EC Declaration of Conformity

Name and address of manufacturer:

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

Whose single Authorized Representative

MedNet EC-REP GmbH
Borkstrasse 10, 48163 Münster, Germany
SRN of the Authorized
Representative:DE-AR-000000002

We declare on our own responsibility that the medical device

Name	Disposable Medical Face Mask	Basic UDI-DI	697351235MDMSK01TC
Model	17.5×9.5cm, 14.5×9.5cm, 12.5×7cm		
Classification	I,(MDR,Annex VIII Rule I)		

meets all the provisions of the Regulation (EU)2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, which apply to it.

- Conformity assessment procedure:Annex II and Annex III
- The aforementioned device has been assigned to class I according to Appendix VIII of the Regulation (EU)2017/745. It bears the CE mark:

CE

- Applied Standards:

EN ISO14971:2019
EN ISO13485: 2016
ISO10993-5:2009
MEDDEV 2.12/1 rev 8
EN 1041:2008+A1:2013
EN 14683: 2019
ISO10993-10:2010
EN ISO15223-1:2021
ISO10993 -1:2018
MEDDEV 2.7/1 rev 4

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, OCT 18,2021
Place, date

Xiaolin Zheng, G.M.
Legally binding signature; Function