

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: Blades surgical detachable -UNSPS Code 42291613

DRAFT
T/P

GEM Version 3

S.NO	PARAMETER	HINT	TYPE OF FIELD	VALUES	UNIT	CATEGORY OF FIELD
GENERAL FEATURES						
1	Product	--	ENUMERABLE	Detachable surgical blades	--	MANDATORY
2	Blade Type	--	ENUMERABLE	Detachable Bard Parker	--	MANDATORY
TECHNICAL FEATURES						
1	Size and Shape of blade	--	ENUMERABLE	As per Cl 5.1 of IS:3319/1995(Latest Revision)	--	MANDATORY
2	Commercial Designation of blades as per IS:3319/1995 (Latest Revision)	--	NUMERIC	10, 11, 12, 15, 20, 21, 22, 23, 24, 25, 13, 14, 16, 17, 18, 19	--	GOLDEN PARAMETER
3	Tip of blade well defined, central and sharp	--	ENUMERABLE	Yes	--	MANDATORY
4	Cutting edge shall be free from waviness, jags, feathers, nicks and other defects	--	ENUMERABLE	Yes	--	MANDATORY
5	Both the surfaces of blade shall be smooth, and free from tool marks and any sign of corrosion	--	ENUMERABLE	Yes	--	MANDATORY
6	Edges other than the cutting edge shall not be sharp	--	ENUMERABLE	Yes	--	MANDATORY
7	Blade shall fit to the corresponding mount of the handle snugly	--	ENUMERABLE	Yes	--	MANDATORY
8	Blade shall be flat and shall not sprung	--	ENUMERABLE	Yes	--	MANDATORY
9	Thickness of the blade is uniform	--	ENUMERABLE	Yes	--	MANDATORY
10	Both the surfaces of the blade shall be free from roughness and waviness,	--	ENUMERABLE	Yes	--	MANDATORY
11	Disposable blade	--	ENUMERABLE	Yes	--	MANDATORY
12	Hardness of the Stainless blade or Carbon steel blade when tested shall meet the requirement of Cl 7.1 of IS:3319/1995 (Latest Revision)	--	ENUMERABLE	Yes	--	MANDATORY
13	Sterilized blade	--	ENUMERABLE	Yes	--	MANDATORY
14	Method of sterilization	--	ENUMERABLE	Ionizing (Gamma) radiation process	--	MANDATORY
15	Blades shall satisfy the sterility when tested in accordance with IS:10150/1981	--	ENUMERABLE	Yes	--	MANDATORY
16	Blades should meet the performance requirements when tested as per Cl 9.2 of IS:3319/1995(Latest Revision)	--	ENUMERABLE	Yes	--	MANDATORY

DIMENSIONS, MATERIAL & CONSTRUCTION

1	Material of Blade	--	ENUMERABLE	Carbon Steel	Stainless Steel				--	GOLDEN PARAMETER
2	Carbon steel composition for blades	--	ENUMERABLE	As per Cl 4.1 of IS:3319/1995(Latest					--	MANDATORY
3	Stainless steel designation for blades	--	ENUMERABLE	Shall conform to X30Cr13 of IS:6911/1992	Shall conform to X40Cr13 of IS:6911/1992				--	GOLDEN PARAMETER
4	Thickness of Blades mm	$0.37 \leq N \leq 0.42$	Numeric	0.37 to 0.42					mm	MANDATORY
5	Dimensions of blades for small size fittings	--	ENUMERABLE	As per Table 1 of IS:3319/1995(Latest Revision)					--	MANDATORY
6	Dimensions of blades for Large size fittings	--	ENUMERABLE	As per Table 2 of IS:3319/1995(Latest RA)					--	MANDATORY

PACKING & MARKING

1	Permanent marking on the Blades	--	ENUMERABLE	As per Cl 10.1.1 of IS:3319/1995 (Latest Revision)					--	MANDATORY
4	Marking on Packages of sterile blades	--	ENUMERABLE	As per Cl 10.1.3, 10.1.3.1, 10.1.3.2 of IS:3319/1995(Latest Revision)					--	MANDATORY
6	Primary packing material for blades	--	ENUMERABLE	Wrpped in Volatile Corrosion Inhibitor (VCI) coated paper and sealed in Aluminium foil of minimu thickness 0.04mm with heat sealing coating					--	MANDATORY
8	primary packing & outer Packing of sterile blades	--	ENUMERABLE	As per Cl 11.2 of IS:3319/1995(Latest Revision)					--	MANDATORY
10	Each outer container containing the packages of Sterilized blades shall be provided with sterilization indicator on its outer surface to ensure that the contents of the package have undergone sterilization and to distinguish the sterilization packages from Non-sterile packages	--	ENUMERABLE	Yes					--	MANDATORY
11	Number of blades in a Primary Pack (Nos.)	--	NUMERIC	One					Nos	MANDATORY
12	Number of Primary packages in an outer package (Nos)	--	NUMERIC	5, 6, 10, 20, 30, 50, 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
SHELF LIFE / WARRANTY										
1	Shelf life/warranty	--	NUMERIC	60					Month	MANDATORY
2	Minimum Shelf life at the time of supply	--	ENUMERABLE	2/3rd of total shelf life					--	MANDATORY

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REMARKS



