

Declaration of Conformity

Manufacturer: Conod Medical Co., Limited

Address: No.11 Hongfeng Road, Baimao Industrial Park, Changshu City, Jiangsu Province,
215532. P.R. China

European Representative: Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg Germany

Product: Urethral Catheter

GMDN Code: 34917

UMDNS Code: 10685

Model Code: Silicone (Two-way: 6Fr-26Fr, Three-way: 12Fr-26Fr)

Classification (MDD, Rule V of Annex IX): IIb

Conformity Assessment Route: Annex II without section 4

We herewith declare that the above mentioned products meet the provisions of the following EC council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

DIRECTIVES

General applicable directives:

Medical device directive: Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC).

Notified Body: TUV SUD Product Service GmbH, Ridlerstr.65, 80339 Munchen , Germany

NB Identification number: 0123

EC Certificate: G1 071789 0043 Rev.02

Expiry date of the certificate: 2024-05-26

Start of CE Marking: Not until now.

Place, Date: Conod Medical Co., Limited. No.11 Hongfeng Road, Baimao Industrial Park,
Changshu city, Jiangsu Province, 215532. P.R. China 2019-10-25

Signature _____ *SPM. 2019.10.25.*

Name: Song Pingran

Position: Head Regulatory Affair
