## **IRENE**

## **Product Quality Report**

Record Number: ZL-230116-6903- 25 Document Number: ZT/JL-8.2-03-ZL03-001 **Product** ACUTEC™ Headless **Product** Lot Ref. Φ3.5×20mm 2200113078 ZT. T52073520 Name Compression Screw Specification Number Number Inspection National Medical Device Registration Standard 20163462434 Cannulated Screws Standard Inspection No. Inspection Item Standard Requirement Inspection Result 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 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 4 **Dimensions** 2.4 **Fulfilled** Registration Standard 20163462434. It shall meet the requirements of Clause 2.5 of Technical Requirements in National Medical Device 2.5 5 **Delivery Status Fulfilled** Registration Standard 20163462434. **Final Inspection Result ☑**Qualified □Disqualified Inspector/Date Verifier/Date Authorizer/Date 2022-08-13 2022-08-13 2022-08-13

