EU Declaration of Conformity

According to Art. 19 of Regulation (EU) 2017/745 on Medical Devices

Manufacturer

Name: Ningbo Albert Novosino Co.,Ltd.

Address: No.1 Xinheng 3 Road, Cicheng Town Jiangbei District, 315036 Ningbo, Zhejiang China

Trademark: N.A.

European Authorized Representative

Name: Humiss International B.V.

Address: Joop Geesinkweg 701, 1114 AB Amsterdam-Duivendrecht, the Netherlands

SRN: NL-AR-000001490

Tel: +31 (0)20 369 8116 **Fax:** +31 (0) 20 369 8114 **E-mail:** ce-tech@humiss.com

SRN: CN-MF-000008571 Trade name: Enema Kit Product Name: Enema Kit

Product code/Catalogue number: 1L, 1.5L, 2L,3L,4L

Basic UDI-DI: 697191946EK4H UMDNS Code: 11-582

Classification (acc. MDR, Annex VIII): Class Ⅰ , Rules 5 CE certificate No.: N.A.

Name and ID of the Notified Body: N.A.

We hereby declare under our sole responsibility that the class I medical devices listed above are in conformity with the general safety and performance requirements which apply (Annex I of the European Union Medical Device Regulation 2017/745). All supporting documentations are retained under the premises of the manufacturer.

This declaration is made in accordance with Annex Ⅳ of the European Union Medical Device Regulation 2017/745 and is valid for an undetermined period of time.

I, Jorome Zhang, hereby declare that the equipment specified above conforms to MDR 2017/745.

Regulation:

EU MDR 2017/745 REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017

Applicable Standards:

EN ISO13485: 2016 EN ISO14971: 2019 EN ISO 15223-1: 2016 EN ISO10993-1: 2020

EN ISO10993-5: 2009 EN ISO10993-10: 2013 EN 1041:2008+A1:2013 EN 62366-1:2015

Name of the authorized person: **Jorome Zhang**

Position: Corporate Representative

Signature: Jorome Zhang Date: June 29, 2021

宁波洛孚医疗科技有限公司

Ningbo Albert Novosino Co.,Ltd.