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: Stethoscope

Classification (MDD, Annex IX): I, rule 1.

UMDNS-Code: 13750

Conformity Assessment Route: Annex V

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:

EN ISO 13485:2016 Medical devices-Quality management systems-Requirements for regulatory purpose(ISO13485:2016)

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstr. 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, 2023-03-01
Signature:
Name: Yingxia Xu
Position: General Manager

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

Digitally signed by Granaci Boris
Date: 2023.03.15 15:19:25 EET
Reason: MoldSign Signature
Location: Moldova