

**01. EC Declaration of Conformity**

Manufacturer: Name: ANHUI RONGDA MEDICAL EQUIPMENT CO.,LTD  
Add: Industrial park,Renhe Town,Tianchang city 239300,Anhui,China

European Representative: Name: ZOUSTECH S.L.  
Add: Pso. Castellana,141-Planta 19, 28046-Madrid, Spain

Product Name: Disposable Medical Face Mask

Object of the declaration: Model: RDYL-00305, With Earloop

UMDNS Code: 12-447

Classification (MDD, Annex IX): I , rule 1

Conformity Assessment Route: Annex VII

We herewith declare in sole responsibility that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer. We are exclusively responsible for the declaration of conformity.

**DIRECTIVES**

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC modified with the Directive 2007/47/EC

Applicable standards by EU

ENISO13485:2016 EN 14683:2019+AC:2019 ISO14971:2019

ISO10993-1:2018 ENISO10993-5:2009 ISO10993-10:2010

ENISO 15223-1:2016 EN1041:2008/A1:2013

Place of Issue: TIANCHANG, CHINA

Date of Issue: 2020-05-19

Signature:

Mr.Yihong Zhang

Position: General Manager

