## **IRENE**

## **Product Quality Report**

Document Number: ZT/JL-8.2-03-ZL03-001 Record Number: ZL-230116-6903-17 ACUTEC™ Headless Product Lot Ref. Product 2200155497 Ф 2.5×24mm ZT. T52072524 Number Compression Screw Specification Number Name 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 2.1 **Fulfilled** 1 Material Registration Standard 20163462434. Mechanical Titanium Alloy Hardness of Cannulated screws and washers:≥260HV10 2.2 **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 2.3 Registration Standard 20163462434. **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 2.5 **Fulfilled** 5 **Delivery Status** Registration Standard 20163462434. Final Inspection Result **☑**Qualified □Disqualified Verifier/Date Authorizer/Date Inspector/Date 北方地清 2022-10-25 2022-10-25 2022-10-25 李小三

