

# EC Certificate

Production Quality Assurance  
Directive 93/42/EEC on Medical Devices, Annex V

Registration No.: DD 2175876-1

Manufacturer: SHENYANG AERTI TECH CO., LTD.  
No.77-1, 13th Road, Shenyang Economic & Technological Development  
Area, Shenyang City, 110027 Liaoning, P.R. China

Products: Medical Oxygen Concentrators

TÜVRheinland

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Report No.: 190130204-120

Effective date: 2021-04-07

Expiry date: 2024-05-26

Issue date: 2021-04-09



Wenxiang Zhang  
TÜV Rheinland LGA Products GmbH  
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

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TÜV Rheinland LGA Products GmbH • 51105 Köln

SHENYANG AERTI TECH CO., LTD.  
No.77-1, 13th Road, Shenyang Economic & Technological Development  
Area, Shenyang City, 110027 Liaoning, P.R. China

Contact

Tel. +49 911 655-5225

Mail: service  
@de.tuv.com

Date: April 15, 2021

**Application for: Production Quality Assurance**

Certificate No. : DD 2175876-1

Requirement : Annex V

Dear Madam or Sir,

Enclosed please find the new certificate No. DD 2175876-1 replacing the previous certificate.

With effective date of the new certificate, the previous certificate becomes invalid.

Best regards,

Wenxiang Zhang  
Certification body

TÜV Rheinland  
LGA Products GmbH

Am Grauen Stein  
51105 Köln  
Germany

Headquarter

Tillystraße 2  
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Nuremberg HRB 26013  
VAT No.: DE 811835490

Chairman of the  
Supervisory Board

Dipl.-Ing. Ralf Scheller

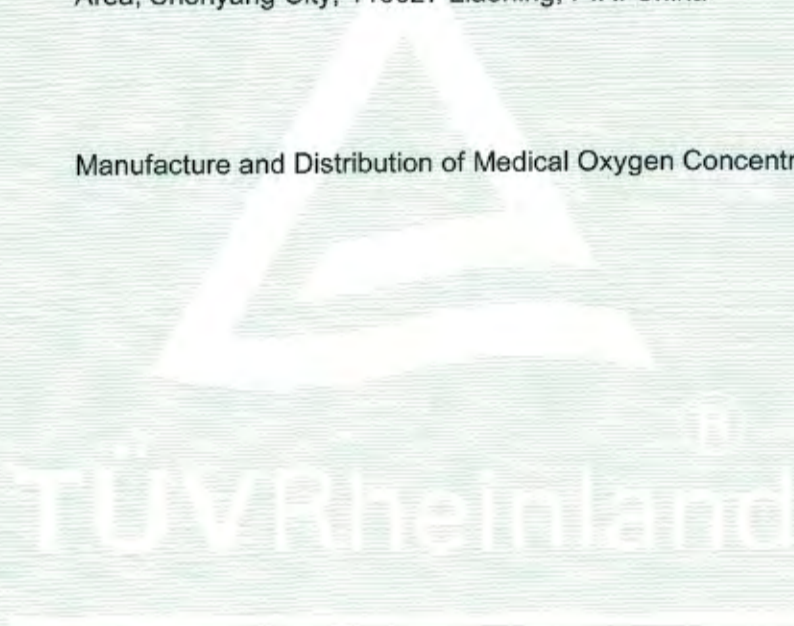
# Certificate

**Quality Management System  
EN ISO 13485:2016**

Registration No.: SX 2175876-1

Organization: SHENYANG AERTI TECH CO., LTD.  
No.77-1,13th Road, Shenyang Economic & Technological Development  
Area, Shenyang City, 110027 Liaoning, P.R. China

Scope: Manufacture and Distribution of Medical Oxygen Concentrators



The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.  
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 190130204-120  
Effective date: 2021-04-09  
Expiry date: 2024-04-08  
Issue date: 2021-04-09



Wenxiang Zhang  
TÜV Rheinland LGA Products GmbH  
Tillystraße 2 · 90431 Nürnberg · Germany



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SHENYANG AERTI TECH CO., LTD.  
No.77-1,13th Road, Shenyang Economic & Technological Development  
Area, Shenyang City, 110027 Liaoning, P.R. China

Contact

Tel. +49 911 655-5225

Mail: [service@de.tuv.com](mailto:service@de.tuv.com)

Date April 15, 2021

Application for: QMS

Certificate No. : SX 2175876-1

Requirement : EN ISO 13485:2016

Dear Madam or Sir,

Enclosed please find the new certificate No. SX 2175876-1 replacing the previous certificate.

With effective date of the new certificate, the previous certificate becomes invalid.

Best regards,

Wenxiang Zhang  
Certification body

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Board of Management

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