



Declaration of Conformity

Manufacturer:

Weihai Shengjie Medical Technology Co.,Ltd.

No.58-3, Chuhe South Road,High-tech Industrial Zone, Weihai City, Shandong, China

European Representative:

Caretachion GmbH

Niederrheinstr.71,40474 Duesseldorf,Germany.

DIMID: DE/0000048026

Tel: 0049-21130036618

E-mail:info@caretechion.de

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Product Name: Disposable Medical Face Mask

Basic UDI-DI:

Model/Size

Type/Model	Size
Model A	Universal, 155*105mm
Model B	Universal, 155*105mm
Model C	Universal, 175*95mm
Model D	Universal, 195*85mm

Intended Purpose:

This Disposable Medical Face Mask is suitable for the wearer in the general medical environment where there is no risk of bodily fluids and spillage.

Risk Class of the Device: The medical device has been assigned to class I, ANNEX VIII rule 1 Medical Device REGULATION (EU) 2017/745.

It bears the mark



The product meets the provisions of Medical Device REGULATION (EU) 2017/745 and conforms to Standards as following

- EN 14683: 2019
- EN/ISO14971:2019
- ISO10993-1:2018
- EN/ISO15223-1:2016
- EN1041:2008

Conformity Assessment Path: Following the procedure relating to the EC Declaration of Conformity set out in ANNEX IX of Medical Device REGULATION (EU) 2017/745.

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

The above mention declaration of conformity is exclusively under the responsibility of Weihai Shengjie Medical Technology Co.,Ltd.

Weihai, 2020.4.21

Place, date


Wang Xuebin, Vice General manager
Legally binding signature, Function