

Document Name	EU Declaration of Conformity			Page	Page 1 of 1
Document No.	CE-RD-01-01	Version	01	Effective Date	2021-10-12

EU Declaration of Conformity

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

Manufacturer: Name: Anhui Rongda Medical Equipment Co., Ltd.
Add: Industrial Park, Renhe Town, Tianchang City 239300, Anhui, China
Trade name / Trademark: RONGDA™
SRN: Not available yet
European Representative: Name: MedPath GmbH
Add: Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany
SRN: DE-AR-000000087
Product Name: SMILE MASK
Trade name: SMILE MASK
Product type: With earloop
Product size: 17.5cm×9.5cm
Basic UDI: Not available yet
UMDNS Code: 12-447
Classification acc. to MDR Ax. VIII: Class I, Rule 1
Applied Common Specification/ standard: ENISO13485:2016 EN ISO14971:2019 ISO10993-1:2018
ENISO10993-5:2009 ENISO10993-10:2013 EN1041:2008/A1:2013
ENISO 15223-1:2016
Conformity assessment procedure: MDR Annex II + Annex III
CE certificate No.: N.A.
Name/address of the Notified Body: N.A.
ID of the Notified Body: N.A.

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/745 on Medical Devices (MDR). All supporting documentations are retained under the premises of the manufacturer.

Place of Issue: Tianchang, CHINA

Date of Issue: 2021-10-12

Signature:



Mr. Yihong Zhang

Position: General Manager

Company seal: