



武汉金瑞达医疗用品有限公司

DANSU-CHINA HEALTH CARE CO., LTD.

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NO. 2023-10-12037

DECLARATION OF CONFORMITY

Manufacturer:	Dansu-China Health Care Co., Ltd. No. 366 Pengjialing, Yongfeng Street Hanyang District 430050 Wuhan		
European Representative:	Shanghai International Holding Corp. GmbH(Europe) Eiffestraße 80, 20537 Hamburg, Germany		
SRN:	Manufacturer: CN-MF-000012826	ERP: DE-AR-000000001	
Medical Device:	Sterile Disposable Dressing Packs and Procedure Packs		
Classification:	Class IIa, Sterile, Rule 6		
Conformity Assessment Route:	Annex IX		
Declare that this DOC is issued under our sole responsibility and refers to the following object:			
EMDN Code:	T0202		
Types/Model:	IUD Insertion Kit-H7 19010		
Basic UDI-DI:	6947329669473296024372N		

Meet the provisions of the Regulation EU 2017/745(MDR) and all applicable European Union harmonized standards.
It bears the mark



This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

STANDARDS APPLIED:

ISO13485: 2016 Medical devices—Quality management systems—Requirements for regulatory purposes

Medical Device Directive:	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices. All supporting documentation is retained at the premises of the manufacturer
Notified Body:	TÜV SÜD Product Service GmbH Ridlerstr. 65, 80339 München, Germany
NB Identification number:	0123
Certificate No.:	G2 059454 0028 Rev. 01
Expire date:	2024/05/26
Start of CE Marking:	2021/02/04

Management Representative

Position, Name, Signature



Bill Dai

Place of Issue: WuHan

Date of Issue: 2023-10-12