

EC Declaration of Conformity

Manufacturer: AnDum Protective Equipment Technology (Changzhou) Co.,Ltd.

Address: No. 216, Qianjie, Hengshanqiao Town, Changzhou Economic Zone, Changzhou, Jiangsu , China

Authorized representative: Caretechion GmbH

Address: Niederrheinstr 71, 40474 Duesseldorf, Germany

Tel: +49 211 3003 6618

Product: Disposable medical face mask

Type: EN 14683:2019 Type I/Type IIR

Classification: Class I ,According to Rule 1, Annex IX of MDD 93/42/EEC as amended by Directive 2007/47/EC

Harmonized Standards:

EN ISO 14971:2012, EN ISO 15223-1:2016, EN 1041:2008, EN 14683:2019+AC:2019

EN ISO 10993-1:2009/AC:2010, EN ISO 10993-5:2009, ISO 10993-10:2010

Conformity Assessment Route: Annex VII of Directive 93/42/EEC as amended by 2007/47/EC.

We herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC as amended by 2007/47/EC for medical devices. All supporting documentation is retained under the premises of the manufacturer.

Year of CE marking: **2020**

Signed for and on behalf of:

Company: AnDum Protective Equipment Technology (Changzhou) Co.,Ltd.

General Manager:

Chunhua Liu

Signature

刘春华



Place & Date: Changzhou City, 22th October, 2020

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