04-002 Declaration of Conformity

（9F-5B Oxygen Concentrator）

No.: TD-OXG-9F-5B(CE)-04-002

Version: A/3

Prepared by:

Reviewed by:

Approved by:

Date: 2025.02.07

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
4	A/3	Su Wujun	Updated the (EC) Certificate No. and the Authorized Representative address	2025.02.07

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, 78628 Rottweil, GERMANY

SRN: DE-AR-000005481

3. Basic UDI-DI

Basic UDI-DI: 6933257923 25J3

4. Device Information

Product Category: Oxygen Concentrator

Trade Name: Oxygen Concentrator

Mode: 9F-5B

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.

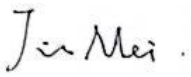
8. Notified Body

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. 01
Place of Issue:	Dan Yang, Jiangsu, P.R. CHINA
Date of Issue:	2025-02-07
Signature:	
Name:	Jie Mei
Position:	Person Responsible for Regulatory Compliance