



DECLARATION OF CONFORMITY

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

Manufacturer:

European Authorized Representative:

3A Inno UG(haftungsbeschränkt)
Eisfelder Str. 12, D-96450 Coburg, Germany
Disposable Medical Masks (Non-sterile)

The medical device:

Product code:

Trade Mark:

SRN:

Basic UDI:

Intended purpose:

Not Applicable

Not available yet

Not available yet

This product meets European Standard EN 14683, Type II R.

As a medical face mask, it is intended to provide a barrier to minimize the direct transmission of infective agents between staff and patient. It is designed to be fluid resistant to splash and spatter of blood and other infectious materials.

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:

EN 14683:2019+AC:2019 Medical Face Masks. Requirements And Test Methods Type II R 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:

09-JUN-2020

Expire date of the Certificate:

08-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.

Hunan, 09-JUN-20

Place, Date

