

EU Declaration of Conformity

Manufacturer: 3A Medical Products Co., Ltd.

SRN: /

European: Shanghai International Holding Corporation GmbH (Europe)

Representative: Eiffestrasse 80, Hamburg, Deutschland

SRN: /

Product Name: Disposable Medical Face Mask

Specification: 17.5cmx9.5cm

GMDN Code: DE/CA05

UMDN Code: DE/0000040627

UDI-DI: /

Classification (MDR, Annex VI): Class I, Rule 1.

Conformity Assessment Route: EU DECLARATION OF CONFORMITY following the Annex II + Annex III + Article 19 of MDR (EU) 2017/745.

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EU Regulation and Standards. All supporting documentations are retained under the premises of the manufacturer.

The manufacturer is exclusively responsible for the declaration of conformity.

General applicable regulations, directives:

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC.

Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

Applied standards, common specification, guidance:

EN14683:2019+AC:2019, EN ISO 14971:2012, EN ISO 15223-1:2016, EN ISO 1041:2008

A1:2013, EN ISO 10993-1:2009/AC:2010, EN ISO 10993-5:2009, EN ISO 10993-10:2013,

EN14683:2019+AC:2019.

Signature:

Name: Billy Zhang

Position: General Manager

Place/data:

File Na: GDRY/CE20-04-30, ver. A/0

