## **IRENE**

## **Product Quality Report**

Document Number: ZT/JL-8.2-03-ZL03-001 Record Number: ZL-230116-7895-07 ACUTEC™ Headless Product Lot Ref. Product Φ3.5×34mm 2200110734 ZT.T52073534 Specification Name Compression Screw Number Number 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 Material 2.1 **Fulfilled** 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. 2.3 **Fulfilled** 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 4 **Dimensions** 2.4 **Fulfilled** Registration Standard 20163462434. It shall meet the requirements of Clause 2.5 of Technical Requirements in National Medical Device **Delivery Status** 2.5 5 **Fulfilled** Registration Standard 20163462434. Final Inspection Result **☑**Qualified □Disqualified Inspector/Date Verifier/Date Authorizer/Date 2022-08-09 2022-08-09 2022-08-09