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Product Quality Report

Document Number: ZT/JL-8.2-03-ZL03-001 Record Number: ZL-230116-7895-03 ACUTEC™ Headless **Product Product** Lot Ref. Φ3.5×30mm 2200109098 ZT.T52073530 Compression Screw Specification Number Number Name 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 2.1 **Fulfilled** Material 1 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 **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 5 Fulfilled Registration Standard 20163462434. □Disqualified Final Inspection Result ☑ Qualified Verifier/Date Inspect.or/Date Authorizer/Date 李小三 2022-08-08 2022-08-08 2022-08-08