

Declaration of Conformity

Manufacturer: **Ningbo Foyomed Medical Instruments Co., Ltd.**

Room 805-806, No. 299 of Jiangnan Yipin Garden, Hi-Tech Zone,
315040, Ningbo, PEOPLE'S REPUBLIC OF CHINA

European Representative: **Prolinx GmbH**
Brehmstr. 56, 40239, Duesseldorf (Germany)

Product Name: **PE/CPE Shoe Cover**

Classification (MDD, Annex IX): **I**

Conformity Assessment Route: **Annex VII**

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. We are exclusively responsible for the 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). Amended by DIRECTIVE 2007/47/EC

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

(ISO) Certificate(s): Q6 093011 0010 Rev. 00

Expire date of the Certificate: 2025-01-26

Place, Date of Issue: Ningbo, 2022-09-07

Signature: 
Name: Yingxin Ku
Position: General Manager

宁波凡友医疗器械有限公司
NINGBO FOYOMED MEDICAL INSTRUMENTS CO., LTD