



宁波星创医疗器械有限公司
NINGBO SINTRUE MEDICAL INSTRUMENTS CO., LTD.

Certificate of Analysis

Product Name:Surgical Blades(carbon steel)			Specification: 10/15/22/23/24#			
Quality: 1000 PCS			Standard Applied: SHXB20160062&YY/T 0174-2019			
LOT: 20210920		MFG DATE: 20210920			EXP DATE: 20260919	
Standard	Items	Inspection Items	Test	Inspection Level	Defects Quality	Result
2.1	Measures	δ : 30°-35°	30 35°	S-2 AQL=4.0 (1 , 2)	0	Pass
		b : 1.18 mm— 2 mm	1.19-1.98			
		b1: 2.43 mm—3.77 mm	2.45-3.76			
		L1: 17.83 mm—24.27mm	17.81-24.25			
		L2: 4.5mm—7.65mm	4.4-7.64			
2.2.1	Roughness	Blades $\leq$ 0.4 μ m Edge $\leq$ 0.8 μ m	0.3 0.78	S-4 AQL=4.0 (3 , 4)	0	Pass
2.2.2	Edge	no leaks, rolls, or cracks on edge,both	good		0	Pass
2.2.3	Edge Surface	edge width is similar	good	S-4 AQL=10 (7 , 8)	0	Pass
2.2.4	Blade Surface	Smooth, no spots,folds or cracks on surface	good		0	Pass
2.2.5	Packing	Packing mark is clear	good		0	Pass
2.3	Sharpness	$\leq$ 0.80N	0.6	S-2 AQL=4.0 (1 , 2)	0	Pass
2.4.1	Hardness	$\geq$ 750HV ₁₀	792 HV10		0	Pass
2.4.2	Flexibility	Good flexibility,not out of shape after test	good		0	Pass
	Sterilization	Blade is sterilize after irradiation		11PCS	0	Pass

Final Result: ☒ Accpetable ☐ Unaccpetable

Inspector:Liu Mei

Auditor:Wang yuanyuan

Date:2021.09.22

