

### **Declaration of Conformity**

#### Manufacturer:

### Name: Jiangsu Yuyue Medical Equipment & Supply CO., LTD.

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

European Representative:

### Name: Metrax GmbH

# Address:Rheinwaldstr. 22, D-78628 Rottweil, Germany VAT: DE 166 892 350

Product Category: Oxygen concentrator

Model: 8F-5A

UMDNS Code: 12873

Classification: II a based on MDD 93/42/EEC Annex IX rule 11

Conformity Assessment Route: MDD Annex V

We declare the compliance of the above medical device with the applicable requirements of Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES (MDD 93/42/EEC).All the supporting documents and files are retained under the premises of the manufactures. We are exclusively responsible for the Declaration of Conformity.

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

Notified Body Number: 0123

Certificate : G2 055329 0025 Rev.00

Valid from : 2020-03-30

Valid until : 2024-05-26

Place, Date of Issue: Danyang, Jiangsu, P.R.C

Signature: 900mm.

Name: Guomin Jing

Position: Management Representative

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