



NINGBO GREETMED MEDICAL INSTRUMENTS CO., LTD.

Declaration of Conformity

Manufacturer:

Ningbo Greetmed Medical Instruments Co., Ltd.

Address: 18F-3, No.1 Building, Wante Business Centre, 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: Condom

Model: GT113-100

Size: 49mm, 52mm, 55mm

Length 180mm - 190mm

Thickness 0,05mm-0,08mm

Classification (MDD, Annex IX): IIb

Conformity Assessment Route: Annex II

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)

(EC) Certificate(s): G10732830045 Rev.00

Expire date of the Certificate: 2024-04-17

Place, Date of Issue: Ningbo, 2019-08-27

Signature:

Name: Li Guirong

Position: General Manager

