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Product Quality Report

Document Number: ZT/JL-8.2-03-ZL03-001 Record Number: ZL-230116-7895-01 ACUTEC™ Headless **Product** Ref. Product Lot Ф 3.5×26mm 2200049221 ZT.T52073526 Specification Compression Screw Number Name 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 2.1 **Fulfilled** 1 Material Registration Standard 20163462434. Mechanical Titanium Alloy Hardness of Cannulated screws and washers:≥260HV10 2 2.2 **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 2.3 Registration Standard 20163462434. 3 Surface Quality **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 4 Dimensions **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 Verifier/Date Inspector/Date Authorizer/Date 2022-04-25 2022-04-25 2022-04-25