NINGBO GREETMED MEDICAL INSTRUMENTS CO., LTD.

Declaration of Conformity

Manufacturer:

Ningbo Greetmed Medical Instruments Co., Ltd.

Address: 16F-1, Building 1, No.98 Chuangyuan Road, Hi-Tech Zone, 315042 Ningbo, Zhejiang Province, 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

Product Name: hypodermic needle

Size:

SyriPIC 26G x 12 mm (Ref. 20120)

SyriPIC 25G x 16 mm (Ref. 20220)

SyriPIC 26G x 25 mm (Ref. 20320)

SyriPIC 24G x 25 mm (Ref.20420)

SyriPIC 23G x 25 mm (Ref.20520)

SyriPIC 27G x 19 mm (Ref.20720)

SyriPIC 30G x 13 mm (Ref. 20820)

UMDNS Code: 12745

Classification (MDD, Annex IX): IIa (Rule 6 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.

Ningbo Greetmed Medical Instruments Co., Ltd. is exclusively responsible for 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).

Standard Applied:

ISO7864:2016,ISO14971:2019 ,ISO 11607-1:2019 , ISO11607-2:2019, IS010993-1: 2018 , ISO 10993-5: 2009, ISO 10993-7: 2008, ISO 10993-10: 2010, ISO11135-1: 2014, ISO15223-1:2021 , ISO 11737-1: 2018 , ISO14155-1:2020, ISO14155-2:2003, EN556-1:2001, BS EN 556-2-2015

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 MÜnchen, Germany
Identification number: CE0123

(EC) Certificate(s): G20732830046Rev.01

Expire date of the Certificate: May 26, 2024

Place, Date of Issue: Ningbo, April 26, 2021

Signature: 

Name: Li Guirong

Position: General Manager