Valved catheter need only saline				
-			1	Bio Compatibility Bacterial Endotoxins Test	
	flush, catheter with				
	intermediate size port with small septum and			E O Residual	
	silicon filled suture holes, should be MRI			Function Test	
	compatible with cathlock radio-opaque ring. 8FR with silicon material with peel apart percutaneous introducer system.  Chemo port huber needle 20g and 22g.	,	.0	Acceptance Test	
14 S-13	7 Chemotherapy Port &Non-coring	Unit	1 8	Sterilization	
	needles(Pediatric) Valved catheter need only		2 E	Bio Compatibility	
	saline flush, catheter with intermediate size power		3 E	Bacterial Endotoxins Test	
	port with large septum and silicon filled suture		4 E	O Residual	
	holes, should be MRI		5 F	Function Test	
	compatible with cathlock			Acceptance Test	
	radio-opaque ring. 6FR with silicon material with peel apart percutaneous introducer system . Chemo port huber needle 20g and 22g.				
	introducer system. Chemo port huber needle				





#### NOTE:-

\* The parameters of testing of sutures will be as per the respective pharmacopoeia.

\* The above tests are minimum tests to be performed.

\* For item code R-68 to R-74 bidders should quote the rates including Antibacterial test. any change or amendment found in any Standard protocol i.e IP/BP/USP/ISO/IS etc the parameter will be followed and amended accordingly. As an when required Party specification Parameter will be provided

Rest terms and conditions will remain the same.

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Executive Director (Proc.)
RMSCL