## **IRENE**

## **Product Quality Report**

Document Number: ZT/JL-8.2-03-ZL03-001 Record Number: ZL-230116-7895-15 ACUTEC™ Headless **Product** Product Lot Ref. Φ4.0×22mm 2200136626 ZT.T52074022 Specification Name Compression Screw Number Number Inspection National Medical Device Registration Standard 20163462434 Cannulated Screws Standard Inspection Inspection Item **Standard Requirement** No. Inspection Result Clause It shall meet the requirements of Clause 2.1 of Technical Requirements in National Medical Device 2.1 1 Material **Fulfilled** Registration Standard 20163462434. Mechanical 2 2.2 Titanium Alloy Hardness of Cannulated screws and washers:≥260HV10 **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 Registration Standard 20163462434. 3 Surface Quality 2.3 **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 2.4 **Dimensions** 4 **Fulfilled** Registration Standard 20163462434. It shall meet the requirements of Clause 2.5 of Technical Requirements in National Medical Device 5 **Delivery Status** 2.5 **Fulfilled** Registration Standard 20163462434. Final Inspection Result **M**Oualified □Disqualified Inspector/Date Verifier/Date Authorizer/Date 2022-09-20 2022-09-20 辛小三 120095 2022-09-20 地名和