

Gfile No.GEM/TP/Surgical handles/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: Surgical cutting instruments and snares and related products -UNSPS Code 421600											
Level 4 Category: Handles for surgical blades, detachable -UNSPS Code 42291613										GEM Version 3.0	
S.NO	PARAMETER	HINT	TYPE OF FIELD	VALUES					UNIT	CATEGORY OF FIELD	REMARKS
<b>GENERAL FEATURES</b>											
1	Product	--	ENUMERABLE	Handles for Surgical blades, detachable					--	MANDATORY	
2	Matching blade Type for use of handles	--	ENUMERABLE	Detachable Bard Parker					--	MANDATORY	
<b>TECHNICAL FEATURES</b>											
1	Size and Shape of handle	--	ENUMERABLE	As per CI 5.1 of IS:3319/1995(Latest Revision)					--	MANDATORY	
2	Comercial designation of Handles as per IS:3319/1995 (Latest Revision)	--	Enumerable	3, 3L, 4, 5, 7					--	GOLDEN PARAMETER	
3	Handle mount shall accommodate matching blade without any snug	--	ENUMERABLE	Yes					--	MANDATORY	
4	Handle surface shall be finished smooth with bright or matt finish	--	ENUMERABLE	Yes					--	MANDATORY	
5	Handle has suitable grips for good hold with edges chamfered and rounded	--	ENUMERABLE	Yes					--	MANDATORY	
6	Handle shall be free from burrs, sharp or rough edges, pits, cracks and other surface defects	--	ENUMERABLE	Yes					--	MANDATORY	
7	Handles shall be passivated	--	ENUMERABLE	Yes					--	MANDATORY	
8	Sterility	--	ENUMERABLE	Sterile	Non-sterile				--	MANDATORY,FILTER	
9	Method of sterilization	--	ENUMERABLE	EO	ETO	Gamma	Other	NA	--	MANDATORY	
<b>DIMENSIONS, MATERIAL &amp; CONSTRUCTION</b>											
1	Material of Handles	--	ENUMERABLE	Stainless Steel					--	MANDATORY	
2	Stainless Steel for Handles shall conform to	--	ENUMERABLE	Designation X07Cr18Ni9 of IS:6911/1992	Designation X07Cr17 of IS:6911/1992				--	GOLDEN PARAMETER	
3	Dimensions of handles for small size fittings	--	ENUMERABLE	As per Table 1 of IS:3319/1995(Latest Revision)					--	MANDATORY	
4	Dimensions handles for Large size fittings	--	ENUMERABLE	As per Table 2 of IS:3319/1995(Latest RA)					--	MANDATORY	
<b>PACKING &amp; MARKING</b>											
1	Permanent marking on the Handles	--	ENUMERABLE	As per CI10.2.1 of IS:3319/1995 (Latest Revision)					--	MANDATORY	
2	Marking on the Packages of Handles	--	ENUMERABLE	As per CI 10.2.2 of IS:3319/1995(Latest Revision)					--	MANDATORY	
3	Packaging of Handles	--	ENUMERABLE	As per CI 11.4 of IS:3319/1995(Latest Revision)					--	MANDATORY	
4	Number of handles in a Package (Nos.)	--	NUMERIC	10, 20, 30, 40, 50, 60, 70, 80, 90, 100					Nos	GOLDEN PARAMETER	

STANDARD										
1	Conformity to standard	--	ENUMERABLE	IS:3319/1995 (Latest Revision)					--	MANDATORY
2	Product is ISI Marked	--	ENUMERABLE	Yes					--	MANDATORY
3	BIS Licence No (CM/L No)	Must Declare	NUMERIC						--	MANDATORY
CERTIFICATIONS & REPORTS										
1	Availability of Test report from Govt./ NABL / ILAC accredited Laboratory to prove conforming to the declared specification	--	ENUMERABLE	Yes					--	MANDATORY
2	Test report No. and date	MUST DECLARE	TEXT						--	MANDATORY
3	Name and address of Test Lab	MUST DECLARE	TEXT						--	MANDATORY
4	Certification Available	--	ENUMERABLE	ISO	EU-CE	US-FDA	EU-CE&US-FDA		--	MANDATORY,FILTER
5	Submission of all the test reports to the buyer along with supplies on demand	--	ENUMERABLE	Yes					--	MANDATORY
WARRANTY										
1	Warranty (Year)	--	NUMERIC	3	4	5			Year	GOLDEN PARAMETER

(MANJU SHARMA)  
DY.CEO

(A. KESAVA RAO)  
AD, GEM-SPV