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Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
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BS-MDR-099



Product Service

## 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 109546 0009 Rev. 00**

### Manufacturer:

**Jiangsu Yuyue Medical  
Equipment & Supply Co., Ltd.**

No.1 Baisheng Road Development Zone  
212300 Danyang, Jiangsu  
PEOPLE'S REPUBLIC OF CHINA

SRN Manufacturer - CN-MF-000012834

### 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 109546 0009 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:G10 109546 0009 Rev. 00)

**Report No.:** SH2339202

**Valid from:** 2024-03-04

**Valid until:** 2029-03-03

Christoph Dicks  
Head of Certification/Notified Body

**Issue date:** 2024-03-04



## 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 109546 0009 Rev. 00**

**Classification:** Class IIb  
**Device Group:** Z12159004 - OXYGEN CONCENTRATORS  
**Intended Purpose:** This oxygen concentrator is intended for oxygen supplement.

**Classification:** Class IIa  
**Device Group:** Z1203020408 - PULSE OXIMETERS  
Z1203020501 - NON-INVASIVE OSCILLOMETRIC BLOOD  
PRESSURE GAUGES

**Intended Purpose:** —

**The validity of this certificate  
depends on conditions and/or  
is limited to the following:** —

### Revision History:

Rev.	Dated	Report	Description
00	2024-03-04	SH2339202	Initial issuance


# 04-002 Declaration of Conformity

(8F-5A Oxygen Concentrator)

No.: TD-OXG-8F-5A(CE)-04-002

Version: A/2

Prepared by: 

Reviewed by: 

Approved by: 

Date: 2024.03.06

## Revision History

No.	Version	Reviser	Revised Sections and Content	Revision Date
1	A/0	Wei Yan	New release	2023.09.15
2	A/1	Su Wujun	Modify intended use	2023.11.15
3	A/2	Su Wujun	Update (EC)Certificate(s)	2024.03.06

## EU Declaration of Conformity

### 1. Manufacturer

Name: JIANGSU YUYUE MEDICAL EQUIPMENT & SUPPLY CO., LTD.

Trade Mark: **yuwell**

SRN: CN-MF-000012834

Address: NO.1 Baisheng Road Development Zone, Danyang, Jiangsu  
212300 CHINA

### 2. Authorised Representative

Name: Metrax GmbH

Address: Rheinwaldstr. 22, D-78628 Rottweil, Germany

SRN: DE-AR-000005481

### 3. Basic UDI-DI

Basic UDI-DI: 693325792192J8

### 4. Device Information

Product Category: Oxygen Concentrator

Trade Name: Oxygen Concentrator

Mode: 8F-5A

Photograph:



EMDN Code: Z12159004

Intended Purpose: This oxygen concentrator is intended for oxygen supplement.

Contra-indications: Oxygen poisoning and oxygen allergy user/patient DO NOT using this oxygen concentrator. This device is to be used as an oxygen supplement and is NOT considered life-supporting or life-sustaining. Users who require continuous oxygenation must plan for alternate reserve sources of power and oxygen in the event of a failure or loss of power and oxygen.

## 5. Risk Classification

Risk Classification: IIb according to rule 12 from Annex VIII of MDR (EU) 2017/745

## 6. Reference to CS

There is no any applicable CS.

## 7. Manufacturer Statement

We declare the EU declaration of conformity is issued under the sole responsibility of the manufacturer, and the device covered by the present declaration is in conformity with MDR (EU) 2017/745.

## 8. Notified Body

Name: TÜV SÜD Product Service GmbH, Ridlerstr.65, 80339München, Germany

Identification Number: 0123

## 9. Conformity Assessment Procedure

Based on Annex IX of MDR (EU) 2017/745

## 10. Identification of the Certificate

(EC)Certificate(s): No. G10 109546 0009 Rev. 00

Place of Issue: Dan Yang, Jiangsu, P.R. CHINA

Date of Issue: 2024-03-04

Signature: 

Name: Jie Mei

Position: Person Responsible for Regulatory Compliance