DNV·GL

MANAGEMENT SYSTEM CERTIFICATE

Certificate No:
90732-2010-AQ-SWE-SWEDAC

Initial certification date:
22, December, 2010

Valid:
13, March, 2019 - 22, December, 2019

This is to certify that the management system of

Atlas Copco Industrial Technique AB

Sickla Industriväg 19, 105 23, Nacka, Sweden
and the sites as mentioned in the appendix accompanying this certificate

has been found to conform to the Quality Management System standard:
ISO 9001:2015

This certificate is valid for the following scope:
Design, development, manufacture, marketing, sales, calibration, distribution, hire and service of industrial power tools, assembly systems, quality assurance products, software, hydraulic bolt tensioners, torque wrenches, stud bolts and nuts, adhesive application systems and automation systems, and services.

Place and date:
Solna, 13, March, 2019

SWEDAC ACKREDITERING
Accred. no.1053
Certification of Management Systems
ISO/IEC 17021-1

For the issuing office:
DNV GL - Business Assurance
Box 6046/Hemvärnsgatan 9, 171 06,
Solna, Sweden

Ann-Louise Pått
Management Representative

Digitally signed by Grabazei Alexandru
Date: 2019.07.12 14:49:28 EEST
Reason: MoldSign Signature
Location: Moldova

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

Certificate No: 90732-2010-AQ-SWE-SWEDAC
Place and date: Solna, 13, March, 2019

Appendix to Certificate

Atlas Copco Industrial Technique AB
Locations included in the certification are as follows:

Site Name	Site Address	Site Scope
Atlas Copco (Malaysia) Sdn. Bhd.	26, Jalan Anggerik Mokara 31/47, Kota Kemuning, Seksyen 31 40460, Selangor Darul Ehsan, Shah Alam, West Malaysia, Malaysia	Marketing, sales, calibration and service of industrial power tools, assembly systems and aftermarket products
Atlas Copco (Philippines) Inc.	North Main Avenue Lot 12, Block 2, Laguna Techno Park Biñan, 4024, Laguna, Philippines	Marketing, sales, calibration and service of industrial power tools, assembly systems and aftermarket products
Atlas Copco (South East Asia) Pte Ltd,	25 Tuas Ave 2, Singapore, Singapore, 639456	Marketing, sales, calibration and service of industrial power tools, assembly systems and aftermarket products
Atlas Copco Applications Industrielles SAS	2 avenue de I´Eguillette, ZI du Vert Galant, 95054, Cergy-Pontoise Cedex, France	Marketing, sales, calibration and service of industrial power tools, assembly systems and aftermarket products
Atlas Copco Assembly Systems LLC Atlas Copco Tools & Assembly Systems LLC	3301 Cross Creek Parkway, Auburn Hills, MI, 48326, USA	Development, marketing, sales, calibration and service of industrial power tools, assembly systems and aftermarket products
Atlas Copco Australia Pty Ltd	3 Bessemer Street, Blacktown, NSW, 2148, Australia	Marketing, sales, calibration and service of industrial power tools, assembly systems and aftermarket products
Atlas Copco BLM s.r.l	Via Guglielmo Pepe 11 - 20037 Paderno Dugnano - Italy	Development, manufacture, marketing, sales, calibration and service of industrial power tools, assembly systems, quality assurance products, software and services
Atlas Copco Bolt Tightening Solutions	Innovation Drive, Wolverhampton, WV9 5GA, United Kingdom	Design, development, manufacture, marketing, sales, calibration, distribution, hire and service of hydraulic bolt tensioners, torque wrenches, stud bolts and nuts, and services. The supply of bolt tensioning and torque tightening pumps and hoses.
Atlas Copco Bolt Tightening Solutions	Office S10, Blyth Workspace, Comissioner Quay, Quay Road, Blyth, NE24 3AR, United Kingdom	Design, development, manufacture, marketing, sales, calibration, distribution, hire and service of hydraulic bolt tensioners, torque wrenches, stud bolts and nuts, and services. The supply of bolt tensioning and torque tightening pumps and hoses.
Atlas Copco Brasil Ltda Industrial Tools and Assembly Systems, Sao Paulo	Av.Ceci, 169 Tamboré, Barueri, ., Sao Paulo, Barueri, Brazil	Marketing, sales, instalation, calibration and after sales of industrial power tools, assembly systems, adhesive application and dosing systems
Atlas Copco Hungary Kft.	2310 Szigetszentmiklós, Szigetszentmiklós ÁTI-Sziget, Ipari Park 72.-73, Hungary	Development, manufacture, marketing, sales, calibration and service of industrial power tools,

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		assembly systems and aftermarket products
Atlas Copco IAS GmbH	Gewerbestraße 52, 75015 Bretten-Gölshausen, Germany	Development, manufacturing, distribution and service for adhesive metering and dispensing systems
Atlas Copco IAS GmbH	Bgm.-Graf-Ring 21, 82538, Geretsried, Germany	Development, production, sales and service of joining systems
Atlas Copco IAS LLC	3301 Cross Creek Parkway, Auburn Hills, MI, 48326, USA	Development, manufacturing, distribution, marketing, sales and service for adhesive application systems and automation systems
Atlas Copco India Ltd. Industrial Technique & SCA	Ground Floor and Third Floor, Mantri Alpine, Survey No. 268, 411021 Maharastra - Bavdhan Bk, Pune, Near Bandal Estate, India	Development, marketing, sales, calibration and service of industrial power tools, assembly systems and aftermarket products and the adhesive application systems and automation systems
Atlas Copco Industrial Technique	Naverland 22, 2600, Glostrup, Denmark	Marketing, sales, calibration and service of industrial power tools, assembly systems and aftermarket products
Atlas Copco Industrial Technique AB	Sickla Industriväg 19, 105 23, Nacka, Sweden	Design, development, manufacture, marketing, sales, calibration, distribution, hire and service of industrial power tools, assembly systems, quality assurance products, software, hydraulic bolt tensioners, torque wrenches, stud bolts and nuts, adhesive application systems and automation systems, and services
Atlas Copco Industrial Technique AB	Maskinvägen 4, 815 44, Tierp, Sweden	Development, manufacture, calibration and service of industrial power tools, assembly systems and aftermarket products
Atlas Copco Industrial Technique SA	Innes Road, Boksburg, Jet Park, South Africa, 1459	Marketing, sales, calibration and service of industrial power tools, assembly systems and aftermarket products
Atlas Copco Italy - Industrial Technique	Via Guglielmo Pepe 11 - 20037 Paderno Dugnano (MI) - Italy	Marketing, sales, calibration and service of industrial power tools, assembly systems and aftermarket products
Atlas Copco Mexicana SA de CV	Av. Churubusco No 748, Colonia Venustiano Carranza, 64560, Monterrey, Mexico	Marketing, sales and service of industrial power tools, assembly systems and aftermarket products
Atlas Copco Mexicana SA de CV	Av. Ébano Sin número interior Lote A, Parque Industrial FINSA, 72710, Municipio de Cuautlancingo, Estado de Puebla, Mexico	Marketing, sales and service of industrial power tools, assembly systems and aftermarket products
Atlas Copco Mexicana SA de CV	Blvr. Abraham Lincoln no 13, Los reyes, Zona Industrial, 54073, Tlalnepantla, Estado de Mexico, Mexico	Marketing, sales, calibration and service of industrial power tools, assembly systems and aftermarket products
Atlas Copco Polska Sp.zo.o	Różyniec 83c, 59-706 Gromadka Krzywa, Poland	Calibration and service of industrial power tools
Atlas Copco S.A.E.	Jose Garate 3, Poligono Ind, 28820, Coslada, Spain	Marketing, sales, calibration and service of industrial power tools, assembly systems and aftermarket products
Atlas Copco Shanghai Trading Co. Ltd IT	Building 26, No.518 Xinzhuan Hwy SongJiang District, Shanghai, China,	Marketing, sales, calibration and service of industrial power tools,

	201612	assembly systems and aftermarket products
Atlas Copco Shanghai Trading Co. Ltd IT	No.1500, Shenjiang Road, Jinqiao, Pudong, new district, Shanghai, China,	Marketing, sales, calibration and service of industrial power tools, assembly systems and aftermarket products
Atlas Copco Shanghai Trading Co. Ltd IT	No2, Xijiu Road, Tianjin Airport, Economic Zone, Tianjin, Liaoning, China,	Marketing, sales, calibration and service of industrial power tools, assembly systems and aftermarket products
Atlas Copco Shanghai Trading Co. Ltd IT	No.666 Jinshandadao Road, Huangmaoping, Yubei District, Chongqing, Yubei, China,	Marketing, sales, calibration and service of industrial power tools, assembly systems and aftermarket products
Atlas Copco Shanghai Trading Co. Ltd IT	No.368, Chechengdongqi Road, Longquanyi District, Sichuan Province, Chengdu, Longquanyi, China,	Marketing, sales, calibration and service of industrial power tools, assembly systems and aftermarket products
Atlas Copco Thailand Limited	125 Moo 9 Wellgrow Industrial Estate, Bangna-Trad Rd Km.36 Bangwua, Bangpakong, Chachoengsao, 24130, Thailand	Marketing, sales, calibration and service of industrial power tools, assembly systems and aftermarket products
Atlas Copco Tools & Assembly Systems LLC	1720 Bluegrass Court, Louisville, Ky, 40299, USA	Development, manufacture, marketing, sales, calibration and service of industrial power tools, assembly systems and aftermarket products
Atlas Copco Tools & Assembly Systems LLC	338 Business Circle, Pelham, AL, 35124, USA	Development, manufacture, marketing, sales, calibration and service of industrial power tools, assembly systems and aftermarket products
Atlas Copco Tools & Assembly Systems LLC	726 Great Southwest Parkway, Arlington, Arlington, TX, 76011, USA	Development, manufacture, marketing, sales, calibration and service of industrial power tools, assembly systems and aftermarket products
Atlas Copco Tools & Assembly Systems LLC	2065 S. ELMS Rd., Swartz Creek, MI, 48473, USA	Development, marketing, sales, calibration and service of industrial power tools, assembly systems and aftermarket products
Atlas Copco Tools & Assembly Systems LLC	4428 Underwood Road, Deer Park, Texas, TX, 77536, USA	Marketing, sales, calibration and service of industrial power Tools and aftermarket products
Atlas Copco Tools Central Europe GmbH	Langemarckstrasse 35, 45141 Essen, Germany	Products and services for the industry. Sales, installation, maintenance and repair of industrial tools, assembly systems, software and measurement devices. Calibration of measurement devices, process and tightening analysis, training and consulting in respective fields. Design, Construction and project management of tightening and assembly systems and software solutions.
Atlas Copco Vietnam Company Ltd.	Atlas Copco Vietnam Company Ltd., Viet Nam	Marketing, sales, calibration and service of industrial power tools, assembly systems and aftermarket products
Atlas Copco s.r.o.	V Parku 2336/22, 148 00 Praha 4, Czech Republic	Marketing, sales, calibration and service of industrial power tools,

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		assembly systems and aftermarket products
Atlas Copco s.r.o.	Elektrárenská 4, 831 04 Bratislava, Slovakia (Slovak Republic)	Marketing, sales, calibration and service of industrial power tools, assembly systems and aftermarket products
Chicago Pneumatic Tools India	Chicago Pneumatic Tools, Excellence Center - India, India Land, Global Industrial Park, Plot No 12,Surve, Hinjewadi Phase 1, Taluka Mulshi Pune 411021 - No, 235/8, India	Development, marketing, sales, calibration and service of industrial power tools, assembly systems and aftermarket products and the adhesive application systems and automation systems
Chicago Pneumatic tool	1815 Clubhouse Road, Rock Hill, SC, 29730, USA	Marketing, sales, calibration and service of industrial power tools, assembly systems and aftermarket products
Desoutter GmbH	Edmund-Seng-Straße 3, 63477 Maintal, Germany	Sales, project management, installation, maintenance and repair of industrial tools, measurement devices and assembly systems, calibration of measurement devices and certification of industrial tools, process and tightening analysis and training and consulting in respective fields
Desoutter Industrial Tools	1815 Clubhouse Road, Rock Hill, SC, 29730, USA	Marketing, sales, calibration and service of industrial power tools, assembly systems and aftermarket products
Ets Georges Renault	38, rue Bobby Sands – ZAC de la Lorie, BP 10273, 44818, Saint Herblain Cedex, France	Development, manufacture, marketing, sales, calibration and service of industrial power tools, assembly systems and aftermarket products
Fuji Industrial Technique Co.,Ltd.	537-0003 , Osaka, 2-1-14, kamiji, Higashinari-ku,	Design, development, marketing, sales, calibration and service of industrial power tools, assembly systems and aftermarket products
PT. Atlas Copco Indonesia	Cilandak Commercial Estate Kav. 203, JI. Cilandak KKO, Jakarta, Selatan 12560, Indonesia	Marketing, sales, calibration and service of industrial power tools, assembly systems and aftermarket products
Power Tools Distribution n.v.	Industrielaan 40, 3730, Hoeselt, Belgium	Stockholding, procurement and supply of power tools, spare parts and accessories
Seci-Tec S.A.S.	12 Al Lech Walesa, Pariest Bât, Le Sequoia, 77185, Lognes, France	Marketing, sales, calibration and service of industrial power tools, assembly systems and aftermarket products
Shanghai Tooltec Industrial Tool Co., Ltd.	Building 26 & 37, No.518 Xinzhuan Hwy SongJiang District, Shanghai, China, 201612	Development, manufacture, marketing, sales, calibration and service of industrial power tools, assembly systems and aftermarket products

CERTIFICATE

This is to certify that the company

BHT Hygienetechnik GmbH
Division

Messerschmittstr. 11
86368 Gersthofen
Germany

Scope:
Design and development, manufacturing, sales, installation and maintenance of units and equipment for cleaning, disinfection, drying of contaminated material in hospitals, medical practices, industry and laboratories.

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:

EN ISO 13485 : 2012 + AC : 2012

Certificate registration no.	019906 MP2012
Certificate unique ID	170686045
Effective date	2017-07-16
Expiry date	2020-07-15
Frankfurt am Main	2017-07-12

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

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

Accredited Body: DQS Medizinprodukte GmbH, August-Schanz-Str. 21, 60433 Frankfurt a. M., Germany

EC Certificate

mdc medical device certification GmbH
Notified Body 0483
herewith certifies that

CARL REINER®
Breathing Engineering

Carl Reiner GmbH
Mariannengasse 17
1090 Wien
Austria

for the scope

Laryngoscopes, bronchoscopes, tracheoscopes and adapters for Twin Stream respirator

has introduced and applies a

Quality System

for the design, manufacture and final inspection.

The mdc audit has proven that this quality system meets all requirements according to

Annex II – excluding Section 4 of the Council Directive 93/42/EEC

of 14 June 1993 concerning medical devices.

The surveillance will be held as specified in Annex II, Section 5.

Valid from	2017-10-18
Valid until	2022-10-18
Registration no.	D4004100002
Report no.	P16-01581-84295
Stuttgart	2017-10-18

Head of Certification Body

medical device certification mdc

Benannt durch/Designated by Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten www.zlg.de
ZLG-BS-246.10.06

mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: http://www.mdc-ce.de

Certificate

mdc medical device certification GmbH
certifies that

Carl Reiner GmbH
Mariannengasse 17
1090 Wien
Austria

for the scope

Design, development, production, distribution and maintenance of high frequency ventilators and associated Jet-Endoscopes (Laryngoscopes, Bronchoscopes, Tracheoscopes, Tracheobronchoscopes) as well as non sterile Jet-Accessories and surgical instruments

Distribution, maintenance and repair of medical devices for diagnosis and therapy

has introduced and applies a

Quality Management System

The mdc audit has proven that this quality management system meets all requirements of the following standard

EN ISO 13485

Medical devices – Quality management systems – Requirements for regulatory purposes

EN ISO 13485:2012 + AC:2012 - ISO 13485:2003 + Cor. 1:2009

Valid from	2017-05-03
Valid until	2020-05-03
Registration no.	D4004100001
Report no.	P16-01581-96351
Stuttgart	2017-05-03

Head of Certification Body

medical device certification mdc

DAkkS Deutsche Akkreditierungsstelle D-ZM-16002-06-00

mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: http://www.mdc-ce.de

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ 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 15 06 21697 017

Manufacturer:

EnviteC - Wismar GmbH
Alter Holzhafen 18
23966 Wismar
GERMANY

Facility(ies):

EnviteC - Wismar GmbH
Alter Holzhafen 18, 23966 Wismar, GERMANY

Product Category(ies):

Oxygen Saturation Sensors and Monitors, Sensors and Control Units for Monitoring of Respiratory Parameters and Gas Exchange, Non-invasive Blood Pressure Euipment, Temperature Sensors

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.: 713063594

Valid from: 2015-09-02
Valid until: 2020-09-01

672976

Date, 2015-08-28

Hans-Heiner Junker

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

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

TÜV®

A1 / 04.11

ENVITEC
by Honeywell

Oxygen Sensor OOM201

Use the advantages:

- Compliant with European MDD (CE certification)
- Meets ISO 80601-2-55
- Designed and manufactured according to EN ISO 13485
- Accurate and reliable fast response
- Resistant to N_2O
- Excellent signal stability
- High product quality
- Short delivery times
- Technical support
- Made in Germany
- FDA cleared

From standard sensors to customized sensors

Experienced EnviteC engineers analyze customer requirements. This input is used for different standard and OEM applications, and ongoing support is provided right up to the final integraton in the solution. EnviteC designs customized sensors characterized by a maximum possible degree of precision, for example with different signal levels or temperature compensation elements.

Intendend use

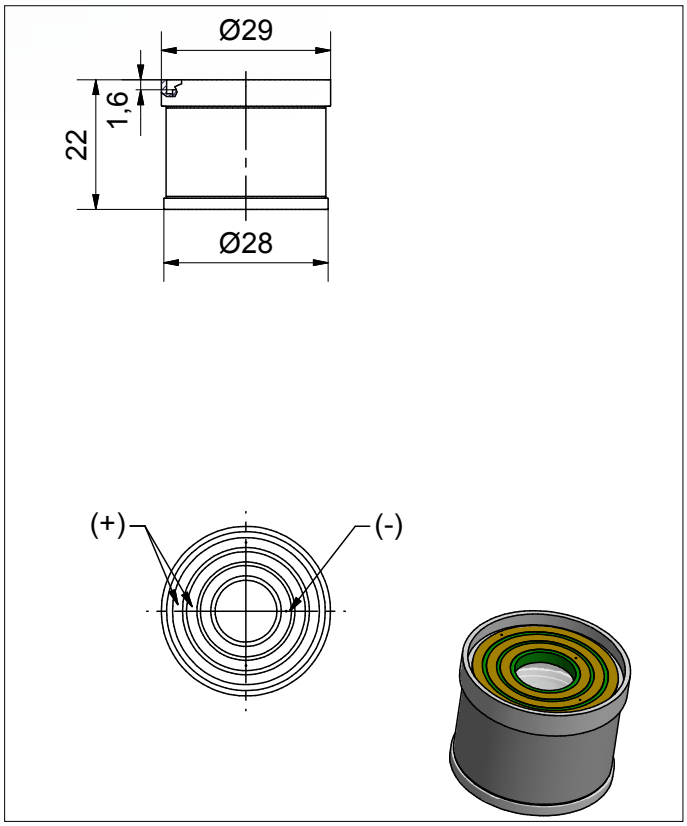
The EnviteC Medical Oxygen Sensors are intended as oxygen-sensing component of an oxygen analyzer that measures oxygen concentration in breathing gas mixtures in the following applications:

Sensing device for oxygen in

- control device of oxygen concentrators
- medical ventilators
- anaesthesia equipment
- incubators.

The use is limited to system monitoring. The sensors are not suited for breath by breath analysis of breath gases. Please refer to the Instructions for Use! If the sensor is intended to replace the original oxygen-sensing component of an oxygen analyzer, consult the EnviteC XRL Cross Reference List for selecting the appropriate sensor.

Mechanical drawing (All dimension in mm)



General tolerances ISO 2768-c

Additional information

The Instructions for Use as well as the EnviteC XRL Cross Reference List are available under www.EnviteC.com and in the Apple App Store under EnviteC XRL as free download.

For more information please contact us!
We look forward to assisting you either on the phone or in a personal talk.

Technical Specifications OOM201

Measurement range	0 % ... 100 % oxygen (at atmospheric pressure)
Nominal sensor lifetime	≥ 500 000 % volume oxygen hours
Output in ambient air	14 mV ... 20.7 mV (Dual Cathode), load 600 Ohms
Electrical interface	Gold plated slip rings
Accuracy	meets ISO 80601-2-55 requirements
Repeatability	< 1 % volume O_2 at constant temperature and pressure
Linearity error	< 3 % relative
Response time	< 12 s to 90 % of final value
Zero offset voltage	< 200 µV in 100 % nitrogen, applied for 5 min
Cross interference	meets ISO 80601-2-55 requirements
Influence of humidity	-0.03 % rel. per % RH at 25 °C
Pressure range	0.6 bar ... 2 bar (ppO_2 0 ... 1250 mbar O_2)
Influence of pressure	proportional to change in oxygen partial pressure
Influence of mechanical shock	< 1 % relative after a fall from 1 m
Operating temperature	0 °C ... +50 °C
Temperature compensation	no temperature compensation
Operating humidity	0 % ... 99 % RH non-condensing
Long term output drift	< 1 % volume oxygen per month typically < -15 % relative over lifetime
Storage temperature	-20 °C ... +50 °C
Recommended storage	+5 °C … +15 °C
Recommended load	≥ 10 kOhms
Warm-up time	< 30 minutes, after replacement of sensor
Weight	approximately 28 grams
Part number	01-00-0014

All specifications are applicable at standard conditions:
1013 hPa, 25 °C dry ambient air

For suitable accessories and sensors please refer to the EnviteC Cross Reference List under www.EnviteC.com and in the Apple App Store unter EnviteC XRL as free download.

EnviteC-Wismar GmbH
a Honeywell Company
Alter Holzhafen 18, 23966 Wismar, Germany
Phone: +49 (0)3841-360-1
Phone: +49 (0)3841-360-200
Fax: +49 (0)3841-360-222
Internet: www.envitec.com
Email: info@envitec.com

Doc. No. 001-33-Datasheet_OOM201-0
March 2016

ENVITEC
by Honeywell

ENVITEC
by Honeywell

Oxygen Sensor OOM202

Use the advantages:

- Compliant with European MDD (CE certification)
- Meets ISO 80601-2-55
- Designed and manufactured according to EN ISO 13485
- Accurate and reliable fast response
- Resistant to N_2O
- Excellent signal stability
- High product quality
- Short delivery times
- Technical support
- Made in Germany
- FDA cleared

From standard sensors to customized sensors

Experienced EnviteC engineers analyze customer requirements. This input is used for different standard and OEM applications, and ongoing support is provided right up to the final integraton in the solution. EnviteC designs customized sensors characterized by a maximum possible degree of precision, for example with different signal levels or temperature compensation elements.

Intendend use

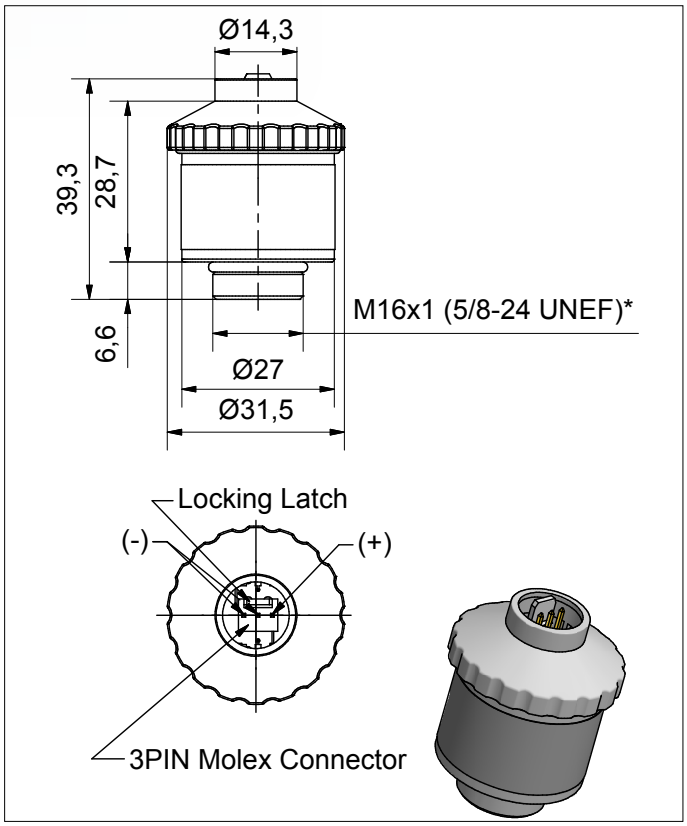
The EnviteC Medical Oxygen Sensors are intended as oxygen-sensing component of an oxygen analyzer that measures oxygen concentration in breathing gas mixtures in the following applications:

Sensing device for oxygen in

- control device of oxygen concentrators
- medical ventilators
- anaesthesia equipment
- incubators.

The use is limited to system monitoring. The sensors are not suited for breath by breath analysis of breath gases. Please refer to the Instructions for Use! If the sensor is intended to replace the original oxygen-sensing component of an oxygen analyzer, consult the EnviteC XRL Cross Reference List for selecting the appropriate sensor.

Mechanical drawing (All dimension in mm)



General tolerances ISO 2768-c
*Intermediate thread: Metric / Unified Extra Fine

Additional information

The Instructions for Use as well as the EnviteC XRL Cross Reference List are available under www.EnviteC.com and in the Apple App Store under EnviteC XRL as free download.

For more information please contact us!
We look forward to assisting you either on the phone or in a personal talk.

Technical Specifications OOM202

Measurement range	0 % ... 100 % oxygen (at atmospheric pressure)
Nominal sensor lifetime	≥ 1 000 000 % volume oxygen hours
Output in ambient air	13 mV ... 16 mV
Electrical interface	3 pin (Molex® 22-11-1031)
Accuracy	meets ISO 80601-2-55 requirements
Repeatability	< 1 % volume O_2 at constant temperature and pressure
Linearity error	< 3 % relative
Response time	< 12 s to 90 % of final value
Zero offset voltage	< 200 µV in 100 % nitrogen, applied for 5 min
Cross interference	meets ISO 80601-2-55 requirements
Influence of humidity	-0.03 % rel. per % RH at 25 °C
Pressure range	0.6 bar ... 2 bar (ppO_2 0 ... 1250 mbar O_2)
Influence of pressure	proportional to change in oxygen partial pressure
Influence of mechanical shock	< 1 % relative after a fall from 1 m
Operating temperature	0 °C ... +50 °C
Temperature compensation	built-in NTC compensation
Effect of temperature compensation (steady state)	between +25 °C and +40 °C: 3 % relative error between 0 °C and +50 °C: 8 % relative error
Operating humidity	0 % ... 99 % RH non-condensing
Long term output drift	< 1 % volume oxygen per month typically < -15 % relative over lifetime
Storage temperature	-20 °C ... +50 °C
Recommended storage	+5 °C … +15 °C
Recommended load	≥ 10 kOhms
Warm-up time	< 30 minutes, after replacement of sensor
Weight	approximately 28 grams
Part number	01-00-0047

All specifications are applicable at standard conditions:
1013 hPa, 25 °C dry ambient air

For suitable accessories and sensors please refer to the EnviteC Cross Reference List under www.EnviteC.com and in the Apple App Store unter EnviteC XRL as free download.

EnviteC-Wismar GmbH
a Honeywell Company
Alter Holzhafen 18, 23966 Wismar, Germany
Phone: +49 (0)3841-360-1
Phone: +49 (0)3841-360-200
Fax: +49 (0)3841-360-222
Internet: www.envitec.com
Email: info@envitec.com

Doc. No. 001-33-Datasheet_OOM202-0
March 2016

ENVITEC
by Honeywell

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

CERTIFICATE

No. Q5 17 12 21697 018

Holder of Certificate: **EnviteC - Wismar GmbH**
Alter Holzhafen 18
23966 Wismar
GERMANY

Facility(ies):
EnviteC - Wismar GmbH
Alter Holzhafen 18, 23966 Wismar, GERMANY

Certification Mark:

Scope of Certificate: **Design and development, production and distribution of sensors and control units for monitoring of vital physiological parameters, sensors and control units for monitoring of respiratory mechanics parameters and gas exchange, measurement devices and sensors for alcohol blood concentration**

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.: 713119332

Valid from: 2018-02-06
Valid until: 2021-01-30

Date, 2018-02-06

Stefan Preiß

Page 1 of 1

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

TÜV®

DAkkS CRT2 / 10.13

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ 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 02231 002

Manufacturer: **Shenzhen Greatmade Tech limited**
3rd Floor, Building B
Baifuli Industrial Zone, Shanghenglang
Huahui Road, Dalang Street
Longhua New District
518109 Shenzhen, Guangdong Province
PEOPLE'S REPUBLIC OF CHINA

EC-Representative: **Prolinx GmbH**
Brehmstr. 56
40239 Duesseldorf
GERMANY

Product Category(ies): **Spo2 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.: GZ1728501

Valid from: 2018-04-11
Valid until: 2023-04-10

Date, 2018-04-11

Stefan Preiß

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

A1 / 07.09

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ 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 02231 002

Facility(ies): Shenzhen Greatmade Tech limited
3rd Floor, Building B, Baifuli Industrial Zone, Shanghenglang, Huahui Road, Dalang Street, Longhua New District, 518109 Shenzhen, Guangdong Province, PEOPLE'S REPUBLIC OF CHINA

DAkkS CRT2 / 10.13

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

CERTIFICATE

No. Q1N 17 12 02231 001

Holder of Certificate: **Shenzhen Greatmade Tech limited**
3rd Floor, Building B
Baifuli Industrial Zone, Shanghenglang
Huahui Road, Dalang Street
Longhua New District
518109 Shenzhen, Guangdong Province
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Shenzhen Greatmade Tech limited
3rd Floor, Building B, Baifuli Industrial Zone, Shanghenglang, Huahui Road, Dalang Street, Longhua New District, 518109 Shenzhen, Guangdong Province, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: **Design and Development, Production and Distribution of Spo2 sensor, Patient cable and leadwire, Blood pressure cuff**

Applied Standard(s): EN ISO 13485:2012 + AC:2012
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2003 + Cor. 1:2009)
DIN EN ISO 13485:2012
Upgrade required until 2019-03-31

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.: GZ1728501

Valid from: 2018-04-11
Valid until: 2021-04-10

Date, 2018-04-11

Stefan Preiß

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

HK GREATMADE TECH LTD
Keep pace with your need
Contact: Shirley Wang
E-mail : info@greatmade.com , sales@greatmade.com
Website http://www.greatmade.com , www.greatmade.diytrade.com
Tel : 86-0755-28144774 , *Fax* : 86-0755-27185453
Hotmail : greatmade@hotmail.com
Skype : Greatmade01

Reusable/Disposable NIBP Cuff and Air Hose
(Updated on April ,2012)

NIBP CUFF

Greatmade P/N	Description (Cable , Connector)	Unit Price
CF001A	Neonate **Single tube** NIBP cuff , 6-11cm Arm Circumference	
CF002A	Infant **single tube** NIBP cuff , 10-19cm Arm Circumference	
CF003A	Child **single tube** NIBP cuff , 18-26cm Arm Circumference	
CF004A	Adult **single tube** NIBP cuff , 25-35cm Arm Circumference	
CF004LA	Large **Adult Single** Tube Nibp Cuff , 33-47cm Arm Circumference	
CF004TA	THIGH **Single Tube** Nibp Cuff , 46-66cm Arm Circumference	

CF001A - CF004TA

NIBP Cuff

Greatmade P/N	Description (Cable , Connector)	Unit Price
CF001B	Neonate **Dual tube** NIBP cuff , 6-11cm Arm Circumference	
CF002B	Infant **dual tube** NIBP cuff, 10-19cm Arm Circumference	
CF003B	Child **dual tube** NIBP cuff ,18-26cm Arm Circumference	
CF004B	Adult **dual tube** NIBP cuff , 25-35cm Arm Circumference	
CF004LB	Large Adult **Dual Tube** Nibp Cuff, 33-47cm Arm Circumference	
CF004TB	THIGH **Dual tube** NIBP Cuff,46-66cm Arm Circumference	

Adult Longer Type

CF004XL-A	Adult Long Single tube Nibp Cuff , 33-47cm Arm circumference ,L 690mm*W 145mm	
CF004XL-B	Adult Long Dual tube Nibp Cuff ,33-47cm Arm Circumference .	

Connectors and tubes

BP12	HP Cuff connector(male bayonet)		
BP16	HP Air Hose connector to connect monitor plug		
BP19	HP /Spacelab monitor NIBP socket		
BP15	Female Bayonet connector		
BP15-S	Female bayonet socket of NIBP on monitor		
BP22	GE/ Ohmeda Air hose (dual tubes) connector on Equipment Side		
BP24	GE Air hose (dual tubes) connector on Equipment Side		
BP40	Drager NIBP air hose connector assemblies ,to connector equipment end		
BP17	Quick connect submin male connector		
BP18	quick connect submin female connector		

Declaration of Conformity

According to the Medical Devices Directive 93/42/EEC

Manufacturer's Name :	**HK Greatmade Tech LTD**
Manufacturer's Address :	**6th floor, B building, Pinchuangyuan Technology Park, Shuidou New Village, No.42 East of Industrial Rd ,LongHua town , Shenzhen, China**
Product :	**Non-Invasive Blood Pressure Cuff and Air Hose**
Type Designation/Trademark :	**NIBP cuff,Class I**

Product..Part..No..Of..Manufacturer:CF001A,CF002A,CF003A,CF004A,CF004LA, CF004TA,CF001B,CF002B,CF003B,CF004B,CF004LB,CF004TB,CF001C,CF002C,CF003C, CF004C,CF004LC,CF004TC,CF001D,CF002D,CF003D,CF004D,CF004LD,CF004TD, CF005,CF006,CF006–H,CF007L,CF007B,CF008,CF009,CF010,CF011,CF012,CF013,CF014, CF015,CF016,CF017,CF018,CF019,CF020,BP12,BP15,BP04,BP07,BP17,BP18

Authorized representative established within the EU (if applicable):

Company Name :

Company Address :

Person responsible for making this declaration

Name, Surname :	**ZhangHanzhi**
Position/Title :	**Director/ Owner**

Hereby Declares that the Medical device as indicated above conforms with the essential requirements listed in the Annex I of the European Medical Device Directive 93/42/EEC.

ZhangHanzhi

HK GREATMADE TECH LIMITED 香港偉創電子科技有限公司

Shenzhen, China

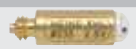
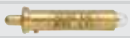
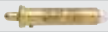
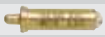
(Place)

(Company stamp and legal signature)

Jan. 6th, 2009

(Date)

HEINE ORIGINAL BULBS

HEINE BULBS	HEINE ref.	GIMA code	Compatible with following HEINE products
 Xenon 2.5 V	035	31769	Transilluminator Finoff alpha+ F.O. and F.O. SP Laryngoscopes - Sanalon handle Glaucotest
 Xenon 2.5 V	037	31771	K100 and Beta® 100, Beta® 100 vet otoscopes Laryngeal mirrors F.O. mini 2000 otoscope Alpha® and Alpha F.O. otoscopes Mini/mini 3000/Alpha/Beta tongue holders
	038	31773	Miroflex ophthalmoscope HFR2 spot retinoscope Delta®10 dermatoscope
	041	31774	Fibralux mini otoscope Mini 2000 combilamp Mini 2000 diplamp Mini 1000 diplamp
	042	31780	Alpha® ophthalmoscope Mini 2000 ophthalmoscope Alpha® Focalux Mini Miroflex ophthalmoscope Mini 2000 Focalux
	056	31770	Minilux otoscope Mini 2000 otoscope
	057	31785	Mini 2000, Mini 3000 laringeal mirrors
	069	31781	Beta® 200, 200 M2, 200S ophthalmoscopes - XHL 2.5 V
 Xenon 2.5 V	077	31772	Beta® 200, 200 VET, 400; K 180 otoscopes Lambda 100 retinometer Delta®10 plus dermatoscope
Xenon 2.5 V	084	31782	K180® ophthalmoscope - 2.5 V
	105	31776	Mini 3000 F.O. otoscope
	106	31777	Mini 3000 ophthalmoscope
	107	31778	Mini 3000 combilamp and diplamp - XHL 2.5 V
	109	31779	Mini 3000 dermatoscope
	110	31775	Mini 3000 otoscope
	070	31783	Beta 200, 200 M2, 200S ophtalmoscopes - XHL 3.5V
	078	31784	Beta 200, 200 Vet, KI80 otoscopes lambda 100 retinometer otoscopes - XHL 3.5V

RIESTER ORIGINAL BULBS

RIESTER BULBS	RIESTER ref.	GIMA code	Bulb	Compatible with following RIESTER products
	10421	31850	Vacuum 2.7 V	Otoscope uni®/speculight
	10424	31851	Vacuum 2.5 V	May-ophthalmoscope uni®
	10487	31825	XL 3.5 V xenon	Otoscope ri-scope® L1
	10488	31852	Vacuum 2.7 V	Pen-scope® and e-scope® otoscope
	10489	31560	HL 2.5 V	Otoscope pen-scope®/ ri-scope® L1 and e-scope®
	10590	31853	HL 2.5 V	Otoscope uni®
	10600	31854	XL 2.5 V	Otoscope ri-mini®, ri-scope® L2/L3 and e-scope®
	10605	31562	HL 2.5 V	Ophthalmoscope ri-mini/ ri-scope® L1, L2, L3, e-scope®, ri-derma®
	10607	31855	XL 3.5 V	Ri-scope® otoscope L2, L3
	10608	31826	XL 3.5 V	Ri-scope® ophthalmoscope L1, L2, L3
	14041	31561	LED 3.7 V	E-scope F.O otoscope
	14051	31563	LED 3.7 V	E-scope ophthalmoscopes

WELCH ALLYN BULBS

WELCH ALLYN BULBS	W. A. ref.	GIMA code	Compatible with following WELCH ALLYN products
	00200-U	32120	Anoscopes: 38800, 380, 385, 395 Illuminators: 41000, 26030 Old products: 235, 77900, 26000, 20100, 21600, 42700, 40510
	03000-U	32123	Ophthalmo: 11710, strabismoscope: 12400, episcope: 47300 Old ophthalmo: 11600, 11605, 11610 Retinoscope: 18000
	03100-U	32124	Otoscopes: 25020, 21700, 20200 Handle: 73500, holder: 28100 Illuminators: 27000, 27050, 26530, 41100, 43300 Old otoscopes: 25000, 25200, 20000
	03300-U	32125	Ophthalmo: 11511-11500
	03400-U	32126	Otoscopes: 24011-24020-24000-24031-21110/1 Handle: 73550, Illuminators: 27200-27250-41110
	03800-U	32127	Pan optic: 11810-11820-11800
	04100-U	32128	Exam light: 48400-48410
	04200-U	32129	Exam light: 48600, 48610-48625-48635, 48700
	04400-U	32130	Ophthalmoscopes: 11400-11411-11470-11475
	04700-U	32131	Laryngo: 680, 690, 692 (size 1-2) Old laryngo: 634, 664, 674, 684, 694 (check size)
	04800-U	32132	Laryngo: 680 (size 2-4), 690, 692 (size 3-4) Old laryngo: 634, 640, 664, 674, 684, 694 (check size)
	04900-U	32133	Ophthalmo: 11720, 11730, 11735, 11620, 11630
	06000-U	32134	Laryngo handles: 60813, 60814, 60713, 60815, 60803, 60804
	06500-U	32135	Macroview otoscope: 23810, 23820
	07800-U	32136	Handle: 73211, 73210, 78000, 73200

COMPATIBLE GERMAN BULBS

GIMA BULBS		GIMA code	Compatible with the following products
LARYNGOSCOPE BULBS - MADE IN GERMANY			
	Conventional laryngoscope SMALL bulb 2.7 V	34324	Gima, Riester, And, Kawe, Timesco Truphatek and most of conventional laryngoscopes in the market (generally used for blades N° 00, 0, 1)
	Conventional laryngoscope LARGE bulb 2.7 V	34325	Gima, Riester, And, Kawe, Truphatek, Timesco and most of conventional laryngoscopes in the market (generally used for blades N° 2, 3, 4)
	Xenon halogen bulb for F.O. Laryngoscope and otoscope	34485	Gima, And, Kawe and most of F.O. laryngoscopes in the market. Compatible for products that use Heine Bulb # 035
OTOSCOPE-OPHTHALMOSCOPE BULBS - MADE IN FRANCE-GERMANY			
	Xenon halogen otoscope bulb	31795	Heine mini 3000 otoscopes
	Xenon halogen F.O. otoscope bulb	31796	Heine mini 3000 F.O. otoscopes
	Otoscope bulb 2.5V	31449	Parker otoscopes and some otoscopes of Riester, Timesco and Kawe
	Ophthalmoscope bulb 2.5V	31446	Parker ophthalmoscope Parker diagnostic sets
	Xenon halogen bulb for otoscope 2.5V	31478	Gimalux otoscopes, Kawe and Riester mini otoscopes Compatible for products that use Heine bulb #037
	Halogen bulb for ophthalmoscope and dermatoscope 2.5V	31479	Parker halogen ophthalmoscope
	Xenon halogen ophthalmoscope bulbs 3.5 V	31428	Gima Xenon - halogen diagnostic sets - ophthalmoscope
OTO-OPHTHALMO-DERMATOSCOPE BULBS - OTHER COUNTRIES			
	Halogen Dermatoscope bulb 2.5 V	31188	Gima dermatoscope Compatible for products that use Heine Bulb #038
	Xenon halogen otoscope bulbs 3.5 V	31427	Gima Xenon - halogen diagnostic sets - otoscope

Reg. Numero / *Reg. Number*	MED 26036	Revisione / *Revision*	20
Primo rilascio / First i*ssue date*	2006-10-25	Valido da / *Valid from*	2016-10-24
Scadenza / *Valid until*	2021-10-24	Ultima modifica / *Last change date*	2016-11-07

Certificate

Certificato CE del Sistema di Garanzia della Qualità/ *EC Quality Assurance System Certificate*

Si certifica che, sulla base dei risultati degli audit effettuati, il Sistema di garanzia di Qualità della Produzione dell'Organizzazione/ *We certify that, on the basis of the audits carried out, the Production Quality Assurance System of the Organization:*

GIMA S.p.A.

sede operativa / Operational Headquarter:
Via Marconi, 1
20060 Gessate, MI - Italia

sede legale
Via Tommaso Grossi, 2
Milano - Italia

è conforme ai requisiti applicabili della Direttiva 93/42/CEE e successive modifiche ed integrazioni, Allegato V, attuata in Italia con Dlgs. 46 del 1997/02/24 e successive modifiche ed integrazioni per le seguenti tipologie di Dispositivi Medici/ *Is in compliance with the applicable requirements of 93/42/EEC Directive as amended, Annex V, transposed in Italy by Dlgs. 46 of 1997/02/24 as amended for the following Medical Devices:*

Aspiratori chirurgici e accessori / *Surgical aspirators and accessories*
Bilancia ad uso medicale / *Scales for medical use*
Dispositivi accessori per ginecologia e otorinolaringoiatria / *Sterile gynaecology and ENT accessories*
Dispositivi per aerosolterapia / *Nebulizer therapy devices*
Dispositivi per la misurazione della saturazione di O2 / *Oxygen saturation measuring devices*
Dispositivi per la misurazione della temperatura corporea / *Body temperature measuring devices*
Dispositivi per misurazione / *Measuring devices*
Dispositivi per rianimazione ed assistenza respiratoria / *Respiratory care and resuscitation devices*
Dispositivi per terapia termica / *Thermic therapy devices*
Elettrocardiografi / *Electrocardiographs*
Sfigmomanometri / *Sphygmomanometers*

Rif. rapporto di audit/ *Ref. audit report:* 19-20-21/09/2016

Rif. analisi documentazione tecnica/ *Ref. technical documentation analysis:* ==

Rif. analisi dossier progettazione/ *Ref. design dossier analysis:* ==

Chief Operating Officer
Giampiero Belcredi

CE

Organismo Notificato n. 0476
Notified Body nr. 0476

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta all'attività di direzione e coordinamento di Kiwa Italia Holding Srl
Via Cadriano, 23
40057 Granarolo dell'Emilia (BO)
Tel +39.051.459.3.111
Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwacermet.it

Certificate

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*
Aspiratori chirurgici e accessori / *Surgical aspirators and accessories*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 1106

Marca / *Brandname:*
GIMA

Modello / *Model:*

Aspiratori e accessori / *aspirators and accessories*

Tipologia / *Medical Devices:*
Bilancia ad uso medicale / *Scales for medical use*

Classe di rischio / *Risk class:*
I m

Codice NANDO / *NANDO codes:*
MD 0104

Marca / *Brandname:*
GIMA

Modello / *Model:*

ASTRA - FAMILY - PEGASO

Tipologia / *Medical Devices:*
Dispositivi accessori per ginecologia e otorinolaringoiatria / *Sterile gynaecology and ENT accessories*

Classe di rischio / *Risk class:*
I s

Codice NANDO / *NANDO codes:*
MD 7006

Marca / *Brandname:*
GIMA

Modello / *Model:*

Gimabrush

Chief Operating Officer
Giampiero Belcredi

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CERMET

CE

Organismo Notificato n. 0476
Notified Body nr. 0476

Certificate

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*
Dispositivi accessori per ginecologia e otorinolaringoiatria / *Sterile gynaecology and ENT accessories*

Marca / *Brandname:*
GIMA

Modello / *Model:*
Cervical Spoon

Modello / *Model:*
Cervix Brush Plush

Modello / *Model:*
Gima Collector

Modello / *Model:*
Gimabrush Ball

Modello / *Model:*
Kit ORL sterile / *Sterile ENT kit*

Modello / *Model:*
Kit pap test / *Pap smear kit*

Modello / *Model:*
Spatula legno sterile / *Sterile wooden spatula*

Modello / *Model:*
Spatula plastica sterile / *Sterile plastic spatula*

Modello / *Model:*
Speculum perno - mix / *Vaginal Speculum central pin - mix*

Modello / *Model:*
Speculum perno centrale - grande / *Vaginal Speculum central pin- large*

Modello / *Model:*
Speculum perno centrale - medio / *Vaginal Speculum central pin - medium*

Modello / *Model:*
Speculum perno centrale - piccolo / *Vaginal Speculum central pin - small*

Chief Operating Officer
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CERMET

Certificate

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Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*
Dispositivi accessori per ginecologia e otorinolaringoiatria / *Sterile gynaecology and ENT accessories*

Marca / *Brandname:*
GIMA

Modello / *Model:*
Speculum tache - mix / *Vaginal Speculum tache - mix*

Modello / *Model:*
Speculum vite centrale - mix / *Vaginal Speculum middle screw - mix*

Modello / *Model:*
Speculum vite laterale - grande / *Vaginal Speculum side screw - large*

Modello / *Model:*
Speculum vite laterale - medio / *Vaginal Speculum side screw - medium*

Modello / *Model:*
Speculum vite laterale - mix / *Vaginal Speculum side screw - mix*

Modello / *Model:*
Speculum vite laterale - piccolo / *Vaginal Speculum side screw - small*

Modello / *Model:*
Swab plastica sterile / *Sterile plastic swab*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 7006

Marca / *Brandname:*
GIMA

Modello / *Model:*
Proctoscopio adulti / *Adult proctoscope*

Modello / *Model:*
Proctoscopio pediatrico / *Pediatric proctoscope*

Chief Operating Officer
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CERMET

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*
Dispositivi per aerosolterapia / *Nebulizer therapy devices*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 1102

Marca / *Brandname:*
AKOD PHARMA

Modello / *Model:*
AEROSOL A PISTONE

Modello / *Model:*
AEROSOL AD ULTRASUONI

Marca / *Brandname:*
GIMA

Modello / *Model:*
AEROSOL MISTRAL

Modello / *Model:*
AEROSOL A PISTONE

Modello / *Model:*
AEROSOL A PISTONE CORSIA

Modello / *Model:*
AEROSOL A PISTONE EOLO

Modello / *Model:*
AEROSOL AD ULTRASUONI

Kiwa Cermet Italia S.p.A.
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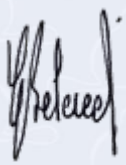
Chief Operating Officer
Giampiero Belcredi



Organismo Notificato n. 0476
Notified Body nr. 0476

Certificate

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*
Dispositivi per la misurazione della saturazione di O2 / *Oxygen saturation measuring devices*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 1302

Marca / *Brandname:*
GIMA

Modello / *Model:*

PULSOSSIMETRO / *PULSE OXIMETER*

Tipologia / *Medical Devices:*
Dispositivi per la misurazione della temperatura corporea / *Body temperature measuring devices*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 1302

Marca / *Brandname:*
ACRAF

Modello / *Model:*

Termometri clinici digitali -Termometro digitale classico Farmamed / *Classic digital Farmamed thermometer*

Modello / *Model:*

Termometri clinici digitali -Termometro digitale Farmamed / *Digital Farmamed thermometer*

Modello / *Model:*

Termometri clinici digitali -Termometro digitale Linea F flessibile / *Digital linea F thermometer flexible*

Modello / *Model:*

Termometri clinici digitali -Termometro digitale NUB Farmamed / *NUB Farmamed Digital thermometer*

Modello / *Model:*

Termometri clinici digitali -Termometro digitale NUB Farmamed Baby / *NUB Farmamed Baby Digital thermometer*

Chief Operating Officer
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CE

Organismo Notificato n. 0476
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CERMET

Certificate

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*
Dispositivi per la misurazione della temperatura corporea / *Body temperature measuring devices*

Marca / *Brandname:*
ACRAF

Modello / *Model:*

Termometri ecologici senza mercurio -Termometro ecologico Farmamed / *Farmamed ecologic thermometer*

Modello / *Model:*

Termometri ecologici senza mercurio -Termometro ecologico linea F / *Linea F ecologic thermometer*

Marca / *Brandname:*
CARREFOUR GS

Modello / *Model:*

Termometri clinici digitali -Termometro digitale Carrefour / *Digital Carrefour thermometer*

Modello / *Model:*

Termometri clinici digitali -Termometro digitale GS / *Digital GS thermometer*

Marca / *Brandname:*
CRAF

Modello / *Model:*

Termometri clinici digitali -Termometro digitale classico Linea F / *Classic digital linea F thermometer*

Marca / *Brandname:*
FederFARMA.co

Modello / *Model:*

Termometri ecologici senza mercurio -Termometro ecologico Profar / *Profar ecologic thermometer*

Marca / *Brandname:*
GABBIANO

Modello / *Model:*

Termometri clinici digitali -Termometro digitale Farmasan / *Farmasan Digital thermometer*

Modello / *Model:*

Termometri ecologici senza mercurio -Termometro ecologico Farmasan / *Farmasan ecologic thermometer*

Chief Operating Officer
Giampiero Belcredi

CE

Organismo Notificato n. 0476
Notified Body nr. 0476

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta all'attività di direzione e coordinamento di Kiwa Italia Holding Srl
Via Cadriano, 23
40057 Granarolo dell'Emilia (BO)
Tel +39.051.459.3.111
Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwacermet.it

CERMET

Certificate

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*
Dispositivi per la misurazione della temperatura corporea / *Body temperature measuring devices*

Marca / *Brandname:*
GIMA

Modello / *Model:*

Termometri clinici digitali -Termometro digitale / *Digital thermometer*

Modello / *Model:*

Termometri clinici digitali -Termometro digitale NUB / *NUB Digital thermometer*

Modello / *Model:*

Termometri ecologici senza mercurio -Termometro ecologico / *Ecologic thermometer*

Marca / *Brandname:*
PB PHARMA

Modello / *Model:*

Termometri clinici digitali -Termometro digitale / *Digital GS thermometer*

Marca / *Brandname:*
QUIDNOVI PHARMA

Modello / *Model:*

Termometri ecologici senza mercurio -Termometro ecologico TECNICO Eco / *TECNICO Eco ecologic thermometer*

Marca / *Brandname:*
SSL HEALTHCARE

Modello / *Model:*

Termometri ecologici senza mercurio -Termometro clinico Realcheck mercury free / *Clinical thermometer Realcheck mercury free*

Marca / *Brandname:*
T&B

Modello / *Model:*

Termometri clinici digitali -Termometro digitale 36.2 T&B / *Digital 36.2 T&B thermometer*

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta all'attività di direzione e coordinamento di Kiwa Italia Holding Srl
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E-mail: info@kiwacermet.it
www.kiwacermet.it

CERMET

Chief Operating Officer
Giampiero Belcredi

CE

Organismo Notificato n. 0476
Notified Body nr. 0476

Certificate

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*
Dispositivi per misurazione / *Measuring devices*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 1302

Marca / *Brandname:*
GIMA

Modello / *Model:*

Altimetro - Plicometro - Metro per neonati / *Height meter - Skinfold caliper - Baby measuring meter*

Tipologia / *Medical Devices:*
Dispositivi per rianimazione ed assistenza respiratoria / *Respiratory care and resuscitation devices*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 1102

Marca / *Brandname:*
GIMA

Modello / *Model:*

Cannule di Guedel sterili / *Sterile Guedel airways*

Modello / *Model:*

Kit pallone silicone adulti / *Silicone resuscitator kit - adult*

Modello / *Model:*

Maschere laringee riutilizzabili / *Reusable laryngeal mask airways*

Modello / *Model:*

Mascherina per rianimazione CPR / *CPR resuscitator mask*

Modello / *Model:*

Palloni rianimatori / *Resuscitators*

Modello / *Model:*

Accessori -Maschere in silicone autoclavabili / *Silicone autoclavable face masks*

Chief Operating Officer
Giampiero Belcredi

CE

Organismo Notificato n. 0476
Notified Body nr. 0476

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta all'attività di direzione e coordinamento di Kiwa Italia Holding Srl
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Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwacermet.it

CERMET

Certificate

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*
Dispositivi per rianimazione ed assistenza respiratoria / *Respiratory care and resuscitation devices*

Marca / *Brandname:*
GIMA

Modello / *Model:*

Accessori -Maschere in silicone con cuscinetto e cuffia autoclavabili / *Silicone autoclavable cushion face masks*

Modello / *Model:*

Accessori -Maschere ossigeno / *Oxygen masks*

Modello / *Model:*

Accessori -Mascherine monouso PVC a cuscino d'aria iniettabile / *Disposable PVC injectable air cushion face masks*

Modello / *Model:*

Accessori -Occhiali ossigeno / *Nasal cannula*

Modello / *Model:*

Accessori -Tubo ossigeno / *Oxygen tubing*

Modello / *Model:*

Accessori -Valvola PEEP / *Peep valve*

Tipologia / *Medical Devices:*
Dispositivi per terapia termica / *Thermic therapy devices*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 1403

Marca / *Brandname:*
ACRAF

Modello / *Model:*

Ghiaccio istantaneo monouso Farmamed Gelo Pack / *Farmamed disposable instant ice cold pack*

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta all'attività di direzione e coordinamento di Kiwa Italia Holding Srl
Via Cadriano, 23
40057 Granarolo dell'Emilia (BO)
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E-mail: info@kiwacermet.it
www.kiwacermet.it

CERMET

Chief Operating Officer
Giampiero Belcredi

CE

Organismo Notificato n. 0476
Notified Body nr. 0476

Certificate

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*
Dispositivi per terapia termica / *Thermic therapy devices*

Marca / *Brandname:*
GIMA

Modello / *Model:*

Ghiaccio istantaneo monouso / *disposable instant ice cold pack*

Modello / *Model:*

Ghiaccio istantaneo PE / *PE instant ice cold pack*

Modello / *Model:*

Ghiaccio istantaneo TNT / *TNT instant ice cold pack*

Marca / *Brandname:*
MENARINI

Modello / *Model:*

Ghiaccio istantaneo monouso Menarini / *Menarini disposable instant ice cold pack*

Tipologia / *Medical Devices:*
Elettrocardiografi / *Electrocardiographs*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 1302

Marca / *Brandname:*
GIMA

Modello / *Model:*

ECG PALMARE

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta all'attività di direzione e coordinamento di Kiwa Italia Holding Srl
Via Cadriano, 23
40057 Granarolo dell'Emilia (BO)
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www.kiwacermet.it

CERMET

Chief Operating Officer
Giampiero Belcredi

CE

Organismo Notificato n. 0476
Notified Body nr. 0476

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*
Sfigmomanometri / *Sphygmomanometers*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 1302

Marca / *Brandname:*
ACRAF

Modello / *Model:*
SFIGMO DIGITALE DA POLSO ROSS ANGELINI

Modello / *Model:*
digitali -SFIGMO DIGITALE DA BRACCIO ROSS ANGELINI

Marca / *Brandname:*
AKOD PHARMA

Modello / *Model:*
SFIGMO DIGITALE DA BRACCIO HL AKOD

Modello / *Model:*
SFIGMO DIGITALE DA POLSO HL AKOD

Modello / *Model:*
SFIGMO DIGITALE DA TAVOLO HL AKOD

Marca / *Brandname:*
GIMA

Modello / *Model:*
a mercurio -STAR

Modello / *Model:*
a mercurio -YTON

Modello / *Model:*
a mercurio -YTON PLAUNAZIDE

Modello / *Model:*
Aneroidi -BOSTON

Chief Operating Officer
Giampiero Belcredi

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta all'attività di direzione e coordinamento di Kiwa Italia Holding Srl
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Organismo Notificato n. 0476
Notified Body nr. 0476

Certificate

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*
Sfigmomanometri / *Sphygmomanometers*

Marca / *Brandname:*
GIMA

Modello / *Model:*
Aneroidi -BOSTON COMBISARTAN

Modello / *Model:*
Aneroidi -BOSTON LATEX-FREE

Modello / *Model:*
Aneroidi -BOSTON LOBIVON

Modello / *Model:*
Aneroidi -BOSTON VALPRESSION

Modello / *Model:*
Aneroidi -BOSTON OLPRESS

Modello / *Model:*
Aneroidi -DALLAS

Modello / *Model:*
Aneroidi -GIMATONO

Modello / *Model:*
Aneroidi -LONDON

Modello / *Model:*
Aneroidi -ROMA

Modello / *Model:*
Aneroidi -SIRIO

Modello / *Model:*
Aneroidi -TOKIO

Modello / *Model:*
Aneroidi -TOKIO ZANTIPRESS

Modello / *Model:*
Aneroidi -YTON

Chief Operating Officer
Giampiero Belcredi

CE

Organismo Notificato n. 0476
Notified Body nr. 0476

Kiwa Cermet Italia S.p.A.
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www.kiwacermet.it

CERMET

Reg. Numero / *Reg. Number*	MED 26036	Revisione / *Revision*	20
Primo rilascio / First i*ssue date*	2006-10-25	Valido da / *Valid from*	2016-10-24
Scadenza / *Valid until*	2021-10-24	Ultima modifica / *Last change date*	2016-11-07

Certificate

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*
Sfigmomanometri / *Sphygmomanometers*

Marca / *Brandname:*
GIMA

Modello / *Model:*
digitali -AUTOMATICO DA POLSO

Modello / *Model:*
digitali -24h

Modello / *Model:*
digitali -AMBULATORIALE

Modello / *Model:*
digitali -AUTOMATICO DA BRACCIO

Modello / *Model:*
digitali -DOMINO

Modello / *Model:*
digitali -SENZA MERCURIO

Modello / *Model:*
digitali -SFIGMO DIGITALE DA BRACCIO HL GIMA

Modello / *Model:*
digitali -SFIGMO DIGITALE DA BRACCIO ROSS GIMA

Modello / *Model:*
digitali -SFIGMO DIGITALE DA POLSO HL GIMA

Modello / *Model:*
digitali -SFIGMO DIGITALE DA POLSO ROSS GIMA

Modello / *Model:*
digitali -SFIGMO DIGITALE DA TAVOLO HL GIMA

Modello / *Model:*
digitali -YTON DIGITALE

Chief Operating Officer
Giampiero Belcredi

CE

Organismo Notificato n. 0476
Notified Body nr. 0476

Kiwa Cermet Italia S.p.A.
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CERMET

Certificate

Reg. Numero / *Reg. Number*	MED 26036	Revisione / *Revision*	20
Primo rilascio / First i*ssue date*	2006-10-25	Valido da / *Valid from*	2016-10-24
Scadenza / *Valid until*	2021-10-24	Ultima modifica / *Last change date*	2016-11-07

La lista completa dei codici, relativi ai modelli certificati, è disponibile presso Kiwa Cermet Italia./ *The complete list of the codes related to the certificated models is available at Kiwa Cermet Italia.* Il presente Certificato è soggetto al rispetto dei requisiti contrattuali di Kiwa Cermet Italia ed è valido solo per le tipologie di dispositivi sopra identificate soggette a sorveglianza/ *This Certificate is subject to Kiwa Cermet Italia regulations and it is valid only for the above mentioned Medical Devices that are subject to survey.* L'allegato tecnico è parte integrante del presente Certificato./ *The technical sheet is an integrating part of this Certificate.*

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta all'attività di direzione e coordinamento di Kiwa Italia Holding Srl
Via Cadriano, 23
40057 Granarolo dell'Emilia (BO)
Tel +39.051.459.3.111
Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwacermet.it

Chief Operating Officer
Giampiero Belcredi

Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Reg. Number	10164 - A	Valid From	2018-10-01
First issue date	2012-10-15	Last change date	2018-10-01
Valid Until	2021-10-14	IAF Sector	29

Quality Management System Certificate

ISO 9001:2015

We certify that the Quality Management System of the Organization:

GIMA S.p.A.

Is in compliance with the standard UNI EN ISO 9001:2015 for the following products/services:

Trade, packaging and service of medical devices (MD), in vitro diagnostic products (IVD), personal protective equipments (PPE), biocides, veterinary items, medical accessories furniture and aids

Chief Operating Officer
Giampiero Belcredi

The maintaining of the certification is subject to annual surveillance and dependent on the observance of Kiwa Cermet Italia contractual requirements.

This certificate is composed of 1 page.

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta all'attività di direzione e coordinamento di Kiwa Italia Holding Srl
Via Cadriano, 23
40057 Granarolo dell'Emilia (BO)
Tel +39.051.459.3.111
Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwacermet.it

GIMA S.p.A.
Registered Headquarters
- Via Grossi, 2 20121 Milano Italia

Certified Sites
- Via Marconi, 1 20060 Gessate (MI) Italia

SGQ N° 007A
SGA N° 010D
PRD N° 069B
FSM N° 0041
PRS N° 089C

CERTIFICATE

Reg. Number	10164 - M	Valid From	2018-10-01
First issue date	2012-10-15	Last change date	2018-10-01
Valid until	2021-10-14		

Quality Management System Certificate

ISO 13485:2016

We certify that the Quality Management System of the Organization:

GIMA S.p.A.

Is in compliance with the standard UNI CEI EN ISO 13485:2016 for the following products/services:

Trade, packaging and service of: medical devices (MD), in vitro diagnostic products (IVD), medical accessories, furniture and aids,

Chief Operating Officer
Giampiero Belcredi

The maintaining of certification is subject to annual surveillance and dependent upon the observance of Kiwa Cermet Italia contractual requirements.

Refer to quality manual for details of exclusion of UNI CEI EN ISO 13485:2016 requirements.

This certificate is composed of 1 page.

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta all'attività di direzione e coordinamento di Kiwa Italia Holding Srl
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GIMA S.p.A.
Registered Headquarters
- Via Grossi, 2 20121 Milano Italia

Certified Sites
- Via Marconi, 1 20060 Gessate (MI) Italia

SGQ N° 007A
SGA N° 010D
PRD N° 069B
FSM N° 004I
PRS N° 089C

EC Certificate

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

Registration No.: HD 60123878 0001

Report No.: 12018179 022

Manufacturer:
OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho,
Hachioji-shi, Tokyo 192-8507
Japan

Products:
Design and Development, Manufacture of Medical Endoscopy Systems, Diagnostic, Operation and Treatment Products

(see attachments for products and additional sites included)

Replaces Approval, Registration No.: HD 60078827 0001

Expiry Date: 2022-11-02

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: 2017-11-03

Date: 2017-10-12

Notified Body

M.Sc. M. Aihara

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.

TÜVRheinland

Doc. 1/1, Rev.0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60123878 0001
Report No.: 12018179 022

Manufacturer: OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho,
Hachioji-shi, Tokyo 192-8507
Japan

Products included:

Medical Endoscopy Systems:
-Endoscopes
-Endotherapy Devices
-Imaging Processors
-Pumps for Endoscopy
-Light Sources
-Position Detecting Units
-Electrothermal Cautery Units
-Integrated Endosurgery Systems
-Endoscopic Regulation/Control Units
Electrosurgical Equipment
Probes and Transducers for Ultrasonic Lithotriptors
Laparoscopic Insufflators
Ultrasound Surgical Equipment
Disinfecting Units
Capsule Endoscopes and Systems
Ultrasound Diagnostic Imaging Systems

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Notified Body

Date: 2017-10-12

M.Sc. M. Aihara

Traducere din limba engleza

TÜVRheinland®

APROBARE

Directiva CE 93/42/CEE Anexa II, excluzând Secţiunea 4
Sistem complet de asigurare a calităţii
Echipamente medicale

Nr. Înregistrare: HD 60123878 0001
Nr. Raport: 12018179 022

Producător: **Olympus Medical Systems Corp.**
2951 Ishikawa-cho
HACHIOJI-SHI, TOKIO 192-8507
JAPONIA

Produse: Proiectare şi dezvoltare, producţie de sisteme de endoscopie medicală, produse de diagnostic, operaţie şi tratament.
(a se vedea atasamentele pentru produse si locatii suplimentare incluse)
Înlocuieşte Aprobarea cu nr. de înregistrare: HD 60078827 0001

Data expirarii: 02.11.2022

Organismul Notificat declară prin prezenta că au fost îndeplinite cerinţele Anexei II, excluzând secţiunea 4 a directivei 93/42/CEE pentru produsele specificate. Producătorul mai sus menţionat a stabilit şi aplică un sistem de asigurare a calităţii, care este supus unei supravegheri periodice, definită în Anexa II, secţiunea 5 a directivei menţionate anterior. Pentru comercializarea echipamentelor din clasa III acoperite de acest certificat, este necesar un certificat CE de examinare proiectare în conformitate du Anexa II, secţiunea 4.

Organism notificat
Ştampilă:
TUV Rheinland LGA Products GmbH
Zertifizierungsstelle
M.Sc. M. Aihara
(semnătură indescifrabilă)

Data intrării în vigoare: 03-11-2017

Data. 12.10.2017

TÜVRheinland

Doc. 1/1 Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Atasament la
Certificat
Nr. de inregistrare: HD 60123878 0001
Nr. raport: 12018179 022

Producător: **Olympus Medical Systems Corp.**
2951 Ishikawa-cho
HACHIOJI-SHI, TOKIO 192-8507
JAPONIA

Produse incluse:
- Sisteme medicale de endoscopie:
  - -Endoscoape
  - -Echipamente endoterapie
  - -Procesoare de imagine
  - -Pompe pentru endoscopie
  - -Surse de lumină
  - -Unităţi de detectare poziţie
  - -Unităţi de cauterizare electrotermică
  - -Sisteme endochirurgicale integrate
  - - Unitati de control/reglare endoscopice
- Echipamente electrochirurgicale
- Sonde şi traductoare pentru litotriptoare cu ultrasunete
- Insuflatoare laparoscopice
- Echipamente chirurgicale cu ultrasunete
- Unitati de sterilizare
- Sisteme şi endoscoape capsulă
- Sisteme de imagistica pentru diagnostic cu ultrasunete

Organism notificat
Ştampilă:
TUV Rheinland LGA Products GmbH
Zertifizierungsstelle
M.Sc. M. Aihara
(semnătură indescifrabilă)

Data: 12.10.2012

ROMÂNIA
MINISTERUL JUSTIŢIEI
MINA FANEA-IVANOVICI
TRADUCĂTOR AUTORIZAT
ENGLEZĂ - FRANCEZĂ
AUT. NR. 22059
TEL.: 0745471452

EC Certificate

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

Registration No.: DD 60123877 0001

Report No.: 12018179 022

Manufacturer: OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho,
Hachioji-shi, Tokyo 192-8507
Japan

Products: Sterile Endotherapy Devices used in conjunction with Endoscopes, Sterile Non Active Instruments used in conjunction with Endoscopes and Sterile Non Active Instruments used in conjunction with Medical Ultrasound Diagnostic Imaging Systems
Replaces Approval, Registration No.: DD 60116725 0001

Expiry Date: 2022-11-02

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.

Effective Date: 2017-11-03

Date: 2017-10-12

Notified Body

M.Sc. M. Aihara

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.

Traducere din limba engleza

TÜVRheinland

CERTIFICAT CE
Directiva CE 93/42/CEE Anexa V
Asigurarea calităţii producţiei
Echipamente medicale

Nr. Înregistrare: DD 60123877 0001
Nr. Raport: 12018179 022

Producător: **Olympus Medical Systems Corp.**
2951 Ishikawa-cho
HACHIOJI-SHI, TOKIO 192-8507
JAPONIA

Produse: Echipamentelor sterile pentru endoterapie, utilizate împreuna cu endoscoape, instrumente sterile non-active utilizate împreună cu endoscoape şi instrumente sterile non-active utilizate împreună cu sisteme medicale de imagistică diagnostic cu ultrasunete.
Înlocuieşte Aprobarea. nr. înregistrare: DD 60116725 0001

Data expirarii: 02.11.2022

Organismul Notificat declară prin prezenta că au fost îndeplinite cerinţele Anexei V a directivei 93/42/CEE pentru produsele specificate. Producătorul mai sus menţionat a stabilit şi aplică un sistem de asigurare a calităţii, care este supus unei supravegheri periodice, definită în Anexa V, secţiunea 4 a directivei menţionate anterior. Pentru comercializarea echipamentelor din clasa IIb şi clasa III acoperite de acest certificat, este necesar un certificat CE de examinare tip în conformitate du Anexa III.

Data intrării în vigoare: 03-11-2017

Data: 12.10.2017

Organism notificat
Ştampilă:
TÜV Rheinland LGA Products GmbH
Zertifizierungsstelle
M.Sc. M. Aihara
(semnătură indescifrabilă)

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho,
Hachioji-shi, Tokyo 192-8507
Japan

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

See attachments for scope

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:	2018-11-04
Certificate Registration No.:	SX 60133824 0001
An audit was performed. Report No.:	12018179 027
This Certificate is valid until:	2021-07-26

Certification Body

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

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

Date 2018-10-30

M.Sc. M. Aihara

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®

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60133824 0001
Report No.: 12018179 027

Organization: OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho,
Hachioji-shi, Tokyo 192-8507
Japan

Scope:

Design and Development, Manufacture, Distibution, Service, Quality Assurance, Planning and Delivery support of Endoscopes, Endotherapy devices, Light Sources, Imaging Processors, Endoscope Position Detecting Units, Electrothermal Cautery Units, Integrated Endosurgery Systems, Endoscopic Regulation/Control Units, Camera Heads/Pumps/Monitors/ Recorders for Endoscopy, Electrosurgical Equipment, Capsule Endoscopes and Systems, Laparoscopic Insufflators, Ultrasound Diagnostic Imaging Systems, Disinfecting Units and Ultrasound Surgical Equipment, Probes and Transducers for Ultrasonic Lithotriptors, Sterile Non Active Instruments used in conjunction with Endoscopes, Sterile Endotherapy Devices used in conjunction with Endoscopes, Sterile Non Active Devices used in conjunction with Medical Ultrasound Diagnostic Imaging Systems and Water Container, Water Supply Tube, Water Feeding valve and Foot Switch for Pump

Certification Body

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

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

Date: 2018-10-30

M.Sc. M. Aihara

Traducere din limba engleză

Certificat

Organismul de certificare al TÜV Rheinland LGA Products GmbH

certifică prin prezenta faptul că organizaţia

OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho
Hachioji-shi, Tokyo 192-8507
Japonia

a implementat şi aplică un sistem de management al calităţii pentru dispozitive medicale pentru urmatoarele domenii:

A se vedea ataşamentul pentru domeniul de aplicabilitate

S-a furnizat dovada faptului ca au fost indeplinte cerintele specificate in

EN ISO 13485:2016

Sistemul de management al calităţii este supus unei supravegheri anuale.

ROMÂNIA
MINISTERUL JUSTIȚIEI
MINA FANEA-IVANOVICI
TRADUCĂTOR AUTORIZAT
ENGLEZĂ * FRANCEZĂ
AUT. NR. 22069
TEL. 0745471452

Data intrării în vigoare: 04.11.2018
Nr. înregistrare certificat: SX 60133824 0001
A fost efectuat auditul, raport nr. 12018179 027
Acest certificat este valabil până la 26.07.2021

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

Organism de certificare
(Semnătură indescifrabilă şi ştampilă TÜV Rheinland LGA Products GmbH)
M.Sc.M. Aihara

Data, 30.10.2018

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

TÜVRheinland®

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Atasament la
Nr. inregistrare certificat SX 60133824 0001
Nr. raport: 12018179 027

Organizatie:

Olympus Medical Systems Corp.
2951 Ishikawa-cho
Hachloji-shi, Tokyo 192-8507
Japonia

Domeniul de aplicabilitate: **Proiectare şi dezvoltare, producţie, distribuţie, service, asigurarea calităţii, planificare şi furnizare asistenţă pentru endoscoape, echipamente endoterapie, surse de lumină, procesoare de imagine, unităţi de detectare a poziţiei endoscopului, unităţi de cauterizare electrotermică, sisteme endochirurgicale integrate, unitati de control/reglare endoscopice, capete cameră/pompe/sisteme monitorizare/sisteme înregistrare pentru endoscopie, echipamente electrochirurgicale, endoscoape capsulă şi sisteme, insuflatoare laparoscopice, sisteme de imagistica pentru diagnostic ecografic, unităţi dezinfectare şi echipamente chirurgicale cu ultrasunete, sonde şi traductoare pentru litotriptoare cu ultrasunete, instrumente sterile inactive utilizate împreună cu endoscoape, echipamente sterile pentru endoterapie utilizate împreună cu endoscoape, echipamente sterile inactive utilizate împreună cu sisteme medicale de imagistica pentru diagnostic ecografic şi recipiente apă, tuburi alimentare apă, supape apă şi întrerupătoare de picior pentru pompe.**

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

Data, 30.10.2018

Organism de certificare
(Semnătură indescifrabilă şi ştampilă TÜV
Rheinland LGA Products GmbH)
M.Sc.M. Aihara

ROMÂNIA
MINISTERUL JUSTIŢIEI
MINA FANEA-IVANOVICI
TRADUCĂTOR AUTORIZAT
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