

Declaration of Conformity

Manufacturer: **Huaian Medicom Medical Technology Co.,Ltd**
No.123,Meicheng West Road ,Huaian223002 ,Jiangsu, China.

European Representative: **Caretechion GmbH**
Niederrheinstr. 71, 40474 Düsseldorf, Germany

Product Name: **IV Catheter**
Specification: **1.With injection port and wings: 14G,16G,18G,20G,22G,24G,26G;**
2.Without injection port,with wings:14G,16G,18G,20G,22G,24G,26G
3.Pen-Like :14G,16G,18G,20G,22G,24G,26G

UMDNS Code: **12-162**

Classification (MDD, Annex IX): **IIa, Rule 7**

Conformity Assessment Route: **Annex VII+Annex V**

We herewith declare under our sole responsibility that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer. The manufacturer is exclusively responsible for the declaration of conformity.

DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC). Amended by DIRECTIVE 2007/47/EC of 5 September 2007

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstr. 65,
80339 München, Germany

NB Identification number: 0123

(EC) Certificate(s): G2 004080 0002 Rev. 01

Expire date of the Certificate: 2023-12-26

Start of CE Marking: Not Yet

Place, Date of Issue: HuaiAn, 2020-03-19

Signature: 

Name: **Gao Qing**

Position: **General Manager**

ZERTIFIKAT ◆ CERTIFICATE ◆ CERTIFICADO ◆ CERTIFICAT ◆ 認證證書 ◆ CERTIFICATE ◆ CERTIFICADO ◆ CERTIFICAT ◆



Product Service

Certificate

No. Q6 004080 0001 Rev. 01

Holder of Certificate: **Huaian Medicom Medical Technology Co., Ltd.**
 No. 123, Meicheng West Road
 223002 Huaian, Jiangsu
 PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: **Production and Distribution of the IV Catheter, Infusion Connector (Heparin Cap, Combi Stopper), 3-way Stopcock with Extension Tube & without Extension Tube, Needle Free Connector (with & without Extension Tube), Suction Connecting Tube (with and without Yankauer Handle), Urine Drainage Bag, Suction Catheter, Nutritive Tube (Stomach Tube & Feeding Tube), Enteral Feeding Bag Set, Nelaton Catheter**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q6 004080 0001 Rev. 01

Report No.: SH21132201
Valid from: 2021-12-29
Valid until: 2024-12-26

Date, 2021-12-29

Christoph Dicks
 Head of Certification/Notified Body