## **IRENE**

## **Product Quality Report**

ocument Nu	umber: ZT/JL-8.2-03-ZL0	3-001		Record Number: ZL-230116-6903-0ろ			
Product Name	DIAMOND™  Cementless Acetabular  Cup Screw	Product Specification	Φ6.5×30mm	Lot Number	2200084131	Ref. Number	ZT. T35006530
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 I	nspection Result			☑Qualified	□Disqualified		
Inspector/Date			Verifier/Date Inspector/Date			Inspector/Date	
	辛小三 120098	2022-07-19	迎出海	2022-07-1	.9	ho that	2022-07-1