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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

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

TÜV Rheinland LGA Products GmbH

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.

Business Stream Products
Certification Department

TÜVRheinland®
LGA
Precisely Right.

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
90431 Nuremberg

Phone. +49 911 655 5225
Fax +49 911 655 5226
service@de.tuv.com
www.tuv.com/safety

Board of Management

Dipl.-Ing.
Jörg Mähler, Spokesman

Dipl.-Kfm.
Dr. Jörg Schlösser

Nuremberg HRB 28013
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

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

Business Stream Products
Certification Department

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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: 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

TÜV Rheinland
LGA Products GmbH

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51105 Köln
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Headquarter

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