



NINGBO GREETMED MEDICAL INSTRUMENTS CO., LTD.

Declaration of Conformity

Manufacturer:

Ningbo Greetmed Medical Instruments Co., Ltd.

Address: 16F-3, No.1 Building, Chuangyuan Road, Hi-Tech Zone, 315042 Ningbo, PEOPLE'S
REPUBLIC OF CHINA

Tel: 86-574-87739070 Fax: 86-574-87722360

European Representative:

Shanghai International Holding Corp. GmbH (Europe)

Address: Eiffestrasse 80, 20537 Hamburg, Germany

Tel: +49-40-2513175 Fax: +49-40-255726

Email: shholding@hotmail.com

Product Name: Umbilical Suction Catheter

Size: FR4, FR5, FR6, FR8

Model: GT025-200

Classification (MDD, Annex IX): IIa (Rule 5 of Annex IX)

Conformity Assessment Route: Annex V.3

We herewith declare 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.

DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC).

Standard Applied: All applicable harmonized Standard (publish in the Official Journal of the European Communities)

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

Identification number: CE0123

EC) Certificate(s): G20732830046 Rev.01

Expire date of the Certificate: May 26th 2024

Place, Date of Issue: Ningbo , Mar 16th 2020

Signature:

Name: Li Guirong

Position: General Manager

