



EU Declaration of Conformity



according to MDR Regulation (EU) 2017/745

for Class I Medical Device (non-sterile, without measuring function, non-reusable)

Manufacturer: CHANGZHOU DSB MEDICAL CO., LTD
Address: #355, Longjin Road, Changzhou Economic Development Zone,
Changzhou City, Jiangsu Province, China
SRN in EUDAMED: CN-MF-000024537

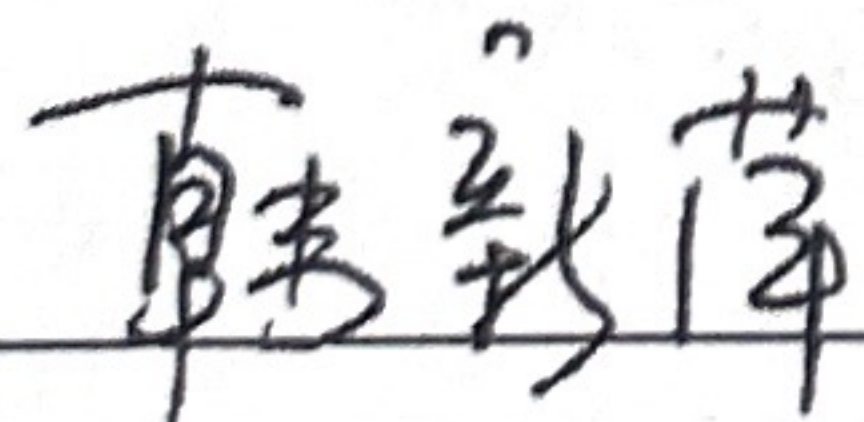
Manufacturer's authorised representative (EC Rep):

Wellkang Ltd (www.CE-marking.eu),
Enterprise Hub, NW Business Complex,
1 Beraghmore Rd, Derry, BT48 8SE, Northern Ireland.
EC Rep's SRN in EUDAMED: XI-AR-000001836.

We, the manufacturer, declare under the sole responsibility of the manufacturer that

the medical device(s)	Product Name	Model/code/Ref, (for identification/traceability)
	Male External Catheter	MECSH18、MECSH20、MECSH25、MECSH29、MECSH32、MECSH36、MECSH41、MECST18、MECST20、MECST25、MECST29、MECST32、MECST36、MECST41、MECUL18、MECUL20、MECUL25、MECUL29、MECUL32、MECUL36、MECUL41
Risk class	Class I , Rule 1 according to Annex III of Regulation(EU) 2017/745 (non-sterile, without measuring function, non-reusable)	
covered by the present declaration is/are in conformity with the MDR- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices and, if applicable, with any other relevant Union legislation.		
Notified Body (name & number), conformity assessment procedure, & Certificate no.	NOT applicable	
Basic UDI-DI	697264257MECSW	
Common specification (CS)	NOT applicable	

Signed for on behalf of DSB MEDICAL CO., LTD

Signature: 

Name of authorized Person: Han Xinping

Date: 2023/09/28

Position held in the company: Management Representative

Place: Changzhou, Jiangsu, China

