



DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Cert GmbH,
Harffstr.47,40591 Düsseldorf, Germany
SRN: DE-AR-000010869

Conformity Assessment

Conformity Assessment Procedure
Annex II+III of Regulation (EU) 2017/745

Applicable Standards

EN ISO 14971:2019
EN ISO 15223-1:2021
EN ISO 20417:2021
EN ISO 10993-1:2020
EN ISO 10993-5:2009
EN ISO 10993-10:2013

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-G02060303-06.
All the supporting documentation is retained at the premises of the manufacturer.
The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer.

Manufacturer

Name: Ningbo Albert Novosino Co.,Ltd.
Address: #4 Building, No. 17, Yunshan Middle Road, Sanqishi Town, Yuyao City, Zhejiang Province, 315412, P. R. China
SRN: CN-MF-000008571

Product Information

Name: Enema Kit
Model: 0.5L, 1L, 1.5L, 1.75L, 2L, 2.5L, 3L, 3.5L, 4L, 450ml
EMDN: G02060303
Classification: Class I, According to Rule 5, Annex VIII, Regulation (EU) 2017/745

Declaration

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the applicable standards above

Signature: Victor Date: 2023.4.26

Position: GM

Place: Zhejiang/China

