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|---------------|------------------------------|---------|----|----------------|-------------|
| Document Name | EU Declaration of Conformity | | | Page | Page 1 of 1 |
| Document No. | CE-RD-01-01 | Version | 04 | Effective Date | 2021-11-16 |

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: Miles-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 x 9.5cm

UMDNS Code: 12-447

Classification acc. to MDR Ax. VIII: Class I, Rule I

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 BS EN14683+AC:2019 EN166:2019 Clause 7.1.3
Clause 5.2.2, Clause 5.2.3, Clause 5.2.4, & Clause 7.3.2
Clause 5.2.5, Clause 5.2.7

This product is Compliant with the Transparent Facemask Technical Specification on GOV.UK.

CE certificate No.: N.A

Name/address of 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: 2021-11-16

Signature:

Mr. Yihong Zhang

Position:

General Manager

Company seal:

