



EU Declaration Of Conformity

Manufacturer **Changzhou Ruide Medical Technology Co., Ltd**

Address **No.8 Hefeng Road, Zhenglu Town, Changzhou City, Jiangsu Province, China**

EC Representative **Luxus Lebenswelt GmbH**
Kochstr. 1, 47877, Willich, Germany
0049-1715605732

Product: **Disposable Medical Mask**

Model: **17.5*9.5cm, 16.5*9.5cm, 14.5*9.5cm, 12.5*9cm**

Classification (MDD, Annex IX): **Class I Rule 1**

We herewith declare 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 DOC.

DIRECTIVES

General applicable directives:

Medical Device Directive : COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC).

Standards:

EN 14683:2019;
ISO 10993-5:2009;
ISO 10993-10:2010;

All applicable harmonized Standards (published in the Official Journal of the European Communities)

Date CE mark was affixed: **April 16, 2020**

Place, Date: **Changzhou, 16.04.2020**

Signature: _____

Name/Position: **Zhai Xiaofeng / G.M**

