IRENE

Product Quality Report

Record Number: ZL-230116-6903-64 Document Number: ZT/JL-8.2-03-ZL03-001 ACUTEC™ Headless **Product** Lot Ref. Product 2200138020 Φ 2.5×8mm ZT. T52072508 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 1 Material 2.1 **Fulfilled** 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 Surface Quality 2.3 Registration Standard 20163462434. **Fulfilled** 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** 4 **Dimensions** 2.4 Registration Standard 20163462434. It shall meet the requirements of Clause 2.5 of Technical Requirements in National Medical Device 2.5 **Fulfilled Delivery Status** 5 Registration Standard 20163462434. □Disqualified Final Inspection Result **☑**Qualified Inspector/Date Verifier/Date Authorizer/Date 办板情 辛小三 120096 2022-09-21 2022-09-21 2022-09-21

