

Product Quality Report

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

Record Number: ZL-230116-6903-02

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|---|--|---|--|------------|---------------------------|-----------------|---------------|
| Product Name | DIAMOND™ Polyethylene Acetabular Cup | Product Specification | 46# (Φ46/Φ28) | Lot Number | 2100096165 | Ref. Number | ZT. P22310046 |
| Inspection Standard | National Medical Device Registration Standard 20173460995_Hip Prosthesis | | | | | | |
| Inspection Item | Inspection Clause | Standard Requirement | Inspection Result | | | Inspection Item | |
| 1 | Material | 2.1 | It shall meet the requirements of Clause 2.1 of Technical Requirements in National Medical Device Registration Standard 20173460995. | | | Fulfilled | |
| 2 | Surface Quality | 2.2 | Appearance: It shall meet the requirements of Clause 2.2.1 of Technical Requirements in National Medical Device Registration Standard 20173460995. Defects: The surface of hip prosthesis must not have discontinuous defects; Roughness: It shall meet the requirements of Clause 2.2.3 of Technical Requirements in National Medical Device Registration Standard 20173460995. Dimensions: It shall meet the requirements of Clause 2.2.4 of Technical Requirements in National Medical Device Registration Standard 20173460995. | | | Fulfilled | |
| 3 | Sterilization | 2.3 | It shall meet the requirements of Clause 2.3 of Technical Requirements in National Medical Device Registration Standard 20173460995. | | | Fulfilled | |
| Final Inspection Result | | <input checked="" type="checkbox"/> Qualified <input type="checkbox"/> Disqualified | | | | | |
| Inspector/Date | | Verifier/Date | | | Inspector/Date | | |
| <div>李永三</div> <div>120095</div> 2022-01-01 | | <div>迟会敏</div> 2022-01-01 | | | <div>郝振清</div> 2022-01-01 | | |

