## **IRENE**

## **Product Quality Report**

ocument Nu	mber: ZT/JL-8.2-03-ZL0		Record Number: ZL-230116-6903-0					
Product Name	DIAMOND™ Polyethylene Acetabular Cup	Product Specification	46# (Φ46/Φ28)	Lot Number	:	2100096164	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		☑Qualified □Disqualified						
Inspector/Date		Verifier/Date Inspector/Date						
<b>学小三</b> 120095		2022-01-01	迎会和	202	2-01-01	They	友情	2022-01-0

