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Product Quality Report

Document Number: ZT/JL-8.2-03-ZL03-001 Record Number: ZL-230116-7895-16 Ref. ACUTEC™ Headless Product Lot **Product** Φ4.0×24mm 2200136627 ZT.T52074024 Compression Screw Specification Number Number Name Inspection National Medical Device Registration Standard 20163462434 Cannulated Screws Standard Inspection **Standard Requirement Inspection Result** No. Inspection Item Clause It shall meet the requirements of Clause 2.1 of Technical Requirements in National Medical Device **Fulfilled** 2.1 1 Material Registration Standard 20163462434. Mechanical Titanium Alloy Hardness of Cannulated screws and washers:≥260HV10 **Fulfilled** 2.2 2 **Properties** 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. **Fulfilled** Surface Quality 2.3 3 Appearance: The surface of cannulated screws and washers should be smooth and free of defects such as sharp edges, burrs, and attachments. It shall meet the requirements of Clause 2.4 of Technical Requirements in National Medical Device **Fulfilled** 2.4 Dimensions 4 Registration Standard 20163462434. It shall meet the requirements of Clause 2.5 of Technical Requirements in National Medical Device 2.5 **Fulfilled** 5 **Delivery Status** Registration Standard 20163462434. ☑Qualified **Disqualified** Final Inspection Result Verifier/Date Authorizer/Date Inspector/Date 2022-09-20 2022-09-20 2022-09-20 地名和