

# EC-Declaration of Conformity

**Manufacturer:**

Name : METKO Medikal ve Tibbi Cihazlar Dış Ticaret Ltd. Şti.  
Address : İvedik O. S. B. Ağaç İşleri Sanayi Sitesi 1354 Cad. 1358 Sok. No:9  
06378 Yenimahalle - Ankara \ Turkey  
Tel : + 90 312 387 12 46 (pbx)  
Fax : + 90 312 387 12 51  
E-mail : metko@metkold.com  
Web : www.metkold.com

**Authorized European Representative:**

Name : Medset Medizintechnik GmbH  
Address : Curslackner Neuer Deich 66 D-21029 Hamburg \ Germany  
Tel : 0049 40 725 822-0  
Fax : 0049 40 725 822-11  
E-mail : info@medset.com  
Web : www.medset.com

**Product:** Adaptor & Extension Cable for Pulse Oximetry (SpO2) Sensors, (GMDN Code: 37808)  
Adaptor & Extension Cable for Medical Temperature Probes, (GMDN Code: 37340)  
Adaptor & Extension Cable for Nebulizer and Flow Sensor, (GMDN Code: 37340)  
Adaptor & Extension Cable for Disposable IBP Transducers, (GMDN Code: 36550)

**Reference Numbers:**

AEC-51XX, AEC-52XX Pulse Oximetry (SpO2) Sensor Adaptor & Extension Cables, (XX variables: 00-99)  
FMT400/AEC-XX, FMT400/AEC/Z, FMT400/AEC/Z-E, FMT400/AEC/Z-R, FMT400/AEC/Z-P, FMT400/AEC3-XX,  
FMT400/AEC3/Z and FMT400/AEC3/Z-E, FMT400/AEC3/Z-R Temperature Probe Adaptor & Extension Cables,  
(XX variables: -, BL, E, EBL, ES, EGE, EGE2, EHP, ESW, EMN, GE, HP, S, SPL, SW, MN, NKN, THT, THT2, MTR, RMMM,  
R, RHP, RS, RSW, RGE, RMN, RBL, P, PHP, PS, PSW, PGE, PMN, PBL)  
Nebulizer and Flow Sensor Adaptor & Extension Cables AEC-ARG, AEC-ARG/GE, AEC-SLE, AEC-GEEC, AEC-FAB  
IBP-YY/ZXX IBP Transducer Adaptor & Extension Cables, (YY variables: 01-10, Z variables: 0-3, XX variables: 01-50)  
IBP-ADP/XXX IBP Transducer Adaptor & Extension Cables, (XXX variables: 000-100)

**Classification:** Class I Medical Device, Annex IX Rule 1  
**Conformity Assessment Procedure:** Annex VII

*We herewith declare that the above mentioned products meet the Essential requirements and conforms to the Medical Device Directive 93/42/EEC.*

**Standards:**

EN 60601-1:2006	Medical electrical equipment, Part 1: General requirements for basic safety and essential performance
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements
EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices
EN ISO 14155:2011	Clinical investigation of medical devices for human subjects - Good clinical practice
EN ISO 14971:2012	Medical Devices - Application of Risk Management to Medical Devices
EN 62366-1:2015	Medical devices - Application of usability engineering to medical devices
EN ISO 9001:2015	Quality management systems-Requirements
EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes

**Date of issue:** 10.02.2020

**Signature:**

**Name:** Filiz ERSOY  
**Position:** Company Manager

# EC-Declaration of Conformity

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**Authorized European Representative:**

Name : Medset Medizintechnik GmbH  
Address : Curslackener Neuer Deich 66 D-21029 Hamburg \ Germany  
Tel : 0049 40 725 822- 0  
Fax : 0049 40 725 822-11  
E-mail : info@medset.com  
Web : www.medset.com

**Product:**

ECG – EKG Cables & Leadwires  
ECG Suction & Clamp Electrodes  
ECG Adaptors for Cables and Leadwires

**Reference Numbers:**

E100/XYZ/I, E101/XYZ/I, E103/XYZ/I, E104/XYZ/I, E105/XYZ/I, E106/XYZ/I, E107/XYZ/I, 100/XYZ/A, E101/XYZ/A, E103/XYZ/A, E104/XYZ/A, E105/XYZ/A, E106/XYZ/A and E107/XYZ/A Series **Diagnostic EKG Cables** (X: A to Z; Y: N, R; Z: O, B, G, P and S); E100/MDR/GI, E100/MDR/GA, E100/MDR/SI and E100/MDR/SA **Diagnostic EKG Cables**; E200-YXXX/Z, E201-YXXX/Z, E202-YXXX/Z, E204-YXXX/Z, E205-YXXX/Z, E206-YXXX/Z, E207-YXXX/Z, E208-YXXX/Z and E209-YXXX/Z Series **ECG Cables** (Y: 3, 4, 5, 6; XXX: (000-999); Z: SA, SI, GA, GI, VA, VI, OA, OI); E21-XX, E22-XX, E23-XX, E31-XX, E32-XX, E33-XX, E40-XX, E41-XX, E42-XX, E43-XX, E51-XX, E52-XX, E53-XX, E61-XX, E62-XX, E63-XX, E71-XX, E72-XX, E73-XX, E80-XX, E81-XX, E82-XX, E83-XX, E91-XX, E92-XX and E93-XX Series **ECG Leadwires set** (XX: 3A, 3I, 5A, 5I, 6A, 6I, 3IT, 3AT, 5IT, 5AT, 3AN, 3IN, 5AN, 5IN, 3AM and 3IM); MT32X, MT52X, MT62X Series **ECG Leadwires set** (X: I, A); E21-XX, E22-XX, E23-XX, E31-XX, E32-XX, E33-XX, E41-XX, E42-XX, E43-XX, E51-XX, E52-XX, E53-XX, E61-XX, E62-XX, E63-XX, E71-XX, E72-XX, E73-XX, E81-XX, E82-XX, E83-XX, E91-XX, E92-XX and E93-XX Series **ECG Leadwires** (XX: 0C, 0L, 0R, 0N, 0F, 0V, LA, RA, RL and LL); E32-XX-OR **ECG Leadwires set** (XX: 3I, 3A, 5I, 5A, 3IM, 3AM); E82-XX-OR **ECG Leadwires set** (XX: 3I, 3A); E101XX/10, E102XX/10, E103XX/10, E104XX/10, E105XX/10, E112XX/10, E117XX/10, E118XX/10, E119XX/10, E120XX/10 and E121XX/10 Series **Diagnostic EKG Leadwires set** (XX: BI, SI, GI, PI, BA, SA, GA and PA); E101XX/YY, E102XX/YY, E103XX/YY, E104XX/YY, E105XX/YY, E112XX/YY, E117XX/YY, E118XX/YY, E119XX/YY, E120XX/YY and E121XX/YY Series **Diagnostic EKG Leadwires** (XX: BI, SI, GI, PI, BA, SA, GA and PA), (YY: R, N, F, L, C1, C2, C3, C4, C5, C6, RA, RL, LA, LL, V1, V2, V3, V4, V5, V6, 3A, 3B, 5A, 5B); E106XX/5, E107XX/5, E108XX/5, E109XX/5, E110XX/5, E111XX/5, E113XX/4, E114XX/6 and E122XX/6 Series **Diagnostic EKG Leadwires set** (XX: BI, SI, GI, PI, BA, SA, GA and PA); E110GX/5-OR and E111GX/5-OR **Diagnostic EKG Leadwires set** (X: I, A); HLXXZ-YYZ Series **ECG Holter Leadwires** (XX: 01-20; Z: A, B, C, D, E or empty; YY: 01-20 or empty); SE1, SE2 **ECG Suction Electrode set**, CEAI1, CEAI2, CEAA1, CEAA2 **ECG Clamp Electrodes**, MTM/01 **Multi Parameter Cable**, BS3, BS4, BG3, BG4, BA4 **ECG Adaptors**

**Classification:** Class I Medical Device, Annex IX Rule 1

**Conformity Assessment Procedure:** Annex VII

**GMDN Code:** 35562

*We herewith declare that the above mentioned products meet the Essential requirements and conforms to the Medical Device Directive 93/42/EEC.*

**Standards:**

EN 60601-1:2006	Medical electrical equipment, Part 1: General requirements for basic safety and essential performance
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements
EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices
ANSI/AAMI EC53:2013	ECG Trunk cables and leadwires
EN ISO 14155:2011	Clinical investigation of medical devices for human subjects - Good clinical practice
EN ISO 14971:2012	Medical Devices - Application of Risk Management to Medical Devices
EN 62366-1:2015	Medical devices - Application of usability engineering to medical devices
EN ISO 9001:2015	Quality management systems-Requirements
EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes

**Date of issue:** 05.02.2020

**Signature:**

**Name:** Filiz ERSOY  
**Position:** Company Manager

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Fax : 0049 40 725 822-11  
E-mail : info@medset.com  
Web : www.medset.com

**Product:** Electrosurgery Cables & Accessories

*Electrosurgery Bipolar Cables, (GMDN Code: 35041)*  
*Electrosurgery Monopolar Cables, (GMDN Code: 61876)*  
*Electrosurgery Dispersive Cables, (GMDN Code: 35041)*  
*Electrosurgery Bipolar Adaptors, (GMDN Code: 35041)*  
*Electrosurgery Disposable Grounding Plates, (GMDN Code: 11500)*  
*Electrosurgery Reusable Grounding Pads, (GMDN Code: 42551)*  
*Electrosurgery Reusable Connection Cable for Universal Patient Return Electrodes, (GMDN Code: 35041)*  
*Tip Clean Sponge, (GMDN Code: 35043)*

## Reference Numbers:

ESU-BP/XXY Series, ESU-BP/CONA, ESU-BP/CONAL, ESU-BP/OWE, ESU-BP/FWE, ESU-BP/BWE, ESU-BP/LWE, ESU-BP/GYR,  
ESU-BP/GYRL (XX variables: AA to ZZ; Y variables: -, L, T, TL)  
ESU-MP/XXY Series (XX variables: AA to ZZ; Y variables: -, L)  
RDC-XXY Series (X variables: A to Z; Y variables: 3, 5, 3A and 5A)  
ESU-ADP/XX Series (XX variables: 01 to 10)  
RGPC-XX Series (XX variables: 00 to 99)  
FMT-MX, FMT-BX and FMT-CXX Series (X variable: A, P), (XX variable: BA, BP, MA, and MP)  
FMT-RGPX Series (X variable: B, M)  
FMT-MDX (X variables: 1 to 9)  
TSC 01

**Classification:** Class I Medical Device, Annex IX Rule 1

**Conformity Assessment Procedure:** Annex VII

*We herewith declare that the above mentioned products meet the Essential requirements and conforms to the Medical Device Directive 93/42/EEC.*

## Standards:

EN 60601-1:2006 Medical electrical equipment, Part 1: General requirements for basic safety and essential performance  
EN IEC 60601-2-2:2018 Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories  
EN ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements  
EN 1041:2008+A1:2013 Information supplied by the manufacturer of medical devices  
EN ISO 17664:2017 Sterilization of medical devices - Information to be provided by the manufacturer for the processing of re-sterilizable medical devices  
EN ISO 14155:2011 Clinical investigation of medical devices for human subjects - Good clinical practice  
EN ISO 14971:2012 Medical Devices - Application of Risk Management to Medical Devices  
EN 62366-1:2015 Medical devices - Application of usability engineering to medical devices  
EN ISO 9001:2015 Quality management systems-Requirements  
EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes

**Date of issue:** 10.02.2020

## Signature:



**Name:** Filiz ERSOY  
**Position:** Company Manager

# EC-Declaration of Conformity

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E-mail : info@medset.com  
Web : www.medset.com

**Product:** Reusable and Disposable NIBP Cuffs, NIBP Hoses

## Reference Numbers:

FMT-SX, FMT-SX/BPYY-Z (Reusable Cuff with bladder /Single tube/ X (size): 1, 2, 3, 4, 4L, 5, 6; YY variable: 00 to 99; Z variable: -, H, P)  
FMT-DX, FMT-DX/BPYYYY (Reusable Cuff with bladder /Double tube/ X (size): 1, 2, 3, 4, 4L, 5, 6; YYYY variable: 0000 to 9999)  
FMT-SBX, FMT-SBX/BPYY-Z (Reusable Cuff without bladder /Single tube/ X (size): 1, 2, 3, 4, 4L, 5, 6; YY variable: 00 to 99; Z variable: -, H, P)  
FMT-DBX, FMT-DBX/BPYYYY (Reusable Cuff without bladder /Double tube/ X (size): 1, 2, 3, 4, 4L, 5, 6; YYYY variable: 0000 to 9999)  
FMT-DSX, FMT-DSXS, FMT-DSXT, FMT-DSX/BPYY-Z, FMT-DSXS/BPYY-Z, FMT-DSXT/BPYY-Z (Single Patient Use Cuff /Single tube/ X: sizes, 1 to 13; YY variable: 00 to 99; Z variable: -, H, P)  
FMT-DDX, FMT-DDXS, FMT-DDXT, FMT-DDX/BPYYYY, FMT-DDXS/BPYYYY, FMT-DDXT/BPYYYY (Single Patient Use Cuff /Double tube/ X: sizes, 1 to 13; YYYY variable: 0000 to 9999)  
FMT-ASX, FMT-ASX/BPYY-Z (ABPM Cuff / X (size): 3, 4, 5; YY variable: 00 to 99; Z variable: -, H, P)  
SBPXX/BPXX-Z (Single Line Hose, 3.0 m) (XX variable: 00 to 99; Z variable: -, H, P)  
DBPXXX/BPXXX (Double Line Hose, 3.0 m) (XXX variable: 00 to 99 or 0000 to 9999)  
CEBPXX/BPXX-Z (Coiled Extendable Hoses) (XX variable: 00 to 99; Z variable: -, H, P)

**Classification:** Class I Medical Device, Annex IX Rule 1

**Conformity Assessment Procedure:** Ek VII

**GMDN Codes:** 34978, 37326

*We herewith declare that the above mentioned products meet the Essential requirements and conforms to the Medical Device Directive 93/42/EEC.*

## Standards:

EN 60601-1:2006	Medical electrical equipment, Part 1: General requirements for basic safety and essential performance
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements
EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices
EN ISO 81060-1:2012	Non-invasive sphygmomanometers - Part 1: Requirements and test methods or non-automated measurement type
EN 1060-3:1997+A2:2009	Non-invasive sphygmomanometers - Part 3: Supplementary requirements for electromechanical blood pressure measuring systems
EN ISO 14155:2011	Clinical investigation of medical devices for human subjects - Good clinical practice
EN ISO 14971:2012	Medical Devices - Application of Risk Management to Medical Devices
EN 62366-1:2015	Medical devices - Application of usability engineering to medical devices
EN ISO 9001:2015	Quality management systems-Requirements
EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes

**Date of issue:** 03.01.2020

**Signature:**



**Name:** Filiz ERSOY  
**Position:** Company Manager



# EC-Declaration of Conformity

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E-mail : info@medset.com  
Web : www.medset.com

**Product:** Pulse Oximetry (SpO2) Sensors

## Reference Numbers:

Non- Sterile Reusable Pulse Oximetry (SpO2) Sensors: FMT-RAF/XXX, FMT-RAFB/XXX, FMT-RPF/XXX, FMT-RYS/XXX, FMT-RAS/XXX, FMT-RASB/XXX, FMT-REC/XXX, FMT-RPS/XXX, FMT-RIS/XXX, FMT-RNS/XXX, FMT-RWS/XXX (XXX variable: ADC-L, AT-L, BCI, BCI-L, BCI-LR, BLT, BLT-LC, BLT-LR, BLT-LV, BRC-L, BYS-L, CHC-LR, CMN-LR, CNC-LR, CRD-L, CRT, CRT-L, CRT-LL, CSI, DGC-L, DLP, DLW-L, DTS, DTS-L, DTX, DTX-L, DXT, DXT-L, EDN-LR, EMT-LD, EMT-LO, GLD-LL, GLD-LR, GOX-L, GTG-LR, HPB-L, HPS-L, IFM-L, INV-L, KNT-L, LHM, MEK, MEK-L, MEK-LD, MEK-LH, MEM-L, MMH-L, MND-L, MND-LO, MNM-L, MRQ-L, MRQ-LM, MRQ-LO, MSD, MSM-L, MTN-L, MTN-LM, MTN-LO, NKN, NKN-L, NKN-LC, NKN-LO, NKN-LR, NLC, NLC-L, NLC-LN, NLO, NLO-L, NLO-LO, NON, NON-L, NTG, NTG-L, NTG-LR, NVM, NVM-L, OHM-L, OHM-S, OXN, OXY, PLC, PLC-L, PLM-LR, PLS, PLS-L, PRN-LR, PTS-L, RGB-LR, RSD-L, SHA-L, SIE-L, SPL-L, SW-L, TRS-L, TRT-L, UTS-L)  
SENSORPLUS SP01XXXX, SP02XXXX, SP03XXXX, SP04XXXX, SP05XXXX. (XXXX variable: 0001 to 0089)  
Sterile Disposable Pulse Oximetry (SpO2) Sensors: FMT-DAF/XXX, FMT-DPF/XXX, FMT-DIF/XXX, FMT-DNF/XXX, FMT-DVF/XXX (XXX variable: BCI, CSI, DTX, MEK, MSD, MSM, NKN, NLC, NLO, NON, NVM, OHM, OXN, OXY)  
Non-Sterile Disposable Pulse Oximetry (SpO2) Sensors: SENSORPLUS SP06XXXX, SP07XXXX, SP08XXXX, SP09XXXX, SP10XXXX (XXXX variable: 0010 to 0071)

**Classification:** Class II b Medical Device, Annex IX Rule 10

**GMDN Codes:** 37808, 31658

**Conformity Assessment Procedure:** Annex II-3

*We herewith declare that the above mentioned products meet the Essential requirements and conforms to the Medical Device Directive 93/42/EEC with Medical Device Directive 2007/47/EC.*

## Standards:

EN 60601-1:2006	Medical electrical equipment, Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests (IEC 60601-1-2:2014 4 <sup>th</sup> Ed.)
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements
EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices
EN ISO 10993-1:2009	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 10993-10:2013	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
EN ISO 80601-2-61:2011	Medical electrical equipment-Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
EN ISO 14155:2011	Clinical investigation of medical devices for human subjects - Good clinical practice
EN ISO 14971:2012	Medical Devices - Application of risk management to medical devices
EN 62366-1:2015	Medical devices - Application of usability engineering to medical devices
EN ISO 14698-1:2003	Cleanrooms and associated controlled environments - Biocontamination control - Part 1: General principles and methods
EN 14698-2:2003	Cleanrooms and associated controlled environments - Biocontamination control - Part 2: Evaluation and interpretation of biocontamination data
EN ISO 14644-2:2015	Cleanrooms and associated controlled environments - Part 2: Specifications for monitoring and periodic testing to provide continued compliance with ISO 14644-1
EN ISO 14644-3:2005	Cleanrooms and associated controlled environments - Part 3: Test methods
EN ISO 14644-4:2001	Cleanrooms and associated controlled environments - Part 4: Design, construction and start up
ISO 14644-5:2004	Cleanrooms and associated controlled environments - Part 5: Operations
AAMI/ISO 11135:2014	Sterilization of health care products - Ethylene oxide - Requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO 11737-1:2018	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products
EN ISO 11737-2:2009	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
EN ISO 14644-1:2015	Cleanrooms and associated controlled environments Part 1: Classification of air cleanliness by particle concentration
EN ISO 10993-7:2008	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
EN ISO 10993-11:2010	Biological evaluation of medical devices - Part 11: Systemic toxicity tests
EN ISO 11607-1:2017	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2:2017	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 9001:2015	Quality management systems-Requirements
EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
MDD 93/42/EEC	Council Directive 93/42/EEC of 14 June concerning medical devices
MDD 2007/47/EC	Council Directive 2007/47/EC of 5 September 2007 European Parliament concerning medical devices
RoHS 2011/65/EU	Council Directive 2011/65/EU of 8 June 2011 Restriction of the use of certain hazardous substances

## Notified Body:

**KIWA Certification Services Inc.**  
ITOSB 9. Cadde No:15 Tepeören-Tuzla İstanbul / Turkey

## EC-Mark:



**Number of Certificate:** 1984-MDD-10-075  
**Start of EC Mark:** 19.11.2004  
**Duration of Validity:** 16.04.2019 – 20.11.2020  
**Date of issue:** 16.04.2019

## Signature:

**Name:** Filiz ERSOY  
**Position:** Company Manager

# 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



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 Pätt**  
Management Representative

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 l'Éguillette, 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, Commissioner 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,

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

		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	Różynec 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,

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

ACCREDITED UNIT: DNV GL Business Assurance Sweden AB, Box 6046, 171 06 Solna, Sweden. TEL: +46 8 587 940 00. <http://assurance.dnvgl.com>



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

	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, Xiju 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,

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

ACCREDITED UNIT: DNV GL Business Assurance Sweden AB, Box 6046, 171 06 Solna, Sweden. TEL:+46 8 587 940 00. <http://assurance.dnvgl.com>

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

		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, Jl. 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

## EC Certificate

### Full Quality Assurance System according to Medical Devices Directive 93/42/EEC Annex-II Section 3

**Certificate Number: 1984-MDD-10-075**

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subjected, transposing annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive.

**Organization:**

### **METKO MEDİKAL VE TIBBİ CİHAZLAR DIŞ TİCARET LİMİTED ŞİRKETİ**

İvedik OSB Ağaç İşleri San. Sitesi 1354. Cadde 1358. Sokak No:9 06378  
Yenimahalle, Ankara, Turkey

**Products:** Sterile and Non-Sterile Pulse Oximetry (SpO2) Sensors and Medical Temperature Probes, Sterile Disposable Pressure Transducer

The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

**Report Number:** M.3393.10  
**Date of first issue:** 23 December 2010  
**Date of last issue:** 16 April 2019  
**Revision Number:** 09  
**Expiry Date:** 20 November 2020

Kiwa Certification Services Inc. is Notified Body under Council Directive 93/42/EEC concerning medical devices with identification number: 1984



16 April 2019, Istanbul, Turkey

Head of Notified Body

CERTIFICATE



**CMAC**

I.S. „Centrul de Metrologie Aplicată și Certificare”

**CERTIFICAT DE CONFORMITATE**Nr. de înregistrare **13 C003116-19**

Data emiterii 02 septembrie 2019 Valabil până la 02 septembrie 2020

**ORGANISMUL DE CERTIFICARE**

ORGANISMUL DE CERTIFICARE PRODUSE (OCP) din cadrul I.S. „Centrul de Metrologie Aplicată și Certificare” (I.S. CMAC). Adresa: str. E. Coca, 28, MD 2064, mun. Chișinău;

tel.: 022 719279, 022 750463; fax: 022 745489.

PRIN PREZENTUL DOCUMENT SE CONFIRMĂ FAPTUL CĂ PRODUSELE IDENTIFICATE ANTEA:

DENUMIREA / DESCRIEREA

Lămpi UV cu raze ultraviolete marca "Haining New Light"

tipuri: T8 15W..., T8 30W..., T...W....

unde (...) - cifre și/sau litere care reprezintă variantele modelului.

Livrarea conform contractelor cu "Haining New Light Source Trading Co., Ltd.", China.

Codul NCM  
8539SÎNT CONFORME CU CERINȚELE OBLIGATORII STABILITE ÎN :  
SM EN 62035:2015 (p.p. 4.2, 4.3.1, 4.3.2, 4.4.1-4.4.3).**PRODUCĂTOR**

"Haining Xinguangyuan Lighting Co., Ltd.", China.

Codul țării

CN

**SOLICITANT**

"ECOCHIMIE" S.R.L., MD-2060, str. Valea Crucii, 2-85, mun. Chișinău.

Depozit - mun. Chișinău, bd. Dacia, 49/6.

Codul IDNO

1002600052156

**CERTIFICATUL ESTE ELIBERAT ÎN BAZA**

Raport de evaluare final Nr. 2885-RE din 30.08.2019, eliberat de OCP din cadrul I.S. CMAC, str. E. Coca, 28, mun. Chișinău, MD 2064; Raport de încercări Nr. 21/08 din 28.08.2019, eliberat de LÎPI din cadrul I.S. CMAC, MD 2064, mun. Chișinău, str. E. Coca, 28, certificat de acreditare Nr. LÎ - 093 din 23.11.2016.

**INFORMAȚIE SUPPLEMENTARĂ:**

Schema de certificare 2. Supravegherea se va efectua una dată pe an de către OCP din cadrul I.S. CMAC. Certificatul este valabil doar în cazul asigurării cu informație în limba de stat a fiecărei unități de produs conform legislației în vigoare. Acord Nr. 6562/2019 din 02.09.2019, Nr. 2637.



Conducătorul organismului de certificare

L.S.

Expert

Digitally signed by Cojocaru Vera  
Date: 2020.05.21 14:04:27 EEST  
Reason: MoldSign Signature  
Location: Moldova

Nr. RO 003116



# CERTIFICAT D'ENREGISTREMENT

Le Système de Management de :

## **GROUPE AMORGOS - VLAD et Batteries 4Pro.com**

Site principal : 400 Rue Emille Dewoitine, 37210 Parçay-Meslay, France.

a été enregistré par Intertek comme étant conforme aux exigences de la norme :

**ISO 14001:2015**

**ISO 9001:2015**

Le Système de Management est applicable à :

VLAD : Études de conception, d'adaptation, assemblage et fourniture de batteries, d'accumulateurs et de piles pour les applications industrielles et médicales.

B4P : Vente en ligne de piles, d'accumulateurs, batteries et autres articles connexes.

**Certificat n° :**

0085241

**Date de certification initiale :**

03 décembre 2018

**Date de certification :**

03 décembre 2018

**Date d'émission du certificat :**

17 décembre 2018

**Date d'expiration :**

02 décembre 2021



**Calin Moldovean**

Président, Business Assurance

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



# CERTIFICAT D'ENREGISTREMENT

Ce document confirme que le système de management de :

**V.L.A.D.**

Adresse principale:

400 Rue Emile Dewoitine  
37210 PARÇAY-MESLAY  
France

a été enregistré par Intertek comme satisfaisant aux exigences de la norme :

**ISO 13485:2016**

Le système de management est applicable à :

Études de conception, d'adaptation, assemblage et fourniture de batteries d'accumulateurs et de piles pour les applications médicales

Numéro de certificat :

0086983

Date de certification initiale:

2019-02-01

Date d'entrée en vigueur de la certification:

2019-02-01

Date d'expiration du certificat:

2022-01-31



**Calin Moldovean**

President, Business Assurance

Intertek Testing Services NA Ltd., 1829,  
32<sup>nd</sup> Avenue, Lachine, QC, H8T 3J1,  
Canada



# Certificate of Approval

This is to certify that the Management System of:

**Atlas Copco Ltd (trading as Atlas Copco Medical)**

Unit 18, Nuffield Way, Abingdon, Oxfordshire, OX14 1RL, United Kingdom

has been approved by LRQA to the following standards:

ISO 13485:2003  
EN ISO 13485:2012



David Derrick

Issued by: Lloyd's Register Quality Assurance Ltd

Current Issue Date: 27 September 2017  
Expiry Date: 31 March 2019

Original Approval:  
3 April 2013

Approval Certificate Number: LRQ 4007749/B

The scope of this approval is applicable to:

**Design and manufacture of Medical Gas equipment.**



001



# CERTIFICATE

Number: 2116830

The management system of the organization(s) and locations mentioned on the addendum belonging to:

## Philips Electronics Nederland B.V.

Philips Innovation Services

High Tech Campus 34

5656 AE Eindhoven

The Netherlands

including the implementation meets the requirements of the standard:

## ISO 13485:2016

### Scope:

Design, development and manufacture for third parties of electronic, optical, mechatronic and software components for use in medical devices and prototypes; including provision of related services: secondment and consultancy.

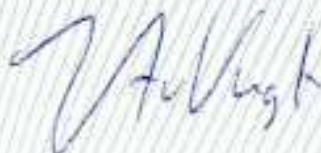
Certificate expiry date: 1 January 2021  
Certificate effective date: 8 March 2019  
Certified since: 15 December 2008

This certificate is valid for the organization(s) and/or locations mentioned on the addendum.

DEKRA Certification B.V.



B.T.M. Holtus  
Managing Director



J.A. van Vugt  
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed





## NÜVE SANAYİ MALZEMELERİ İMALAT VE TİCARET ANONİM ŞİRKETİ

SARACALAR MAHALLESİ SARACALAR KÜMEEVLERİ NO:4/2  
AKYURT – ANKARA – TURKEY

with a scope of

**DESIGN, MANUFACTURE, SALES AND AFTER SALES  
SERVICES OF LABORATORY AND STERILIZATION EQUIPMENTS**

Has established a quality management system in accordance  
with international standard.

*“ Following elements of the standard are excluded “*

*“None“*

### ISO 9001:2015

Certificate No : M 8215  
Initial Certification Date : 28 April 2010  
Certification Date : 19 February 2019  
Expiration Date : 18 February 2022



Quality Management System  
TS EN ISO/IEC 17021-1

AB-0006-YS



TÜRKAK BDS NO  
YS-4AF4-45D4



General Manager

Kiwa Certification Services Inc.

ITOSB 9. Cadde No. 15 Tepeören Tuzla - Istanbul - Turkey

Tel: + 90 216 593 25 75 Faks : + 90 216 593 25 74

Web: [www.kiwa.com.tr](http://www.kiwa.com.tr) E-mail: [info@kiwa.com.tr](mailto:info@kiwa.com.tr)

*Certificate is valid till expiration date, subject to successful completion of periodical surveillance audits.*

Please contact above numbers for detailed information.



CERTIFICATE



# NÜVE SANAYİ MALZEMELERİ İMALAT VE TİCARET ANONİM ŞİRKETİ

SARACALAR MAHALLESİ SARACALAR KÜMEEVLERİ NO:4/2  
AKYURT – ANKARA – TURKEY

with a scope of

**DESIGN, MANUFACTURE AND AFTER SALES SERVICES OF  
LABORATORY AND STERILIZATION EQUIPMENTS**

Medical devices - Quality management systems - Requirements for  
regulatory purposes

*"Following elements of the standard are excluded"*

*" 7.5.5 " " 7.5.7 " " 7.5.9.2 "*

## EN ISO 13485:2016

Certificate No : M 8216  
Initial Certification Date : 28 April 2010  
Certification Date : 19 February 2019  
Expiration Date : 18 February 2022



Medical Device Q.M.S.  
TS EN ISO/IEC 17021-1

AB-0006-YS



TÜRKAK BDS NO  
YS-4DCF-FE40

General Manager

Kiwa Certification Services Inc.  
İTOSB 9. Cadde No. 15 Tepeören Tuzla - Istanbul - Turkey  
Tel: + 90 216 593 25 75 Faks : + 90 216 593 25 74  
Web: [www.kiwa.com.tr](http://www.kiwa.com.tr) E-mail: [info@kiwa.com.tr](mailto:info@kiwa.com.tr)

*Certificate is valid till expiration date, subject to successful completion of periodical surveillance audits.*

Please contact above numbers for detailed information.



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 18 03 84065 005

**Manufacturer:** **Nuova GmbH**  
Lübecker Str. 17  
23909 Ratzeburg  
GERMANY



**Facility(ies):** Nuova GmbH  
Lübecker Str. 17, 23909 Ratzeburg, GERMANY

**Product Category(ies):** **Oxygen 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.:** 713129331

**Valid from:** 2018-06-18

**Valid until:** 2023-06-17



**Date,** 2018-04-18

Stefan Preiß



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





E



E-15/4

- Connector: modular jack
- Measuring range: 0-100% O<sub>2</sub>
- Output signal: 8-12 mV
- Response time: < 16 seconds
- Warranty: 16 months
- Storage: up to 6 months



Management Service

# CERTIFICATE

The Certification Body  
of TÜV SÜD Management Service GmbH

certifies that

## OSRAM

**OSRAM GmbH**  
Marcel-Breuer-Straße 6  
80807 München  
Germany

including the sites and scope of application  
see enclosure

has established and applies  
a Quality Management System.

An audit was performed, Order No. **707056398**.

Proof has been furnished that the requirements  
according to

### ISO 9001:2015

are fulfilled.

The certificate is valid from **2019-12-21** until **2022-12-20**.

Certificate Registration No.: **12 100 52177 TMS**.

Product Compliance Management  
Munich, 2019-12-09





Management Service

### Enclosure of Certificate Registration No.: 12 100 52177 TMS

Sites	Scope of application
<b>Germany</b>	
<b>OSRAM GmbH</b> Marcel-Breuer-Straße 6 80807 München Germany	Headquarters - Corporate Management, Corporate Quality, Corporate Environmental Protection, Health and Safety, Procurement, Design & Development, Customer Service, Sales, Marketing, Information Technology, Human Resources, Logistics
<b>OSRAM GmbH</b> Parkring 29-33 85748 Garching Germany	
<b>OSRAM GmbH</b> Nonnendammallee 44 13629 Berlin Germany	Development and production of HID lamps for different applications
<b>OSRAM GmbH</b> Industriestraße 20b 85072 Eichstätt Germany	Development and production of XBO Xenon short-arc lamps for CINEMA projection
<b>OSRAM GmbH</b> Mittelstetter Weg 2 86830 Schwabmünchen Germany	Design, development and manufacturing of pre-materials for lamps and components
<b>OSRAM GmbH</b> An der Bahnbrücke 89542 Herbrechtingen Germany	Design, development and manufacturing of automotive lamps and LED systems for automotive applications
<b>OSRAM GmbH</b> Karl-Schurz-Str. 38 33100 Paderborn Germany	Development of lighting control systems

Product Compliance Management  
Munich, 2019-12-09



ZERTIFIKAT ◆ CERTIFICATE ◆ 認 證 證 書 ◆ CERTIFICADO ◆ CERTIFICAT



Management Service

## Enclosure of Certificate Registration No.: 12 100 52177 TMS

Sites	Scope of application
<b>Germany</b>	
<b>OSRAM Opto Semiconductors GmbH</b> Leibnizstraße 4 93055 Regensburg Germany	Design, development and production of opto semiconductor wafer, opto electronic components and displays
<b>Austria</b>	
<b>OSRAM a. s.</b> <b>Niederlassung Österreich</b> Leonard-Bernstein-Straße 10 1220 Wien Austria	Sales
<b>Czech Republic</b>	
<b>OSRAM Česká republika s.r.o.</b> Zahradní 1442/46 792 01 Bruntál Czech Republic	Development, manufacturing and sales of fine wires and coils, dies and nozzles; manufacturing of Display/Optic lamps and products
<b>France</b>	
<b>OSRAM SASU</b> rue Gaston Ramazzotti 18 67120 Molsheim France	Sales and distribution of lamps, luminaires and light components
<b>ADB STAGELIGHT SASU</b> Zone industrielle de Rouvroy 02100 Rouvroy France	Manufacturing and sales of lighting devices for theater, TV, museum. - Luminaires - Accessories and hoisting system - Control systems and dimmers - Network configuration



Product Compliance Management  
Munich, 2019-12-09








Management Service

## Enclosure of Certificate Registration No.: 12 100 52177 TMS

Sites	Scope of application
<b>Italy</b>	
<b>Clay Paky S.p.A.</b> Via Pastrengo 3/b 24068 Seriate (BG) Italy	Design, manufacture and sale of luminaires, lighting effects and accessories for art, stage and entertainment applications
<b>OSRAM (OEC) S.p.A.</b> <b>Società Riunite OSRAM Edison Clerici</b> Viale dell'Innovazione n. 3 20126 Milano Italy	Sales
<b>OSRAM S.p.A.</b> Via Castagnole 65/A 31100 Treviso Italy	Development and production of LED Light Engines and Modules, LED power supplies, Light Management Systems, Luminaires, traditional and LED lamps, electronic ballasts
<b>OSRAM CONTINENTAL Italia S.r.l.</b> Via Castagnole 65/A 31100 Treviso Italy	Production of lighting systems and electronic products
<b>Slovak Republic</b>	
<b>OSRAM, a.s.</b> Komárňanská cesta 7 940 02 Nové Zámky Slovak Republic	Development, manufacturing, sales of high pressure discharge lamps (HPD), halogen lamps and tungsten lamps. Development and assembly of luminaries. Machine and equipment engineering
<b>Sweden</b>	
<b>OSRAM AB</b> Arenavägen 39 121 77 Johanneshov Sweden	Sales

  
Product Compliance Management  
Munich, 2019-12-09





Management Service

### Enclosure of Certificate Registration No.: 12 100 52177 TMS

Sites	Scope of application
<b>United Kingdom</b>	
<b>OSRAM Ltd.</b> 450 Brook Drive, Green Park Reading RG2 6UU United Kingdom	Sales, marketing and distribution of lighting products
<b>OSRAM Ltd.</b> Centrix House, 26 Crow Lane East Newton-le-Willows, Merseyside WA12 9UY United Kingdom	Sales, marketing and distribution of lighting products
<b>P.R. China</b>	
<b>OSRAM China Lighting Ltd.</b> No. 1 North Industrial Road Foshan City, Guangdong Province P.R. China Post Code: 528000	Manufacturing and sales of lighting products
<b>OSRAM Guangzhou Lighting Technology Limited</b> Room 1105, 1106, 1107, No.15 Fuhua Road, Zhongcun Street, Panyu District Guangzhou City, Guangdong Province P.R. China Post Code: 511400	Sales and service of module, driver, control system and related accessories used for luminaire
<b>OSRAM Kunshan Display Optic Ltd.</b> No.2 building, No.179; 2nd floor 6 # Building, No. 199, Waihejing Road, Kunshan Free Trade Zone, Kunshan Development Zone Kunshan, Jiangsu Province, P.R. China Post Code: 215300	Design, development and manufacturing of P-VIP lamp and LED systems

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### Enclosure of Certificate Registration No.: 12 100 52177 TMS

Sites	Scope of application
<b>P.R. China</b>	
<b>OSRAM Opto Semiconductors (China) Co. Ltd.</b> No. 57, XiQin Rd Wuxi XinWu District, Jiangsu, P.R. China Post Code: 214028	Production of opto semiconductor components
<b>OSRAM CONTINENTAL Kunshan Intelligent Lighting Co., Ltd.</b> No. 6 & No. 7 building, No.276 Xiongying Road, Economic & Technological Development Zone Kunshan, Jiangsu Province, P.R. China Post Code: 215300	Manufacturing of electronic ballast and SSL (Solid State Lighting) products
<b>OSRAM Asia Pacific Management Company Shenzhen Branch</b> 2F, Block B, Jianxing Building, No. 3151 Shahe West Road, Xili, Nanshan District Shenzhen, P.R. China Post Code: 518055	Design and Development, quality management and marketing of Solid State Lighting (SSL) products
<b>Hong Kong</b>	
<b>Traxon Technologies Ltd.</b> 108-113 & 208-213 Wireless Centre, 3 Science Park East Avenue, Hong Kong Science Park, Shatin Hong Kong	Design, manufacturing control and sales of LED lighting and power system

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## Enclosure of Certificate Registration No.: 12 100 52177 TMS

Sites	Scope of application
<b>India</b>	
<b>OSRAM Lighting Private Ltd.</b> 1st Floor, Surinder Jhakar Bhavan, Plot Number 3, Sector - 32 Gurgaon, Haryana - 122001 India	Design, development, testing, approbation, marketing, sales & distribution of lighting products
<b>Malaysia</b>	
<b>OSRAM Opto Semiconductors (Malaysia) SDN. BHD</b> Bayan Lepas Free Industrial Zone Phase 1 11900 Bayan Lepas, Penang Malaysia	Design, development and production of opto semiconductor wafer, opto electronic components and displays
<b>OSRAM Opto Semiconductors (Malaysia) Sdn. Bhd.</b> Zon Industri Fasa 1, Taman Perindustrian Hi-Tech Kulim 09090 Kedah Darul Aman Malaysia	Design and production of opto semiconductor wafer, opto electronic components and displays
<b>Mexico</b>	
<b>OSRAM S.A. de C.V.</b> Av. 1o. de Mayo, No. 120, Piso 5 Col. San Andrés Atoto 53500 Naucalpan de Juárez, Estado de México Mexico	National headquarters and sales for SP, DS, LS & OS
<b>OSRAM de Mexico S.A. de C.V. (Planta Monterrey)</b> Av. TLC No. 50, Parque Industrial Stiva, Aeropuerto Apodaca, Nuevo León C.P. 66600 Mexico	Design and manufacturing of electronic ballasts, drivers and LED products.

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### Enclosure of Certificate Registration No.: 12 100 52177 TMS

Sites	Scope of application
<b>USA</b>	
<b>OSRAM Opto Semiconductors, Inc.</b> Kifer Road 1150 Sunnyvale, CA 94086 USA	Sales, marketing, customer service and logistics
<b>OSRAM SYLVANIA INC</b> 129 Portsmouth Avenue Exeter, NH 03833 USA	Manufacture of LED converter platelets
<b>OSRAM SYLVANIA INC</b> 275 West Main Street Hillsborough, NH 03244 USA	Design, development & manufacturing of automotive light sources
<b>OSRAM SYLVANIA INC</b> 816 Lexington Avenue Warren, PA 16365 USA	Manufacture of molded plastic components, small metal stampings for the lighting and automotive industries and molded plastic parts for various applications
<b>OSRAM SYLVANIA INC</b> 71 Cherry Hill Drive Beverly, MA 01915 USA	Corporate Innovations Americas
<b>OSRAM SYLVANIA INC</b> 200 Ballardvale Street Wilmington, MA 01887 USA	Business Unit DS Management Processes (marketing, controlling, development, industrialization, quality, procurement, logistics) for lighting industry LED products, drivers and ballasts
<b>Bulgaria</b>	
<b>OSRAM EOOD</b> Plot 879, Koshovete Area, Plovdiv District 4199 Trud Bulgaria	Production of electronic lighting products

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