



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

Doc. No: MDR-DOC-20200605155

**Manufacturer:** Ningbo Rouse Ruijian Technology Co. , Ltd.  
Yu shantou village, dongqiao town, haishu district, ningbo city, zhejiang province, China  
315157

**European Authorized Representative:** 3A Inno UG(haftungsbeschränkt)  
Eisfelder Str. 12, D-96450 Coburg, Germany

**The medical device:** Disposable Face Mask

**Product code:** LZ202001

**Trade Mark:** Not Applicable

**SRN:** Not available yet

**Basic UDI:** Not available yet

**Intended purpose:** This product meets European Standard EN 14683, Type I.  
As a medical face mask, it is intended to provide a barrier to minimize the direct transmission of infective agents between staff and patient. The medical face masks may also be intended to be worn by patients and other persons to reduce the risk of spread of infections, particularly in epidemic or pandemic situations.

**Classification:** Class I (Annex V of Directive 93/42/EEC concerning Medical Devices and Annex VIII of Regulation (EU) 2017/745 on the Medical Devices)

**Harmonised Standard which Comply with:** EN14683:2019+AC:2019 Medical Face Masks. Requirements And Test Methods Type I and all applicable harmonized standards published in the Official Journal of the European Union

**Conformity assessment procedure:** Self certification + type testing

**Start of CE marking:** 05-JUN-2020

**Expire date of the Certificate:** 04-JUN-2021

**Notified Body:** Not Applicable

**Certificate:** Not Applicable

*We, the manufacturer, herewith declare under our sole responsibility that the above mentioned products meet the provisions of the Regulation (EU) 2017/745 on the Medical Devices (MDR) and the Directive 93/42/EEC concerning Medical Devices (MDD). All supporting documentation is retained under the premises of the manufacturer.*

Ningbo, 05-JUN-2020  
Place, Date

Lijun Ye, General Manager  
Ningbo Rouse Ruijian Technology Co., Ltd.



12/20