

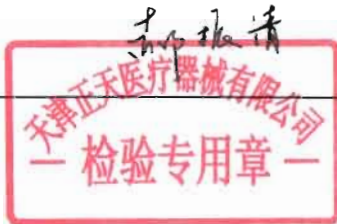


## Product Quality Report

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

Record Number: ZL-230116-7895-04

|  |   |   |  |            |  |                   |              |
|--|---|---|--|------------|--|-------------------|--------------|
| Product Name   | ACUTECH™ Headless Compression Screw   | Product Specification   | Φ3.5×32mm  | Lot Number | 1900069634   | Ref. Number       | ZT.T52073532 |
| 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 |   |  2022-06-09 |  |            |  2022-06-09 |                   |              |