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Product Quality Report

Record Number: ZL-230116-7895-08 Document Number: ZT/JL-8.2-03-ZL03-001 Ref. ACUTEC™ Headless Product Lot Product Ф 3.5x36mm 2200049224 ZT.T52073536 Compression Screw Specification Number Number Name Inspection National Medical Device Registration Standard 20163462434 Cannulated Screws Standard Inspection Standard Requirement Inspection Item Inspection Result No. Clause It shall meet the requirements of Clause 2.1 of Technical Requirements in National Medical Device **Fulfilled** 1 Material 2.1 Registration Standard 20163462434. Mechanical **Fulfilled** 2.2 Titanium Alloy Hardness of Cannulated screws and washers:≥260HV10 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** 3 Surface Quality 2.3 Registration Standard 20163462434. 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** 2.4 4 **Dimensions** 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. □Disqualified **☑**Qualified Final Inspection Result Authorizer/Date Inspector/Date Verifier/Date 2022-04-26 地名和 2022-04-26 2022-04-26