



EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class IIa and Class IIb Devices)

No. G10 092486 0011 Rev. 01

Manufacturer:

**Suzhou Yuyue Medical
Technology Co., Ltd.**

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

SRN Manufacturer - CN-MF-000015854

Authorized Representative:

Metrax GmbH
Rheinwaldstr. 22, 78628 Rottweil, GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s). The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.

The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.

The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples. All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with.

For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G10 092486 0011 Rev. 01

Report No.: SH2485204

Preceding Certificate No.: G10 092486 0011 Rev. 00

Valid from: 2024-10-11

Valid until: 2028-09-13

Date of Initial Issuance: 2023-09-14

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2024-10-11



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No. G10 092486 0011 Rev. 01

Classification: Class IIa
Device Group: R020107 - THERMOREGULATED BREATHING CIRCUITS
Intended Purpose: -

Classification: Class IIa
Device Group: R0301020302 - HIGH FLOW THERAPY NASAL CANNULAS (HFNC)
Intended Purpose: -

Classification: Class IIa
Device Group: R060280 - HUMIDIFICATION SYSTEMS - ACCESSORIES
Intended Purpose: -

Classification: Class IIa
Device Group: R060202 - OXYGEN ADMINISTRATION HUMIDIFICATION SYSTEMS
Intended Purpose: -

Classification: Class IIa
Device Group: R03010102 - CPAP AND NIV MASKS
Intended Purpose: -

Classification: Class IIa
Device Group: Z12030102 - CONTINUOUS POSITIVE PRESSURE EQUIPMENT
Intended Purpose: -

The validity of this certificate depends on conditions and/or is limited to the following: - none -

Revision History:

Rev.	Dated	Report	Description
00	2023-09-14	SH22852MDRA01	Initial issuance
01	2024-10-11	SH2485204	-

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