



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: Intrauterine Contraceptive Device (Copper TCU380A)

Model: TCU380A

Classification (MDD) III

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

Place, Date of Issue: Ningbo, Nov.28, 2020

Signature:

Name: Li Guirong

Position: General Manager

