ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Digitally signed by Trocin Caterina
Date: 2021.02.08 14:52:16 EET
Reason: MoldSign Signature
Location: Moldova

Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 17 12 32913 036

Manufacturer:

Ningbo David Medical Device Co., Ltd.
No.2, Keyuan Road
Shipu Science and Technology Park, Xiangshan
315731 Ningbo, Zhejiang Province
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80
20537 Hamburg
GERMANY

Product Category(ies):

Infant Incubator, Transport Incubator,
Infant Radiant Warmer,
Neonate Bilirubin Phototherapy Equipment,
Infant T-piece Resuscitator

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: SH1701122

Valid from: 2018-03-05
Valid until: 2022-10-23

Date, 2018-03-05

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate
Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 17 12 32913 036

Facility(ies):

Ningbo David Medical Device Co., Ltd.
No.2, Keyuan Road, Shipu Science and Technology Park, Xiangshan, 315731 Ningbo, Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 032913 0038 Rev. 00

Holder of Certificate: **Ningbo David Medical Device Co., Ltd.**
No.2, Keyuan Road
Shipu Science and Technology Park, Xiangshan
315731 Ningbo, Zhejiang Province
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Ningbo David Medical Device Co., Ltd.
No.2, Keyuan Road, Shipu Science and Technology Park,
Xiangshan, 315731 Ningbo, Zhejiang Province, PEOPLE'S
REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate: Design and Development,
Production and Distribution of Infant Incubator,
Transport Incubator, Infant Radiant Warmer,
Neonate Bilirubin Phototherapy Equipment,
Far-Infrared Radiant Heater, Low-Pressure Aspirator,
Breath Resuscitation Bag, Infant Non-contact Oxygen Hood,
Infant Bed, Infant Head Fixing Unit,
Medical Air/Oxygen Blender,
Infant T-piece Resuscitator

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH1901124

Valid from: 2019-06-27
Valid until: 2022-05-31

Date, 2019-06-27

Stefan Preiß
Head of Certification/Notified Body

TÜV®

A4 / 07.17

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜVRheinland®

Zertifikat

Die Zertifizierungsstelle der
TÜV Rheinland LGA Products GmbH

bescheinigt, dass die Organisation

Löwenstein Medical GmbH & Co. KG
Arzbacher Str. 80
56130 Bad Ems
Deutschland

für den Geltungsbereich:

Entwicklung, Herstellung, Vertrieb und Service von Medizinprodukten für die Anästhesie, Intensivtherapie, Neonatologie, Phototherapie, Homecare, Schlafdiagnostik und Pulmologie

ein Qualitätsmanagementsystem für Medizinprodukte eingeführt hat und anwendet.

Der Nachweis wurde erbracht, dass die Forderungen der

EN ISO 13485:2016

erfüllt sind. Das Qualitätsmanagementsystem unterliegt einer jährlichen Überwachung.

Dieses Zertifikat ist gültig ab:	2019-10-23
Zertifikat-Registrier-Nr.:	SX 60142607 0001
Ein Audit wurde durchgeführt, Bericht-Nr.:	60252185 002
Dieses Zertifikat ist gültig bis:	2022-08-22

Zertifizierungsstelle

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

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Datum 2019-10-23

Dipl.-Ing. I. Munkler

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Löwenstein Medical GmbH & Co. KG
Arzbacher Str. 80
56130 Bad Ems
Deutschland

has established and applies a quality management system for medical devices for the following scope:

Design and development, manufacture, distribution and service of medical devices for anaesthesia, intensive care, neonatology, phototherapy, homecare, sleep diagnostic systems and pulmonology

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2019-10-23
Certificate Registration No.:	SX 60142607 0001
An audit was performed. Report No.:	60252185 002
This Certificate is valid until:	2022-08-22

Certification Body

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

TÜVRheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date 2019-10-23

Dipl.-Ing. I. Munkler

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

EG-Zertifikat

Richtlinie 93/42/EWG Anhang II, ohne Abschnitt 4
Vollständiges Qualitätssicherungssystem
Medizinprodukte

Registrier-Nr.: HD 60146428 0001

Berichts-Nr.: 60252185 002

Hersteller:
Löwenstein Medical GmbH & Co. KG
Arzbacher Str. 80
56130 Bad Ems
Deutschland

Produkte:
Medizinprodukte für Anästhesie, Intensivtherapie, Neonatologie, Phototherapie, Homecare, Schlafdiagnostik und Pulmologie

Gültig bis: 2024-05-26

Hiermit erklärt die Benannte Stelle, dass die Anforderungen nach der Richtlinie 93/42/EWG Anhang II ohne Abschnitt 4 für die aufgeführten Produkte erfüllt sind. Der oben genannte Hersteller hat ein Qualitätssicherungssystem eingeführt und wendet es an. Dieses Qualitätssicherungssystem ist Gegenstand einer regelmäßigen Überwachung nach Anhang II Abschnitt 5 der oben genannten Richtlinie. Um Medizinprodukte der Klasse III, die Gegenstand dieses Zertifikates sind, auf den Markt zu bringen, ist eine EG-Auslegungsprüfbescheinigung nach Anhang II Abschnitt 4 erforderlich.

Gültig ab: 2020-04-02

Datum: 2020-04-02

Benannte Stelle

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Dipl.-Ing. I. Munkler

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH ist eine Benannte Stelle
nach Richtlinie 93/42/EWG über Medizinprodukte mit der Kennnummer 0197.

EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60146428 0001

Report No.: 60252185 002

Manufacturer:
Löwenstein Medical GmbH & Co. KG
Arzbacher Str. 80
56130 Bad Ems
Deutschland

Products:
Medical devices for anesthesia, intensive care, neonatology, phototherapy, homecare, sleep diagnostic and pulmonology.

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 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 II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2020-04-02

Date: 2020-04-02

Notified Body

Dipl.-Ing. I. Munkler

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

EC Certificate
Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
9909-2017-CE-ROC-NA-PS Rev. 1.0	PRJC-268377-2010-PRC-TWN	13 November 2022

This is to certify that the quality system of:

VADI Medical Technology Co., Ltd. Yangmei
No. 198, Lane 298, Huandong Rd., Zhongshan Village, Yangmei Dist., Taoyuan City 32665, Taiwan

For design, production and final product inspection/testing of:

Emergency Medical Care Devices

Has been assessed with respect to:

The conformity assessment procedure described in Article 11.3.a and Annex II excluding section 4 (Module H) of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and Date:
Høvik, 01 February 2018

NORWEGIAN ACCREDITATION
PROD 021
Notified Body No.: 2460

For:
DNV GL NEMKO PRESAFE AS

Palani Damodharan

This Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

VADI Medical Technology Co., Ltd.
Yangmei
No. 198, Ln. 298, Huandong Rd.
Zhongshan Village
Yangmei Dist.
Taoyuan City
32665
Taiwan

Holds Certificate Number: **MD 692156**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The design and manufacture of respiratory gas humidifier, breathing system heater, resuscitator sets, connectors for breathing circuit, non-sterile medical tubing and filter, sterile single use breathing circuit, bacterial filter and electric power percussor.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2018-05-03
Latest Revision Date: 2019-10-04

Effective Date: 2019-10-16
Expiry Date: 2022-10-15

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