

File No.GEM/TP/Needle Holders/2018 (Version 3.0)										Draft T/P		
Level 1 Category: Medical Equipment and Accessories and Supplies -UNSPS Code 42000000												
Level 2 Category: Surgical Products - UNSPS Code 42290000												
Level 3 Category: Suture and Surgical Tissue Closure Instruments and Related Products -UNSPS Code 42292900												
Level 4 Category: Needle Holders for Paediatric Surgery -(RBSK) - UNSPS Code 42292903										GEM Version 3.0		
S.NO	PARAMETER	HINT	TYPE OF FIELD	VALUES						UNIT	CATEGORY OF FIELD	REMARKS
GENERAL FEATURES												
1	Product Description	--	ENUMERABLE	Mayo Hegar Needle Holder	Crile Wood Needle Holder					--	MANDATORY	
2	Clinical Purpose	--	ENUMERABLE	To hold a suturing needle for closing wounds during suturing and surgical procedures in Paediatric surgery						--	MANDATORY	
3	Conformity to Standard	--	ENUMERABLE	IS:7870-1992 (Latest Revision)						--	MANDATORY	
4	Reusable	--	ENUMERABLE	Yes						--	MANDATORY	
5	Sterile	--	BOOLEAN	Yes	No					--	MANDATORY,FILTER	
6	Autoclavable	--	BOOLEAN	Yes	No					--	MANDATORY, FILTER	
MATERIAL AND CONSTRUCTION												
1	Material	--	ENUMERABLE	Medical Grade Stainless Steel						--	MANDATORY	
2	Latex Free Material	--	ENUMERABLE	Yes						--	MANDATORY	
3	Thick non slip Handle	--	ENUMERABLE	Yes						--	MANDATORY	
4	Corrosion Resistant and Rust Free	--	ENUMERABLE	Yes						--	MANDATORY	
5	Needle Holder shall be free from cracks, pits, scales, seams, burrs and other surface defects	--	ENUMERABLE	Yes						--	MANDATORY	
6	Jaw Pattern	--	ENUMERABLE	Straight	Curved					--	MANDATORY, FILTER	
7	Tungsten carbide insert at the jaws	--	BOOLEAN	Yes	No					--	GOLDEN	
8	Serrated Jaws	--	BOOLEAN	Yes						--	MANDATORY, FILTER	
9	Type of serration	--	ENUMERABLE	Diamond Cut Type						--	MANDATORY, FILTER	
10	Shank Pattern	--	ENUMERABLE	Straight	Curved					--	MANDATORY, FILTER	
11	The jaws shall close and open smoothly with even movement	--	ENUMERABLE	Yes						--	MANDATORY	
12	On closure, the jaws shall meet fully and accurately	--	ENUMERABLE	Yes						--	MANDATORY	
13	Joint of the Needle holder	--	ENUMERABLE	Box type						--	MANDATORY	

14	The joints shall have no undue play	--	ENUMERABLE	Yes					--	MANDATORY	
15	Rachet Teeth of combination 3 in 3	--	ENUMERABLE	Yes					--	MANDATORY	
16	Handle Type	--	ENUMERABLE	Finger Loops					--	MANDATORY	
17	Size of Finger Loops as per Section 6 of IS:3642(part 1)/1990	--	ENUMERABLE	No. 1	No. 2	No. 3	No. 4		--	MANDATORY, FILTER	
18	Needle Holder Overall Straight Length (mm)	--	MEASURABLE	130 to 205					mm	GOLDEN PARAMETER	
19	Width of Finger loops in fully closed condition (mm)	--	NUMERIC	70					mm	MANDATORY	
20	The needle holder shall be polished bright or dull and passivated	--	ENUMERABLE	Yes					--	MANDATORY	
21	Golden color Polishing	--	BOOLEAN	Yes	No				--	MANDATORY, FILTER	
MARKINGS											
1	Needle holder shall be clearly and indelibly marked with manufacturer's name initials or recognized trade mark and the words 'Stainless Steel'	--	BOOLEAN	Yes	No				--	MANDATORY, FILTER	
2	Product is ISI marked	--	BOOLEAN	Yes	No				--	MANDATORY, FILTER	
3	CM/L No (If ISI Marked)	Must Declare, Write '0" if not applicable	NUMERIC						--	MANDATORY	
PACKAGING											
1	Packing	--	ENUMERABLE	Packed in Polyethylene Bag	Wrapped in Wax Paper				--	MANDATORY, FILTER	
2	Price Unit	--	ENUMERABLE	Each Needle Holder					--	MANDATORY	
CERTIFICATIONS & REPORTS											
1	Submission of Test Report from Central Govt./NABL/ILAC accredited Lab to prove the conformity to declared specification at the time of supply	--	ENUMERABLE	YES					--	MANDATORY	
2	Product certification	--	ENUMERABLE	BIS	ISO	EU-CE	US-FDA	EU-CE/US - FDA	--	MANDATORY, FILTER	
3	Submission of all the certifications and test reports to the buyer along with supplies on demand	--	ENUMERABLE	Yes					--	MANDATORY	
WARRANTY											
1	Warranty (Yrs)	--	NUMERIC	1	2	3	4	5	Year	GOLDEN PARAMETER	

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