## **IRENE**

## **Product Quality Report**

Record Number: ZL-230116-6903-{} Document Number: ZT/JL-8.2-03-ZL03-001 ACUTEC™ Headless **Product** Ref. **Product** Lot 2200113832 ZT. T52072526 Φ 2.5×26mm Number Name Compression Screw Specification Number Inspection National Medical Device Registration Standard 20163462434 Cannulated Screws Standard Inspection **Standard Requirement** No. Inspection Item 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 **Fulfilled** 2 2.2 Titanium Alloy Hardness of Cannulated screws and washers:≥260HV10 **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 **Delivery Status** 2.5 **Fulfilled** 5 Registration Standard 20163462434. Final Inspection Result **☑Qualified** □Disqualified Verifier/Date Authorizer/Date Inspector/Date 2022-08-16 2022-08-16 Total 2022-08-16