# 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: 韩新萍

Name of authorized Person: Han Xinping

Date: 2023/09/28

Position held in the company: Management Representative

Place: Changzhou, Jiangsu, China