

Product Quality Report

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

Record Number: ZL-230116-7895-26

Product Name	ACUTEC™ Headless Compression Screw	Product Specification	Φ 4.0×45mm	Lot Number	2200115344	Ref. Number	ZT.T52074045
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		
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