IRENE

Product Quality Report

	Number: ZT/JL-8.2-03-ZL03-001 Record Number t ACUTEC™ Headless Product Lot Ref.						D-4	
Product Name	ACUTEC™ He Compression		Product Specification	Φ4.0×28mm	Lot Number	2200137371	Ref. Number	ZT.T52074028
nspection Standard	National Medical Device Registration Standard 20163462434 Cannulated Screws							
No.	Inspection Item	Inspection Clause	Standard Requirement					Inspection Resul
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 Ins	spection Result			[☑Qualified	□Disqualified		
	Inspector/Date			Verifier/Date			Authorizer/Date	
	辛小三 120095	2022-09-21		迎会和	202	22-09-21	赤板清	2022-09