DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.

Fascinatio Boulevard 522, Unit 1.7,

2909VA Capelle aan den IJssel, The Netherlands

SRN: NL-AR-000000247

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: 2023

EN ISO 10993-23: 2021

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-Q030103-01.

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: MeishiKeli (Xiamen) Technology Co., Ltd

Address: Room 1924, No. 30 Pingshan Nanli, Haicang District, Xiamen City, Fujian Province

SRN: CN-MF-000043944

Product Information

Name: Nasal Rinse Mix

Model: 0.63g/0.9g/1.8g/2.2g /2.25g/2.7g/3.6g/4.5g/5.4g

EMDN: Q030103

Basic UDI-DI: 697364808NasalRinseMixT8

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: Date: 2024.8.28

Cheng xiong Wen

Position: GM Place: Fujian /China