



EU Declaration of Conformity



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

Manufacturer

Name: Ningbo Albert Novosino Co.,Ltd.

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Trademark: N.A.

European Authorized Representative

Name: Humiss International B.V.

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E-mail: ce-tech@humiss.com

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

Product code/Catalogue number: 65ml, 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: 

Date: July 22, 2021

宁波洛孚医疗科技有限公司
Ningbo Albert Novosino Co.,Ltd.