


Product Quality Report

Document Number: ZT/JL-8.2-03-ZL03-001

Record Number: ZL-230116-6903- 28

Product Name	ACUTECH™ Headless Compression Screw	Product Specification	Φ 3.5×26mm	Lot Number	1900090086	Ref. Number	ZT. T52073526
Inspection Standard	National Medical Device Registration Standard 20163462434 Cannulated Screws						
No.	Inspection Item	Inspection Clause	Standard Requirement				Inspection Result
1	Material	2.1	It shall meet the requirements of Clause 2.1 of Technical Requirements in National Medical Device Registration Standard 20163462434.				Fulfilled
2	Mechanical Properties	2.2	Titanium Alloy Hardness of Cannulated screws and washers:≥260HV10				Fulfilled
3	Surface Quality	2.3	Surface defects: The surface of cannulated screws and washers must not have discontinuous defects; The surface roughness shall meet Clause 2.3.2 of Technical Requirements in National Medical Device Registration Standard 20163462434. Appearance: The surface of cannulated screws and washers should be smooth and free of defects such as sharp edges, burrs, and attachments.				Fulfilled
4	Dimensions	2.4	It shall meet the requirements of Clause 2.4 of Technical Requirements in National Medical Device Registration Standard 20163462434.				Fulfilled
5	Delivery Status	2.5	It shall meet the requirements of Clause 2.5 of Technical Requirements in National Medical Device Registration Standard 20163462434.				Fulfilled
Final Inspection Result		<input checked="" type="checkbox"/> Qualified <input type="checkbox"/> Disqualified					
Inspector/Date		Verifier/Date			Authorizer/Date		
 2022-06-09		迟会敏 2022-06-09			孙振清 2022-06-09		

