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Product Quality Report

Document Number: ZT/JL-8.2-03-ZL03-001 Record Number: ZL-230116-7895-21 **Product** ACUTEC™ Headless Product Lot Ref. Φ4.0x32mm 2200113461 ZT.T52074032 Specification Number Name Compression Screw 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 **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 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 **Dimensions** 2.4 **Fulfilled** 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. □Disqualified Final Inspection Result ☑Qualified Inspector/Date Verifier/Date Authorizer/Date 2022-08-15 2022-08-15 2022-08-15