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: **Disposable anesthesia needle and anesthesia kit**

Classification (MDD, Annex IX): **III, rule 7**

Conformity Assessment Route: **Annex II.3 + II.4**

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

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

Signature:
Name: Yingxin Xu
Position: General Manager

Digitally signed by Iurcu Nicolae
Date: 2022.09.13 23:34:56 EEST
Reason: MoldSign Signature
Location: Moldova