IRENE

Product Quality Report

ocument Number: ZT/JL-8.2-03-ZL03-001					Record Number: ZL-230116-7895-24			
Product Name	ACUTEC™ H Compression		Product Specification	Φ4.0×38mm	Lot Number	2200113836	Ref. Number	ZT.T52074038
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 Ins	pection Result				☑Qualified	□Disqualified		
	Inspector/Date			Verifier/Date			Authorizer/Date	
	李小三120095	2022-08-16		远岛省	20.	22-08-16	节场技术	2022-08-
			<u> </u>				溪近天医疗器械	有限公