NINGBO PINMED INSTRUMENTS CO., LTD.

Declaration of Conformity

Manufacturer:

Ningbo Pinmed Instruments Co., Ltd.
Address: Room (22-1)(22-2)， No.455, East Zhongshan Road, Yinzhou District, 315040 Ningbo，PEOPLE'S REPUBLIC OF CHINA
Tel: 86-574-87739070 Fax: 86-574-87722360

European Representative:

Lotus NL B.V.
Address: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

Product Name:see attachment
Size:see attachment
UMDNS Code: see attachment
Classification (MDD, Annex IX): see attachment
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 Pinmed 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).

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

(EC) Certificate(s): G2 095729 0007，G2S 095729 0009
Expire date of the Certificate: 2024-05-26
Place, Date of Issue: Ningbo, 2021-03-26

Signature: 李桂蓉
Name: Li Guirong
Position: General Manager

NINGBO PINMED INSTRUMENTS CO.,LTD 宁波品美医疗器材有限公司 3302100037416

Attachment:

Product Name	Model	UMDNS Code	Classification (MDD, Annex IX)
foley catheter nelaton	FR12-24	10734	IIb (Rule 5 of Annex Ⅸ)
foley catheter tiemann	FR12-24	10762	IIb (Rule 5 of Annex Ⅸ)