

Declaration of Conformity

Manufacturer: RFX + CARE Manufacturing Co., Ltd.

Address: 7 Lanjiang Road, Yuecheng District, Shaoxing, P. R. China

EC-Representative: RFX+Care International A/S

Address: Bakkegaardsvej 408, 3050 Humlebaek, Denmark

Product Name: Face Mask

Specification: 9.5cm*17.5cm-3ply

Model code: D20108

Packaging code:

The quantity of D20108 in different package			
1pc			
50222			
50pcs			
10pcs			
Enco			
5pcs			
3pcs			

UMDNS Code: 16366

Classification: Class I, rule1 Conformity Assessment Route: Annex VII Test standard: EN14683:2019 Type IIR

We herewith declare 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.

RFX + CARE Manufacturing Co., Ltd. is exclusively responsible for the declaration of conformity.

Medical Device Directives

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993

File No/File Name	Edition	Effective Date	Pages
RFX/ JCQ-CE-026-01 Declaration of conformity(face mask)	03	2020-05-06	1 / 2



CE Technical Document

concerning medical devices (MDD 93/42/EEC). Amended by DIRECTIVE 2007/47/EC of 5 September 2007.

Notified Body: TÜV SÜD Product Service GmbH,

Ridlerstrasse 65, 80339 München, Germany number: 0123

NB Identification number:

(QMS) Certificate(s): Expire date of the Certificate: Q5 067759 0027 Rev.01 2022-10-31 2014-10 Shaoxing, 2020-05-06

Start of CE Marking:

Place, Date of Issue:

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General Manager (Signature):

Date: 2020-05-06

File No/File Name	Edition	Effective Date	Pages
RFX/ JCQ-CE-026-01 Declaration of conformity(face mask)	03	2020-05-06	2/2