EU Declaration of Conformity

Manufacturer: Conod Medical Co., Limited
Address: No.11 Hongfeng Road, Baimao Industrial Park, Guli Town, 215532 Changshu City, Jiangsu Province. P.R. China

Authorised Representative: Shanghai International Holding Corp. GmbH (Europe)
Address: Eiffestraße 80, 20537 Hamburg Germany

SRN：CN-MF-000012600

Product Name: Enema set(kit)

Product reference	Basic UDI-DI
DYNDE70100A	69558240CW0100000EB0003TM

Intended purpose: This product is intended to instill water or non-medicated enema solution into the colon through a rectal tubing inserted into the rectum to promote evacuation of the contents of the lower colon.

Classification (MDR, Rule V of Annex Ⅷ): Ⅰ
Conformity assessment route: Article19+Annex Ⅱ＋Annex Ⅲ

We herewith declare that the above mentioned products meet the provisions of the following regulation and harmonized standards published on the Official Journal of the European Union, and that this EU declaration of conformity is issued under the sole responsibility of Conod Medical Co., Limited.

Regulation

General applicable regulations:

Medical Device Regulation: Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

Place, Date: Conod Medical Co., Limited. No.11 Hongfeng Road, Baimao Industrial Park, Guli Town, 215532 Changshu City, Jiangsu Province. P.R. China 2023-11-22

Signature _____
Name：Chu, Ping
Position: Management Representative

江苏康诺医疗器械股份有限公司
CONOD MEDICAL CO., LIMITED