


## Product Quality Report

Document Number: ZT/JL-8.2-03-ZL03-001

Record Number: ZL-230116-6903-08

| Product Name   | ACUTECH™ Headless Compression Screw   | Product Specification   | Φ 2.5×11mm   | Lot Number | 1800062131      | Ref. Number       | ZT. T52072511 |
|--|---|---|--|------------|-----------------|-------------------|---------------|
| 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.<br>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 |                   |               |
|  2022-06-09 |   | 迪会敏 2022-06-09  |  |            | 郝振清 2022-06-09  |                   |               |

