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Product Quality Report

Document Number: ZT/JL-8.2-03-ZL03-001 Record Number: ZL-230116-7895-14 Ref. Lot ACUTEC™ Headless **Product Product** 2200136049 ZT.T52074020 Φ4.0×20mm Number Number **Compression Screw** Specification Name Inspection National Medical Device Registration Standard 20163462434 Cannulated Screws Standard Inspection Standard Requirement Inspection Result Inspection Item No. Clause It shall meet the requirements of Clause 2.1 of Technical Requirements in National Medical Device **Fulfilled** 2.1 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 **Fulfilled** Registration Standard 20163462434. 2.3 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 **Fulfilled Dimensions** 2.4 4 Registration Standard 20163462434. It shall meet the requirements of Clause 2.5 of Technical Requirements in National Medical Device **Fulfilled** 2.5 5 **Delivery Status** Registration Standard 20163462434. □Disqualified ☑Qualified Final Inspection Result Authorizer/Date Verifier/Date Inspector/Date 2022-09-20 2022-09-20 2022-09-20 地层 3