Product Quality Report

Record Number: ZL-230116-7895-06 Document Number: ZT/JL-8.2-03-ZL03-001 ACUTEC™ Headless **Product** Lot Ref. **Product** Φ3.5×32mm 2200109891 ZT.T52073532 Compression Screw Specification Number Number Name Inspection National Medical Device Registration Standard 20163462434 Cannulated Screws Standard Inspection **Standard Requirement Inspection Result** Inspection Item No. Clause It shall meet the requirements of Clause 2.1 of Technical Requirements in National Medical Device **Fulfilled** 2.1 Material 1 Registration Standard 20163462434. Mechanical 2.2 Titanium Alloy Hardness of Cannulated screws and washers:≥260HV10 **Fulfilled** 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** 2.3 3 Surface Quality 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 Dimensions** 4 Registration Standard 20163462434. It shall meet the requirements of Clause 2.5 of Technical Requirements in National Medical Device **Fulfilled** 2.5 5 **Delivery Status** Registration Standard 20163462434. **☑**Qualified □Disqualified Final Inspection Result Verifier/Date Authorizer/Date Inspector/Date 2022-08-08 2022-08-08



2022-08-08