

EC Declaration of Conformity

Manufacturer:

whose single Authorized Representative:

Xiamen Flyman Technology Ltd Tongan Branch

Area D, Room 401, No.15, Tong An Industrial Park,
Meixi Road, Tong An District, Xiamen, China

MedNet EC-REP GmbH

Borkstrasse 10, 48163 Münster,
Germany

We, the manufacturer, herewith declare that the products

Disposable Medical Face Mask

Specifications / Models: 17.5x9.5cm, 14.5x9.5cm, 12.5x7cm

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to **Class I** according to Annex IX, Rule 1 of the Directive 93/42/EEC. It bears the mark



The product concerned has been manufactured under a quality management system according to **Annex VII** of Directive 93/42/EEC.

Following the procedure relating to the EC Declaration of Conformity set out in Annex VII of Directive 93/42/EEC.

Applied Standards:

EN ISO14971:2012, EN 1041:2008+A1:2013, EN ISO15223-1:2016, EN ISO13485: 2016,
EN 14683: 2019, ISO10993 -1:2018, ISO10993-5:2009, ISO10993-10:2010.

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration.

The above-mentioned declaration of conformity is exclusively under the responsibility of

Xiamen Flyman Technology Ltd Tongan Branch
Area D, Room 401, No.15, Tong An Industrial Park,
Meixi Road, Tong An District, Xiamen, China

Xiamen City, May 20, 2020

Place, date

Xiaolin Zheng, G.M

Legally binding signature, Function

A handwritten signature in black ink, appearing to be 'Xiaolin Zheng', written over a horizontal line.