THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

DQS Holding GmbH has issued an IQNet recognized certificate that the organization

EMA-LED GmbH

Ottostraße 3
63785 Obernburg
Germany

has implemented and maintains a **Quality Management System**.

Scope:
Manufacturing, Distribution and Installation of Surgical and Examination Lightning Systems.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

DIN EN ISO 13485 : 2016 + AC : 2017-07
EN ISO 13485 : 2016 + AC : 2016
ISO 13485 : 2016

Issued on: 2019-02-23
Expires on: 2022-02-22

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document.

Registration number: DE-470339 MP2016

Alex Stoichitoiu
President of IQNet

Michael Drechsel
Managing Director of
DQS Holding GmbH

IQNet Partners*:

AENOR *Spain* AFNOR Certification *France* APCER *Portugal* CCC *Cyprus* CISQ *Italy*
CQC *China* CQM *China* CQS *Czech Republic* Cro Cert *Croatia* DQS Holding GmbH *Germany* FCAV *Brazil*
FONDONORMA *Venezuela* ICONTEC *Colombia* Inspecta Sertifiointi Oy *Finland* INTECO *Costa Rica*
IRAM *Argentina* JQA *Japan* KFQ *Korea* MIRTEC *Greece* MSZT *Hungary* Nemko AS *Norway* NSAI *Ireland*
NYCE-SIGE *México* PCBC *Poland* Quality Austria *Austria* RR *Russia* SII *Israel* SIQ *Slovenia*
SIRIM QAS International *Malaysia* SQS *Switzerland* SRAC *Romania* TEST St Petersburg *Russia* TSE *Turkey* YUQS *Serbia*
IQNet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSAI Inc.

* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com

CERTIFICATE

This is to certify that the company

EMA-LED GmbH

Ottostraße 3
63785 Obernburg
Germany

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ISO 13485 : 2016

Certificate registration no.	470339 MP2016
Certificate unique ID	170722331
Effective date	2019-02-23
Expiry date	2022-02-22
Frankfurt am Main	2019-02-23

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-16021-01-00

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

VD_4.19_03_06

Konformitätserklärung

Produktzulassung

Konformitätserklärung nach RL 93/42/EWG, Anhang VII
Declaration of conformity in accordance with directive 93/42/EWG, Annex VII

Hersteller/ Supplier:	**EMA-LED GmbH**

Adresse/ Company address:	**EMA-LED GmbH** **Ottostraße 3** **63785 Obernburg am Main** **DEUTSCHLAND**

Produktname/ Product name:	**Untersuchungsleuchten/ Examination Lights** **Operationsleuchten/ Operating Lights**
Modell/ Model:	**EMALED 200 M** **EMALED 200 D** **EMALED 200 W** **EMALED 200 F** **EMALED 300 D** **EMALED 300 D +** **EMALED 300 M +** **EMALED 300 F** **EMALED 300 W** **EMALED 300 M** **EMALED 500** **EMALED 500 M** **EMALED 500 V** **EMALED 500 VM** **EMALED 560** **EMALED 560 M** **EMALED 560 V** **EMALED 560 VM** **EMALED 560/500** **EMALED 560/500 M** **EMALED 560/500 V** **EMALED 560/500 VM** **EMALED 560/560/560** **EMALED 560/500/500** **EMALED 560/560/300** **EMALED 560/560/560 V** **EMALED 560/560/560 VM** **EMALED 500/300 +** **EMALED 500/300+ VM** **EMALED 560/300+ V** **EMALED 500 mobile** **EMALED 560 mobile** **EMALED 300/300** **EMALED 300/300 +** **EMALED 500/500** **EMALED 500/500 M** **EMALED 300 F +** **EMALED 300W +** **EMALED 500/500 V** **EMALED 500/500 VM** **EMALED 500/300** **EMALED 500/300 M** **EMALED 500/300 V** **EMALED 500/300 VM** **EMALED 560/560** **EMALED 560/560 M** **EMALED 560/560 V** **EMALED 560/560 VM** **EMALED 560/300** **EMALED 560/300 M** **EMALED 560/300 V** **EMALED 560/300 VM** **EMALED CONTROLLER** **EMALED 560/560/500** **EMALED 500/500/500** **EMALED 560/500/300** **EMALED 560/560/300 V** **EMALED 560/560/300 VM** **EMALED 500/300+ V** **EMALED 560/300+** **EMALED 560/300+ VM** **EMALED 500V mobile** **EMALED 560V mobile**
Zubehör/ Equipment:	**Zwischengestell/ Intermediate Frame** **Deckenscheibe/ Ceiling Disk** **ZG 560** **DS 560** **ZG 300** **DS 300**
Produktklasse/ Product class:	**Klasse I/ Class 1**

Konformitätserklärung

Produktzulassung

Konformitätsbewertungsverfahren/ Conformity assessment procedure:	**Anhang VII/ Annex VII**
Richtlinie// Directive:	**93/42/EWG // 93/42/EEC**
Sicherheitsstandards/ Safety standards:	**EN 60601-1:/A1:2012** **EN 60601-2-41/IEC60601-2-41:2009**
EMV Standard/ EMC standard:	**EN 60601-1-2:2007/EN 60601-1-2:2007**

Erklärung-Nr. / Declaration referenz:	**0000000010**

Hiermit erklären wir, die EMA-LED GmbH, in alleiniger Verantwortung, dass die oben genannten Medizinprodukte die grundlegenden Anforderungen nach Anhang VII der Richtlinie 93/42/EWG erfüllen und gekennzeichnet werden mit/ Hereby we, the EMA-LED GmbH declare with sole responsibility, to accomplish the aforementioned medical products the essential requirements of Annex VII of Directive 93 /42 / EEC and are marked with:

CE

Desweiteren erklären wir, dass die oben genannten Medizinprodukte die Auflagen nach RoHS Directive 2011/65/EC vom Europäischen Parlament vom 08.06.2011 zur Beschränkung der Verwendung bestimmer gefährlicher Stoffe in Elektro- und Elektronikgeräten erfüllen./ Furthermore we declare that the above mentioned medical productsare compliant to the RoHS Directive 2011/65/EC of the European Parliament and the Council from 08.06.2011 on restriction of the use of certain hazardous substances in electrical and electronic appliances.

Diese Konformitätserklärung ist gültig für die Produkte, produziert im Zeitraum vom 12.05.2020 – 11.05.2022 / This declaration of conformity is valid for the products produced during the period from 12.05.2020 – 11.05.2022

Obernburg am Main	12.05.2020	**Waldemar Anton**
Ort/ Municipality	**Datum/ Date of issue**	**Geschäftsführer/ Managing director**

EMA-LED GmbH Ottostr. 3 • 63785 Obernburg Tel. 06022/206311 • Fax 06022/208754

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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD 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 054954 0012 Rev. 03

Manufacturer:

AMBULANC (SHENZHEN) TECH. CO., LTD.
3rd Floor, Block C, Building #5
Skyworth Innovation Industry Park
Tang Tou 1st Road,Shiyan, Baoan District
518108 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

Emergency Ventilator, Transport Ventilator, Ultrasonic Doppler Fetal Monitor, Demand Valve Resuscitator, Inhalation Antalgic Equipment (Sedation System), Nasal Continuous Positive Airway Pressure System, Suction Unit, Emergency Resuscitator, Blender.

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. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G1 054954 0012 Rev. 03

Report No.: BJ20087402

Valid from: 2020-09-24
Valid until: 2024-05-26

Date, 2020-09-24

Christoph Dicks
Head of Certification/Notified Body

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

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

TÜV®

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

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

TÜV SÜD
Product Service

Certificate

No. Q5 054954 0015 Rev. 02

Holder of Certificate: **AMBULANC (SHENZHEN) TECH. CO., LTD.**
3rd Floor, Block C, Building #5
Skyworth Innovation Industry Park
Tang Tou 1st Road,Shiyan, Baoan District
518108 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):
AMBULANC (SHENZHEN) TECH. CO., LTD.
3rd Floor, Block C, Building #5, Skyworth Innovation Industry Park, Tang Tou 1st Road,Shiyan, Baoan District, 518108 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

AMBULANC (SHENZHEN) TECH. CO., LTD.
Rm A1302, 13th Floor, Block A, Shenzhen National Engineering Laboratory Building, No. 20, Gaoxin 7th Road South, Yuehai Sub-District, Nanshan District, 518054 Shenzhen, Guangdong Province, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

tuv-sud.com/ps-cert

Scope of Certificate: **Design and Development, Production and Distribution of Ultrasonic Doppler Fetal Monitor, Inhalation Antalgic Equipment (Sedation System), Ventilator, Demand Valve Resuscitator, Cardio Pump, Vein Locator, Nasal Continuous Positive Airway Pressure System, Vital Signs Monitor, Blender, Emergency Resuscitator, Suction Unit, CPR System.**

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.: BJ19087402
Valid from: 2020-03-16
Valid until: 2023-03-15

Date, 2020-03-16

Christoph Dicks
Head of Certification/Notified Body

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

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