



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

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



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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