

**FUJIAN SHANDESET ENVIROMENTAL
PROTECTION TECHNOLOGY CO.,LTD**

Single-use medical face mask CE TF

Doc. No.: CE-I-01

Revision: 00

Distribution:

Control Status:

Prepared by	Reviewed by	Approved by
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2020/10/07	2020/10/07	2020/10/07

Issue Date: 2020-10-07

Validated Date: 2020-10-07

01 EC Declaration of Conformity

Manufacturer: Name: FUJIAN SHANDESET ENVIROMENTAL PROTECTION TECHNOLOGY CO.,LTD
Add: SONG TANG ROAD 838 ,BAO GAI TECHNOLOGY PARK, SHISHI , QUAN ZHOU CITY, FUJIAN PROVINCE .

European Name: MedPath GmbH
Representative: Add: Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany

Product Name: Single-use medical face mask

Object of the Model: SDS001
declaration: Size: 17.5x9.5 cm
UMDNS Code: 12-447
Classification (MDD, Annex IX): I , rule 1
Conformity Assessment Route: Annex VII

We herewith declare in sole responsibility that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer. We are exclusively responsible for the declaration of conformity.

DIRECTIVES

General applicable directives: Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC

Applicable standards by EU

ENISO13485:2016/AC:2016	EN 14683:2019	ISO14971:2019
ISO10993-1:2018	ENISO10993-5:2009	ISO10993-10:2010
ENISO 15223-1:2016	EN1041:2008/A1:2013	



Start of CE Marking: 2020-06-05

Place of Issue: Quanzhou, CHINA

Date of Issue: 2020-10-7

Signature:

Mr. Mingzhao Wang

Position: General Manager