IRENE

Product Quality Report

Record Number: ZL-230116-6903- // Document Number: ZT/JL-8.2-03-ZL03-001 Ref. ACUTEC™ Headless **Product** Lot Product Φ 2.5×14mm 2200096347 ZT. T52072514 Specification Number Number Name Compression Screw 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 1 Material 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** 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 Dimensions** 2.4 4 Registration Standard 20163462434. It shall meet the requirements of Clause 2.5 of Technical Requirements in National Medical Device **Delivery Status** 2.5 **Fulfilled** 5 Registration Standard 20163462434. Final Inspection Result **☑**Qualified □Disqualified inspector/Date Verifier/Date Authorizer/Date 加拉林 2022-07-17 2022-07-17 2022-07-17