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

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 023094 0064 Rev. 00

Manufacturer: **Ardo medical AG**
Gewerbestraße 19
6314 Unterägeri
SWITZERLAND

Facility(ies): Ardo medical AG
Gewerbestraße 19, 6314 Unterägeri, SWITZERLAND

Product Category(ies): **Medical suction pumps and breast feeding systems (sterile/non-sterile)**

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.: 713161410

Valid from: 2019-12-01
Valid until: 2024-05-26

Date, 2019-10-15

Stefan Preiß
Head of Certification/Notified Body

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

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

TÜV SÜD Product Service

Certificate

No. Q5 023094 0065 Rev. 00

Holder of Certificate: **Ardo medical AG**
Gewerbestraße 19
6314 Unterägeri
SWITZERLAND

Facility(ies): Ardo medical AG
Gewerbestraße 19, 6314 Unterägeri, SWITZERLAND

Certification Mark:

Scope of Certificate: **Design and development, production and distribution of surgical suction pumps and nursing products**
Production and distribution of medical lubricants

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.: 713182229

Valid from: 2020-08-25
Valid until: 2021-02-28

Date, 2020-08-25

Christoph Dicks
Head of Certification/Notified Body

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

TÜV®

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 098084 0003 Rev. 01

Manufacturer:

Orantech Inc.
Zone#A, 4F
1st Bld, 7th Industrial Zone
Yulv Community, GongMing
Guangming New District
518106 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): **Spo2 Sensor, Temperature Probe, Fetal transducer and ETCO2 sensor**

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.: GZ1928002

Valid from: 2020-01-10
Valid until: 2024-05-26

Date, 2020-01-10

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

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

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 098084 0003 Rev. 01

Facility(ies):

Orantech Inc.
Zone#A, 4F, 1st Bld, 7th Industrial Zone, Yulv Community,
GongMing, Guangming New District, 518106 Shenzhen,
PEOPLE'S REPUBLIC OF CHINA

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

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®

CERTIFICATE

Management system as per
ISO 9001 : 2015

In accordance with TÜV NORD CERT procedures, it is hereby certified that

Dräger Nederland B.V.
Huygensstraat 3-5
2721 LT Zoetermeer
Netherlands

with the site Beurtschipperstraat 1, 3194 DK Hoogvliet, The Netherlands

applies a management system in line with the above standard for the following scope

Sales and service of products, systems and services for
- **Gas detection and detection equipment, personal protection, diving technology, fire extinguishing, evacuation and fire detection systems, rescue equipment and system technology solutions**
- **Anesthesia, patient ventilation and inhalation, pediatrics, medical supply units, OR lights, patient monitoring incl. software**
- **Medical gas supply systems**

Certificate Registration No. 44 100 150221-044
Audit Report No. 3522 6064

Valid from 2018-12-02
Valid until 2021-12-01
Initial certification 2015-12-02

Certification Body
at TÜV NORD CERT GmbH

Essen, 2018-11-08

This certification was conducted in accordance with the TÜV NORD CERT auditing and certification procedures and is subject to regular surveillance audits. This certificate is valid in conjunction with the main certificate.

TÜV NORD CERT GmbH Langemarckstraße 20 45141 Essen www.tuev-nord-cert.com

DAkkS Deutsche Akkreditierungsstelle D-ZM-12007-01-01

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

GROUPE AMORGOS – VLAD et Batteries 4Pro.com

Main Site: 400 Rue Emille Dewoitine, 37210 Parcay-Meslay, France.

has been registered by Intertek as conforming to the requirements of:

ISO 14001:2015
ISO 9001:2015

The management system is applicable to:

VLAD: Design, adaptation, assembly and supply studies of batteries, accumulators and accumulators for industrial and medical applications.

B4P: Online sale of batteries, accumulators, batteries and other related items.

Certificate Number:
0085241

Initial Certification Date:
03 December 2018

Date of Certification Decision:
03 December 2018

Issuing Date:
17 December 2018

Valid Until:
02 December 2021

ACCRÉDITATION COFRAC N° 4-0014 PORTÉE DISPONIBLE SUR www.cofrac.fr

Calin Moldovean
President, Business Assurance

Intertek Certification France
Tour PB5, 1 Avenue du Général De Gaulle
92800 Puteaux - France

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 076260 0010 Rev. 00

Manufacturer: **Shenyang Canta Medical Tech. Co., Ltd.**
No.76-39 Shenbei Road
Daoyi Economic Development Zone
Shenbei New District
110136 Shenyang
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): **Oxygen Concentrator for Medical Use, Sleep Apnoea Breathing Therapy Devices.**

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.: BJ19777071

Valid from: 2020-03-02
Valid until: 2024-05-26

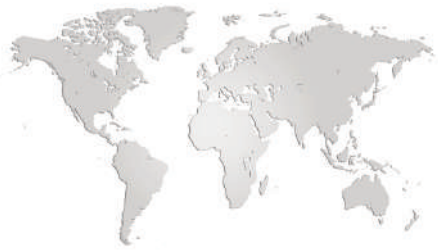
Date, 2020-03-02

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

CERTIFICATE



EN ISO 13485:2016

DEKRA Certification GmbH hereby certifies that the company

IT Dr. Gambert GmbH

Scope of certification:

Design and development, manufacture and distribution of electro-chemical gas sensors for medical equipment

Certified location:

Hinter dem Chor 21, 23966 Wismar, Germany

has established and maintains a quality management system according to the above mentioned standard. The conformity was adduced with audit report no. 50403-Z6-00.

This certificate is valid from 2018-09-17 to 2021-09-16

Registration No.: 50403-14-00

DEKRA Certification GmbH Stuttgart, Handwerkstraße 15, D-70565 Stuttgart

DEKRA Certification

DAkkS Deutsche Akkreditierungsstelle D-ZM-16029-08-00

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2018-08-31

intertek
Total Quality. Assured.

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

V.L.A.D.

Main Site: 400 Rue Emille Dewoitine, 37210 Parcay-Meslay, France

has been registered by Intertek as conforming to the requirements of:

ISO 13485:2016

The management system is applicable to:

Design, manufacturing and supply of batteries for medical applications.

Certificate Number:
0086983

Initial Certification Date:
1 February 2019

Date of Certification Decision:
1 February 2019

Issuing Date:
16 September 2019

Valid Until:
31 January 2022

ISO 13485:2016 CERTIFICATION ™
Intertek

SCC Accredited CB-MS
OCSM Accrédité CCN ™

Calin Moldovean
President

Intertek Testing Services NA Ltd.,
1829, 32nd avenue, Lachine, QC, H8T 3J1,
Canada

Sertifika
Certificate

DSR CERTIFICATION

AKTİF MÜHENDİSLİK DIŞ TİCARET ANONİM ŞİRKETİ

ŞERİFALİ MAH. BAYRAKTAR BULVARI ŞEHİT SK. NO:5 ÜMRANİYE / İSTANBUL

DSR BELGELENDİRME tarafından denetlenmiş ve uygulamakta olduğu
Kalite Yönetim Sisteminin

is audited by DSR Certification and applied
Quality Management System meet the requirements of

ISO 9001:2015

standardına aşağıdaki kapsamda uymakta olduğu gözlenmiştir.
standard for the following activities.

ENERJİ KALİTESİ ÖLÇME KONTROL KORUMA TEST CİHAZLARI ÜRÜN SİSTEMLERİ YAZILIM ÜRETİM TASARIM MÜHENDİSLİK VE EĞİTİM HİZMETLERİ

DESIGN, MANUFACTURE, TRAINING AND ENGINEERING SERVICES OF SOFTWARE POWER QUALITY CONTROL PRODECTION ASSESMENT TEST EQUIPMENTS

Sertifika No / *Certificate No:* **QMS-19.08.351**

22.08.2019 Sertifika Tarihi *Certificate Date*	19.08.2020 Sertifika Son Basım Tarihi *Certificate Last Issue Date*	18.08.2021 Sertifika Geçerlilik Tarihi *Certificate Expiry Date*
	3 Yıl/*Years* Belgelendirme Periyodu *Certification Period*	**EA Kodu**/EA Code: 19-33-37

DSR CERTIFICATION
ISO 9001:2015 CERTIFIED

ONAY
APPROVAL

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF

IAS ACCREDITED
Management Systems Certification Body
MSCB-134

DSR TEKNİK MUAYENE SERTİFİKASYON HİZ. LTD. ŞTİ.
Yeşilbağlar Mah. Selvili Sk. Helis Beyaz Ofis 2/1 A Blok No:207 PENDİK / İSTANBUL / TÜRKİYE Tel: +90 216 606 06 35
E-mail: info@dsrbelgelendirme.com.tr - Web: www.dsrbelgelendirme.com.tr

Sertifika
Certificate

DSR CERTIFICATION

AKTİF MÜHENDİSLİK DIŞ TİCARET ANONİM ŞİRKETİ

ŞERİFALİ MAH. BAYRAKTAR BULVARI ŞEHİT SK. NO:5 ÜMRANİYE / İSTANBUL

DSR BELGELENDİRME tarafından denetlenmiş ve uygulamakta olduğu
Çevre Yönetim Sisteminin

is audited by DSR Certification and applied
Environmental Management System meet the requirements of

ISO 14001:2015

standardına aşağıdaki kapsamda uymakta olduğu gözlenmiştir.
standard for the following activities.

ENERJİ KALİTESİ ÖLÇME KONTROL KORUMA TEST CİHAZLARI ÜRÜN SİSTEMLERİ YAZILIM ÜRETİM TASARIM MÜHENDİSLİK VE EĞİTİM HİZMETLERİ

DESIGN, MANUFACTURE, TRAINING AND ENGINEERING SERVICES OF SOFTWARE POWER QUALITY CONTROL PRODECTION ASSESMENT TEST EQUIPMENTS

Sertifika No / *Certificate No:* **EMS-19.08.351**

22.08.2019 Sertifika Tarihi *Certificate Date*	19.08.2020 Sertifika Son Basım Tarihi *Certificate Last Issue Date*	18.08.2021 Sertifika Geçerlilik Tarihi Certificate Expiry Date
	3 Yıl/*Years* Belgelendirme Periyodu *Certification Period*	**EA Kodu**/EA 19-33-37 Code:

DSR CERTIFICATION
ISO 14001:2015 CERTIFIED

ONAY
APPROVAL

IAF MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT

IAS ACCREDITED
Management Systems
Certificat on Body
MSCB 134

DSR TEKNİK MUAYENE SERTİFİKASYON HİZ. LTD. ŞTİ.
Yeşilbağlar Mah. Selvili Sk. Helis Beyaz Ofis 2/1 A Blok No:207 PENDİK / İSTANBUL / TÜRKİYE Tel: +90 216 606 06 35
E-mail: info@dsrbelgelendirme.com.tr - Web: www.dsrbelgelendirme.com.tr

GMED
GROUPE LNE

CERTIFICAT
CERTIFICATE OF REGISTRATION
N° 24465 rev. 4

GMED certifie que le système de management de la qualité développé par

GMED certifies that the quality management system developed by

SCHILLER MEDICAL
4 rue Louis Pasteur
67160 WISSEMBOURG FRANCE

pour les activités
for the activities

Conception, développement, fabrication, vente et service après-vente de moniteurs-défibrillateurs, défibrillateurs, équipements de surveillance multiparamétriques et de diagnostic, électrodes ECG actives, accessoires associés : Voir addendum.

Design, development, manufacture, sales and servicing of monitors-defibrillators, defibrillators, monitoring and diagnostic medical equipment, active ECG electrodes, associated accessories : See addendum.

réalisées sur le(s) site(s) de
performed on the location(s) of

SCHILLER MEDICAL
4 rue Louis Pasteur - 67160 WISSEMBOURG - FRA

est conforme aux exigences des normes internationales
complies with the requirements of the international standards

ISO 13485 : 2016

Début de validité / *Effective date :* **December 10th, 2018 (included)**
Valable jusqu'au / *Expiry date :* **April 25th, 2021 (included)**
Etabli le / *Issued on :* **December 10th, 2018**

GMED SAS GMED SAS
GMED GROUPE LNE

On behalf of the President
Béatrice LYS
Technical Director

cofrac
CERTIFICATION DE SYSTEMES DE MANAGEMENT
Accréditation n°4-0608
Liste des sites accrédités et portée disponible sur www.cofrac.fr

GMED_SQ-F-V0-07-2018

GMED N° 24465–4
Ce certificat est délivré selon les règles de certification GMED / This certificate is issued according to the rules of GMED certification

Modifie le certificat 24465-3

GMED
GROUPE LNE

Addendum au certificat n° 24465 rev. 4 page 1/1
Addendum of the certificate n° 24465 rev. 4
Dossier / *File* N° P177559-4

Ce certificat couvre les activités et les sites suivants :
This certificate covers the following activities and sites :

SCHILLER MEDICAL
4 rue Louis Pasteur
67160 WISSEMBOURG
FRANCE

Version française :
Conception, développement, fabrication, vente et service après-vente de :
- moniteurs-défibrillateurs, défibrillateurs incluant des équipements avec des stimulateurs cardiaques non implantables,
- équipements de surveillance multiparamétriques et de diagnostic incluant des équipements compatibles avec des dispositifs d'imagerie par résonance magnétique,
- électrodes ECG actives,
- accessoires associés.

Version anglaise :
Design, development, manufacture, sales and servicing of :
- monitor-defibrillators, defibrillators including equipment with non implantable cardiac pacemakers,
- monitoring and diagnostic medical equipment including equipment compatible with resonance magnetic imaging devices,
- active ECG electrodes,
- associated accessories.

On behalf of the President
Béatrice LYS
Technical Director

Certificate JP16/040444

The management system of

ALP Co., Ltd.

3-3-10 Midorigaoka, Hamura-shi, Tokyo 205-0003, Japan

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

Design and development, Manufacture, Installation and Service of moist heat sterilizers for medical use

This certificate is valid from 9 September 2019 until 9 September 2022 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 26 July 2022
Issue 4. Certified since 9 September 2016

Authorised by

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

HC SGS 13485 2016 0118

UKAS MANAGEMENT SYSTEMS
0005

intertek
Total Quality. Assured.

CERTIFICATE OF REGISTRATION

This is to certify that the quality management system of:

Medica Corporation

Main Site: 5 Oak Park Drive

Bedford, Massachusetts 01730 United States

has been assessed by Intertek as conforming to the requirements of:

ISO 13485:2016

The quality management system is applicable to:

The Design, Development, Manufacture, Service, Distribution of in-vitro diagnostic medical devices, in-vitro diagnostic test kits, in-vitro diagnostic reagents, in-vitro diagnostic analyzers/software used in the diagnosis and management of cancer, immune status, disease status, autoimmune status, cardiac markers, protein metabolism, endocrine disorders, blood analytes, urinalysis, blood gases.

Certificate Number:
0082581-01

Initial Certification Date:
2009-04-17

Certificate Issue Date:
2019-01-01

Certificate Expiry Date:
2021-04-16

SCC Accredited CB-MS
OCSM
Accrédité CCN

Calin Moldovean
President

Intertek Testing Services NA Ltd.,
1829, 32nd avenue, Lachine, QC, H8T 3J1,
Canada

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

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

TÜV SÜD Product Service

Certificate

No. Q5 076260 0009 Rev. 02

Holder of Certificate: **Shenyang Canta Medical Tech. Co., Ltd.**
No.76-39 Shenbei Road
Daoyi Economic Development Zone
Shenbei New District
110136 Shenyang
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Shenyang Canta Medical Tech. Co., Ltd.
No.76-39 Shenbei Road, Daoyi Economic Development Zone, Shenbei New District, 110136 Shenyang, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: **Design and Development, Production and Service of Oxygen Concentrators and Sleep Apnoea Breathing Therapy Devices.**

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). 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:Q5 076260 0009 Rev. 02

Report No.: BJ20077701

Valid from: 2020-11-02
Valid until: 2023-10-18

Date, 2020-11-02

Christoph Dicks
Head of Certification/Notified Body

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

Product Service

Certificate

No. Q5 098084 0004 Rev. 01

Holder of Certificate: **Orantech Inc.**
Zone#A, 4F
1st Bld, 7th Industrial Zone
Yulv Community, GongMing
Guangming New District
518106 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):
Orantech Inc.
Zone#A, 4F, 1st Bld, 7th Industrial Zone, Yulv Community, GongMing, Guangming New District, 518106 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: **Design and Development, Production and Distribution of Spo2 Sensor, NIBP Cuff, Temperature Probe, ETCO2 Sensor, Fetal Transducer and Patient Cables and Leadwires**

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). 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:Q5 098084 0004 Rev. 01

Report No.: GZ2028001

Valid from: 2020-09-05
Valid until: 2023-09-04

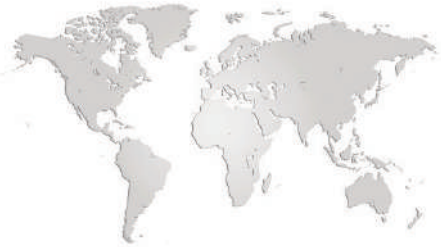
Date, 2020-08-19

Christoph Dicks
Head of Certification/Notified Body

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

EC CERTIFICATE

for the Quality Assurance System



according the Directive 93/42/EEC, Annex II excluding section (4)

As a Notified Body of the European Union, DEKRA Certification GmbH certifies, that the company

IT Dr. Gambert GmbH

Hinter dem Chor 21, 23966 Wismar, Germany

Certified location:

Hinter dem Chor 21, 23966 Wismar, Germany

applies a quality assurance system according to the Directive 93/42/EEC Annex II for the medical devices listed in the annex. The approval is based on the result of the re-certification audit report no. 50403-Z6-00, the decision dated 2018-08-31 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2018-09-17 to 2023-09-16

Registration No.: 50403-16-07

DEKRA Certification GmbH Stuttgart, Handwerkstraße 15 • D-70565 Stuttgart

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-295.10.02

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2018-08-31
Notified Body ID-number: 0124

Annex to the EC Certificate No. 50403-16-07

Valid from 2018-09-17 to 2023-09-16

Revision status of the annex: 0 dated 2018-08-31

Devices/device categories included in the certificate:

Class II a:

- Oxygen sensors
- Nitric oxide sensors

DEKRA Certification GmbH
DEKRA Certification
D-70565 Stuttgart, Handwerkstraße 15

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2018-08-31
Notified Body ID-number: 0124

Best Service of Testing

Certificate of Compliance

Certificate Number: BST13050189Y-1RC-4

Applicant	:	**NANTONG NEW DONAR SPECIALTY LAMP CO., LTD.** Niu Jing Science & Tech Park, No.18 Xing Tai Rd, Gang Zha Economic Development Zone, Nantong 226002, Jiangsu Province, P.R. China
Manufacturer	:	**NANTONG NEW DONAR SPECIALTY LAMP CO., LTD.** Niu Jing Science & Tech Park, No.18 Xing Tai Rd, Gang Zha Economic Development Zone, Nantong 226002, Jiangsu Province, P.R. China
Product	:	**HALOGEN LAMP**
Trade Name	:	**DONAR**
M/N	:	**Reflector Lamp Series: ENX, Reflector Lamp Series: DDL EFM EFN EFP EFR EJA EJM EJV EKE ELC ELH 28452 ; Single-Ended Series: 64620 64621 64609 64638 64647 64650 BLUE-30 BLUE-80 BLUE-90 BTL BTN BTP BTR DKK-24501 DYH DYS EGR EGT ESB EYB JC6V20W/SP JC23V100W X514SP FCS FDS FDV FEL HPL575-115 HPL750-115; Double-Ended Series: DDN DWZ DXM DXX FCM FDF Q150T4/CL25**
Test Standard	:	**EPA3050B:1996、EN1122B:2001、EPA3052:1996、EPA3060A:1996、EPA7196A:1992、EPA3540C:1996、EPA8270D:2007、IEC62321:2008**

The EUT described above has been consolidated by us and found in compliance with the council RoHS directive—2011/65/EU. It is only valid in connection with the test report number: BST13050189Y-1RR-4.

SHENZHEN BST TECHNOLOGY CO.,LTD. APPROVED

Christina
Manager
May. 15, 2013

RoHS

Shenzhen BST Technology Co.,Ltd.
Building No.23-24, Zhiheng Industrial Park, Guankouer Road, Nantou,Nanshan District,Shenzhen,Guangdong,China
Tel:400-882-9628 E-mail:christina@bst-lab.com Complaints hotline:86-755-26747756 http://www.bst-lab.com

ATTESTATION / *CERTIFICATE* **N° 23246 rev. 8**

Délivrée à Paris le 27 janvier 2021

Issued in Paris on January 27th, 2021

ATTESTATION CE / *EC CERTIFICATE*

Approbation du Système Complet d'assurance Qualité/ *Approval of full Quality Assurance System*

ANNEXE II excluant le point 4 Directive 93/42/CEE relative aux dispositifs médicaux

ANNEX II excluding section 4 Directive 93/42/EEC concerning medical devices

Pour les dispositifs de classe III, un certificat CE de conception est requis
For class III devices, a EC design certificate is required

Fabricant / *Manufacturer*

SCHILLER MEDICAL
4 rue Louis Pasteur
67160 WISSEMBOURG FRANCE

Catégorie du(des) dispositif(s) / *Device(s) category*

Défibrillateurs

Defibrillators

Voir document complémentaire GMED / See GMED additional document

n° 37485

GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé P177559, P600789, le système d'assurance qualité - pour la conception, la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe II excluant le point 4 de la Directive 93/42/CEE.

GMED certifies that, on the basis of the results contained in the file referenced P177559, P600789, the quality system - for design, manufacturing, and final inspection - of medical devices listed here above complies with the requirements of the Directive 93/42/EEC, annex II excluding section 4.

La validité du présent certificat est soumise à une vérification périodique ou imprévue
The validity of the certificate is subject to periodic or unexpected verification

Début de validité / *Effective date :* **January 27th, 2021 (included)**

Valable jusqu'au / *Expiry date :* **May 26th, 2024 (included)**

DocuSigned by:
Lionel DREUX
A1D80E08C60D47A...

Lionel DREUX
Certification Director

GMED - 23246 rev. 8
Modifie le certificat 23246-7

GMED_b2p3_new2020-V0-04-

Ce document complémentaire GMED n° 37485 rev. 1 atteste de la validité du certificat CE n° 23246 rev. 8 au regard des informations listées ci-dessous.

This GMED additional document n° 37485 rev. 1 attests to the validity of CE certificate n° 23246 rev. 8 with regard to the information listed below.

Fabricant / *Manufacturer:*

SCHILLER MEDICAL
4 rue Louis Pasteur
67160 WISSEMBOURG FRANCE

Identification des dispositifs / *Identification of devices*

Désignation du dispositif *Device designation*	**Référence commerciale du dispositif ou code article** *Device commercial name or article code*	**Classe du DM** *MD Class*
Défibrillateurs *Defibrillators*	**- Défibrillateur FRED Easy** • **FRED Easy FRENCH FIREMAN** • **FRED Easy DSA (SD card)** • **FRED Easy DSA (Ethernet)** • **FRED Easy DSA / Manuel (SD card)** • **FRED Easy DSA /Manuel (Ethernet)** • **FRED Easy DA (SD card)** • **FRED Easy DA (Ethernet)** • **FRED Easy Life DSA (SD card)** • **FRED Easy Life DA (Ethernet)** • **FRED Easy Life DA (SD card)** • **FRED Easy Life DSA (Ethernet)** • **FRED Easy Online** **- Défibrillateur FRED PA-1**	**IIb**

Site couvert et Activités / *Location and Activities*

SCHILLER MEDICAL - 4 rue Louis Pasteur - 67160 WISSEMBOURG - FRANCE :
Conception, fabrication et contrôle final / *Design, manufacture and final control*

GMED	0459

GMED - 37485 rev. 1
Modifie le document n° 37485 rev. 0

DocuSigned by:
Lionel DREUX
A1D80E08C60D47A...

Lionel DREUX
Certification Director

bsi.

By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 02000**

Issued To: **Teledyne Analytical Instruments**
A business unit of Teledyne Instruments, Inc
16830 Chestnut Street
City of Industry
California
91748
USA

In respect of:

The design and manufacture of oxygen monitors and sensors

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Albert Roossien, Regulatory Lead

First Issued: **1998-07-09** Date: **2019-03-25** Expiry Date: **2023-07-08**

...making excellence a habit.™

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

bsi.

By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 02000**
Date:	**2019-03-25**
Issued To:	**Teledyne Analytical Instruments** **A business unit of Teledyne Instruments, Inc** **16830 Chestnut Street** **City of Industry** **California** **91748** **USA**

Subcontractor:	**Service(s) supplied**
Viamed Ltd 15 Station Road Cross Hills Keighley West Yorkshire BD20 7DT United Kingdom	**EU Representative**

...making excellence a habit.™

bsi.

By Royal Charter

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 02000**

Date: **2019-03-25**

Issued To: **Teledyne Analytical Instruments**
A business unit of Teledyne Instruments, Inc
16830 Chestnut Street
City of Industry
California
91748
USA

Certificate History

Date	Reference Number	Action
09 July 1998		First Issue.
03 March 2000		Addition of Ensambles de Precision, S.A de C.V as manufacturing subcontractor of oxygen sensors and printed wiring assemblies.
11 June 2002		Change of company name.
29 April 2004		Certificate renewal. New certificate format.
07 July 2008	7230667	Certificate renewal.
26 April 2012	7817544	Name change from Teledyne Electronic Technologies to Teledyne Analytical Instruments, A business unit of Teledyne Instruments, Inc.
18 June 2013	7945519	Certificate renewal. Addition of Viamed Ltd as EU representative and removal of Ensambles de Precision, S.A de C.V as a significant subcontractor.

bsi.

By Royal Charter

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 02000**

Date: **2019-03-25**

Issued To: **Teledyne Analytical Instruments**
A business unit of Teledyne Instruments, Inc
16830 Chestnut Street
City of Industry
California
91748
USA

Date	Reference Number	Action
11 May 2018	8896461	Certificate renewal.
Current	7781684	Traceable to NB 0086.

...making excellence a habit.™

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Teledyne Analytical Instruments
a business unit of
Teledyne Instruments, Inc.
16830 Chestnut Street
City of Industry
California
91748-1020
USA

Holds Certificate No: **FM 75659**

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

The design and manufacture of oxygen sensors.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2003-05-29
Latest Revision Date: 2021-01-06

Effective Date: 2021-01-23
Expiry Date: 2024-01-22

...making excellence a habit.™

RADIOMETER

Radiometer Medical ApS
Åkandevej 21
2700 Brønshøj
Tlf.: +45 38 27 38 27
Direkte:
Mobil:
Fax: +45 38 27 27 27
CVR nr. 27509185
www.radiometer.com

February 21,2019

To whom it may concern

This is to verify, that Radiometer Medical ApS has appointed the company;

BSI,
Kitemark Court,
Davy Avenue,
Knowlhill,
Milton Kaynes, MK5 8PP,
UK,

as its Notified Body

BSI has in that capacity issued the attached Certificate no. MD 672317, Effective Date: 2017-12-16, Quality Management system – ISO 13485:2016, covering the Radiometer site:

Radiometer Medical ApS
Åkandevej 21
2700 Brønshøj
Denmark

Best regards,

Zaineb Alhilli
Regulatory Affairs Coordinator
Radiometer Medical ApS

By Royal Charter

Certificate of Registration

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

This is to certify that:

Radiometer Medical ApS
Åkandevej 21
2700 Brønshøj
Denmark

Holds Certificate Number: **MD 672317**

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

Design, development and manufacture and servicing of blood gas analysers, transcutaneous blood gas and pulse oximetry monitors, fluorescence immunoassay analysers, arterial blood samplers and associated reagents, solutions, calibrators, controls, accessories and clinical laboratory information systems.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2017-09-11
Latest Revision Date: 2019-02-20

Effective Date: 2017-12-16
Expiry Date: 2020-12-15

...making excellence a habit.™

Certificate No: **MD 672317**

Location	Registered Activities
Radiometer Medical ApS Åkandevej 21 2700 Brønshøj Denmark	Design, development and manufacture and servicing of blood gas analysers, transcutaneous blood gas and pulse oximetry monitors, fluorescence immunoassay analysers, arterial blood samplers and associated reagents, solutions, calibrators, controls, accessories and clinical laboratory information systems.
Radiometer Medical ApS Priorparken 341 2650 Brondby Denmark	Warehousing
India Development Center (IDC) Building 6A Unit 401&402 and 501&502 RMZ Eco World Sarjapur Marathalli Outer Ring Road Bengalaru 560103 India	Design, development and manufacture and servicing of blood gas analysers, transcutaneous blood gas and pulse oximetry monitors, fluorescence immunoassay analysers, arterial blood samplers and associated reagents, solutions, calibrators, controls, accessories and clinical laboratory information systems.

Original Registration Date: 2017-09-11

Latest Revision Date: 2019-02-20

Effective Date: 2017-12-16

Expiry Date: 2020-12-15