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Product Quality Report

Document Number: ZT/JL-8.2-03-ZL03-001 Record Number: ZL-230116-6903-10 ACUTEC™ Headless Ref. **Product Product** Lot 2200117726 Φ2.5×12mm ZT. T52072512 Number Number Compression Screw Specification Name Inspection National Medical Device Registration Standard 20163462434 Cannulated Screws Standard Inspection Inspection Item Standard Requirement Inspection Result No. Clause It shall meet the requirements of Clause 2.1 of Technical Requirements in National Medical Device **Fulfilled** 1 Material 2.1 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** 3 Surface Quality 2.3 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 Dimensions** 2.4 4 Registration Standard 20163462434. It shall meet the requirements of Clause 2.5 of Technical Requirements in National Medical Device **Fulfilled** 5 **Delivery Status** 2.5 Registration Standard 20163462434. □Disqualified Final Inspection Result **☑**Qualified Authorizer/Date Verifier/Date Inspector/Date Two the it 2022-08-20 2022-08-20 2022-08-20 W & 300