

## 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)

Model Code and Size / Basic UDI-DI:

Enema Bag Set : (500ml ~2000)ml / 69558240CW0100000EB0001TH

Enema Bucket Set:(1000 ml ~2000) ml / 69558240CW0100000EB0002TK

Enema Bag Kit : (500ml ~2000)ml / 69558240CW0100000EB0003TM

Enema Bucket Kit: (1000 ml ~2000) ml /69558240CW0100000EB0004TP

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 2022-07-14

Signature

Name: Yang chong

Position: Management Representative

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