

EU Declaration of Conformity

Manufacturer Name: Suzhou Yuyue Medical Technology Co., Ltd.

Manufacturer address: No.9 Jinfeng Road, Suzhou Science & Technology Town, 215163 Suzhou, Jiangsu, PEOPLE'S REPUBLIC OF CHINA

SRN: CN-MF-000015854

EC-Representative name: Metrax GmbH

Address: Rheinwaldstr.22, 78628 Rottweil, Germany

SRN: DE-AR-000005481

Tel: +49-741-257-0, +49-741-257-223

Fax: +49-741-257-21

Product name: Sleep apnea breathing therapy mask

Trade name: Full Face Mask

Intended Purpose:

The mask is a noninvasive accessory used for channeling airflow (With or without supplemental oxygen) to a patient from a positive airway pressure (PAP) device such as a continuous positive airway pressure (CPAP) or bi-level system.

- The mask is to be used by adult patients (weighing>30kg), intended for single-patient reuse in the home environment.
- The mask is intended for single-patient use in the hospital or institutional environment..

Models: YF-01 / YF-02 / YF-03 / YF-04 / YF-05 / YF-06 / YF-RT01 / YF-RT02 / YF-RT03

Basic UDI-DI: 69221665YFM001ML

EMDN code: R03010102

CS applied: N/A

Classification: Class IIa, Rule 2, according to the Annex VIII of MDR.

Conformity Assessment Route: MDR Annex IX, Chapter I & III

We herewith declare that:

Our sole responsibility to the compliance of the above medical device with the applicable medical devices regulation (EU) 2017/745 of the European Parliament and of the council of 5 April 2017 on medical devices. All the supporting documents and files are retained under the premises of the manufactures.

Suzhou Yuyue Medical Technology Co., Ltd. is exclusively responsible for this declaration of conformity.

Notified Body Name: TUV SUD Product Service GmbH

Address: Ridlerstrasse, 6580339, Munchen, Germany

Code: 0123

CE Certificate No.: G10 092486 0011 Rev.01

Valid until: 2028-09-13

Name: Wang Yubin

Signature:

Wang Yu Bin

Function: General Manager

Place: Suzhou, Jiangsu, P.R.CHINA

Date:

2025.2.7