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Product Quality Report

Record Number: ZL-230116-6903-/2 Document Number: ZT/JL-8.2-03-ZL03-001 ACUTEC™ Headless **Product** Ref. Product Lot Φ2.5×14mm 2200096348 ZT. T52072514 Name Compression Screw Specification Number Number Inspection National Medical Device Registration Standard 20163462434 Cannulated Screws Standard Inspection **Standard Requirement** No. Inspection Item Inspection Result Clause It shall meet the requirements of Clause 2.1 of Technical Requirements in National Medical Device 2.1 **Fulfilled** 1 Material Registration Standard 20163462434. Mechanical 2.2 Titanium Alloy Hardness of Cannulated screws and washers:≥260HV10 2 **Fulfilled 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 3 Surface Quality 2.3 Registration Standard 20163462434. **Fulfilled** 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 2.4 **Fulfilled** 4 **Dimensions** Registration Standard 20163462434. It shall meet the requirements of Clause 2.5 of Technical Requirements in National Medical Device 2.5 **Delivery Status** 5 **Fulfilled** Registration Standard 20163462434. Final Inspection Result **☑Qualified** □Disqualified Verifier/Date Inspector/Date Authorizer/Date 加拉青 李小三 2022-07-20 2022-07-20 2022-07-20