

Product Quality Report

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Record Number: ZL-230116-7895-02

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|---|---|---|--|------------|---------------------------|-------------------|--------------|
| Product Name | ACUTECH™ Headless Compression Screw | Product Specification | Φ 3.5×28mm | Lot Number | 2200109097 | Ref. Number | ZT.T52073528 |
| Inspection Standard | National Medical Device Registration Standard 20163462434 Cannulated Screws | | | | | | |
| No. | Inspection Item | Inspection Clause | Standard Requirement | | | Inspection Result | |
| 1 | Material | 2.1 | It shall meet the requirements of Clause 2.1 of Technical Requirements in National Medical Device Registration Standard 20163462434. | | | Fulfilled | |
| 2 | Mechanical Properties | 2.2 | Titanium Alloy Hardness of Cannulated screws and washers:≥260HV10 | | | Fulfilled | |
| 3 | Surface Quality | 2.3 | 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 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. | | | Fulfilled | |
| 4 | Dimensions | 2.4 | It shall meet the requirements of Clause 2.4 of Technical Requirements in National Medical Device Registration Standard 20163462434. | | | Fulfilled | |
| 5 | Delivery Status | 2.5 | It shall meet the requirements of Clause 2.5 of Technical Requirements in National Medical Device Registration Standard 20163462434. | | | Fulfilled | |
| Final Inspection Result | | <input checked="" type="checkbox"/> Qualified <input type="checkbox"/> Disqualified | | | | | |
| Inspector/Date | | Verifier/Date | | | Authorizer/Date | | |
| <div>辛小三</div> <div>120095</div> 2022-08-07 | | <div>迟会敏</div> 2022-08-07 | | | <div>郭振清</div> 2022-08-07 | | |

