

# 04-002 Declaration of Conformity

(8F-5A Oxygen Concentrator)

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

Version: A/2

Prepared by: *Su Wujun*

Reviewed by: *Wei Yan*

Approved by: *Mao Jian qiang*

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