

Certificate of Approval

This is to certify that the Management System of:

Atlas Copco Compressors LLC, Corporate office

300 Technology Center Way, Suite 550, Rock Hill, SC, 29730, United States

has been approved by Lloyd's Register to the following standards:

ISO 14001:2015, ISO 45001:2018, ISO 9001:2015

Approval number(s): ISO 14001 – 0019527-776, ISO 45001 – 0019525-119, ISO 9001 – 0019526-055

This certificate forms part of the approval identified by approval number: 0019527/ 0019525/ 0019526

The scope of this approval is applicable to:

ISO 14001:2015

Marketing, sales, installation of Oil-Free Air compressors, Oil-Injected Air compressors, Air Blowers, Nitrogen Generators, Air Treatment equipment, Vacuum Pumps and related services and parts.

ISO 45001:2018

Marketing, sales, installation of Oil-Free Air compressors, Oil-Injected Air compressors, Air Blowers, Nitrogen Generators, Air Treatment equipment, Vacuum Pumps and related services and parts.

ISO 9001:2015

Marketing, sales, installation of Oil-Free Air compressors, Oil-Injected Air compressors, Air Blowers, Nitrogen Generators, Air Treatment equipment, Vacuum Pumps and related services and parts.



Paul Graaf

Area Operations Manager North Europe

Issued by: Lloyd's Register EMEA

for and on behalf of: Lloyd's Register Quality Assurance Limited



001

Certificate of Approval

Atlas Copco Compressors LLC
Central Regional Office
2501 Landmeier Road, Elk Grove Village, IL,
60007, United States

ISO 14001:2015
Marketing, sales, installation of Oil-Free Air compressors,
Oil-Injected Air compressors, Air Blowers, Nitrogen
Generators, Air Treatment equipment, Vacuum Pumps
and related services and parts.

ISO 45001:2018
Marketing, sales, installation of Oil-Free Air compressors,
Oil-Injected Air compressors, Air Blowers, Nitrogen
Generators, Air Treatment equipment, Vacuum Pumps
and related services and parts.

ISO 9001:2015
Marketing, sales, installation of Oil-Free Air compressors,
Oil-Injected Air compressors, Air Blowers, Nitrogen
Generators, Air Treatment equipment, Vacuum Pumps
and related services and parts.

Atlas Copco Compressors LLC
Eastern Regional Office
92 Interstate Dr., West Springfield, MA, 01089,
United States

ISO 14001:2015
Marketing, sales, installation of Oil-Free Air compressors,
Oil-Injected Air compressors, Air Blowers, Nitrogen
Generators, Air Treatment equipment, Vacuum Pumps
and related services and parts.

ISO 45001:2018
Marketing, sales, installation of Oil-Free Air compressors,
Oil-Injected Air compressors, Air Blowers, Nitrogen
Generators, Air Treatment equipment, Vacuum Pumps
and related services and parts.



Certificate of Approval

ISO 9001:2015

Marketing, sales, installation of Oil-Free Air compressors, Oil-Injected Air compressors, Air Blowers, Nitrogen Generators, Air Treatment equipment, Vacuum Pumps and related services and parts.

Atlas Copco Compressors LLC Southern Regional Office

15045 Lee Road, Houston, TX, 77032,
United States

ISO 14001:2015

Marketing, sales, installation of Oil-Free Air compressors, Oil-Injected Air compressors, Air Blowers, Nitrogen Generators, Air Treatment equipment, Vacuum Pumps and related services and parts.

ISO 45001:2018

Marketing, sales, installation of Oil-Free Air compressors, Oil-Injected Air compressors, Air Blowers, Nitrogen Generators, Air Treatment equipment, Vacuum Pumps and related services and parts.

ISO 9001:2015

Marketing, sales, installation of Oil-Free Air compressors, Oil-Injected Air compressors, Air Blowers, Nitrogen Generators, Air Treatment equipment, Vacuum Pumps and related services and parts.

Atlas Copco Compressors LLC Western Regional Office

48434 Milmont Drive, Fremont, CA, 94538,
United States

ISO 14001:2015

Marketing, sales, installation of Oil-Free Air compressors, Oil-Injected Air compressors, Air Blowers, Nitrogen Generators, Air Treatment equipment, Vacuum Pumps and related services and parts.



Certificate of Approval

ISO 45001:2018

Marketing, sales, installation of Oil-Free Air compressors, Oil-Injected Air compressors, Air Blowers, Nitrogen Generators, Air Treatment equipment, Vacuum Pumps and related services and parts.

ISO 9001:2015

Marketing, sales, installation of Oil-Free Air compressors, Oil-Injected Air compressors, Air Blowers, Nitrogen Generators, Air Treatment equipment, Vacuum Pumps and related services and parts.



IRELAND

Mullaghboy Industrial Park, Navan
Co. Meath, Ireland

PHONE: +353 (0) 46 907 1333

FAX: +353 (0) 46 907 1331

EMAIL: info@ntron.com

UNITED KINGDOM

Dallam Court, Dallam Lane, Warrington
WA2 7LT, United Kingdom

PHONE: +44 (0) 161 930 8690

FAX: +44 (0) 161 930 8691

WEB: www.ntron.com



EU-Declaration of Conformity

We the Manufacturer
Ntron Ltd.



Mullaghboy Industrial Park,
Navan, County Meath, Ireland

Declares under our sole responsibility that we believe the products identified in this declaration, and to which this declaration relates, are in conformity with the requirements of the following council directives.

Directive 2014/30/EU on the approximation of the laws of the member states relating to Electromagnetic Compatibility (EMC Directive)

Directive 2011/65/EU and of Council of 8th June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS2) as amended by Commission Delegated Directive(EU) of 31 March 2015, 2015/863/EU (RoHS3)

Description of Equipment

Microx and Gasenz Analysers with Electrochemical and Zirconia Sensors

Standards to which conformity is declared.

EN50270:2015 Electromagnetic Compatibility-Electrical apparatus for the detection and measurement of combustible gases, toxic gases or oxygen performance criterion 'C'.

EN61000-6-1:2007 Electromagnetic Compatibility-(EMC) Immunity.

EN61000-6-4:2007 Electromagnetic Compatibility- (EMC) Emissions.

***OJ L 174, 1.7.2011, p.88 & P106 Annex IV 1b.**

Signed for and on behalf of Ntron Ltd.
Mullaghboy Industrial Park, Navan, Co. Meath, Ireland.

Dated 03/01/2022
CETX012 R1.5

Name: David Beirne, Managing Director

Signature:

A handwritten signature in black ink that reads "David Beirne".



EXCELLENCE
THROUGH DIVERSITY

GAS MEASUREMENT SYSTEMS
OXYGEN ANALYSERS
INERTING CONTROL SYSTEMS



ZERTIFIKAT

Die Zertifizierungsstelle
der TÜV SÜD Management Service GmbH

bescheinigt, dass das Unternehmen

BlitzRotary GmbH

Hüfingerstr. 55 • 78199 Bräunlingen
Deutschland

für den Geltungsbereich

Entwicklung, Herstellung und Vertrieb von
Drucklufttechnik, Fahrzeug-Hebetechnik, Reifenfülltechnik,
Messtechnik, Batterieservicetechnik, Sonderwerkzeuge

Waltersbündt 3 • 77749 Hohberg-Hofweier
Deutschland

für den Geltungsbereich

Herstellung und Vertrieb von
Fahrzeug-Hebetechnik, Reifenwucht-,
Montier- und Messtechnik

ein Qualitätsmanagementsystem
eingeführt hat und anwendet.

Durch ein Audit, Bericht-Nr. **707089175**,
wurde der Nachweis erbracht, dass die Forderungen der

ISO 9001:2015

erfüllt sind.

Dieses Zertifikat ist gültig vom **25.04.2018** bis **24.04.2021**.

Zertifikat-Registrier-Nr.: **12 100 55701 TMS**.

Product Compliance Management
München, 25.04.2018





MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:
106973-2011-AQ-SWE-SWEDAC / 2006-
SKM-AE-1093 / 2008-SKM-AHSO-143

Initial certification date:
11 January 2008

Valid:
13 September 2021 – 31 January 2023

This is to certify that the management system of

ESAB GROUP

420 National Business Parkway, 5th Floor, ANNAPOLIS JUNCTION, MD, 20701, USA

and the sites as mentioned in the appendix accompanying this certificate

has been found to conform to the Management System standards:

ISO 9001:2015/ ISO 14001:2015/ ISO 45001:2018

including STEMFS 2014:2 for the sites Göteborg, Laxå and Perstorp

This certificate is valid for the following scope:

**Development, design, production, sales and distribution of welding and cutting products
with associated services**

Place and date:
Solna, 13 September 2021



For the issuing office:
DNV - Business Assurance
Elektroatan 10, 171 54, Solna, Sweden

Ann-Louise Pätt
Management Representative

MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:
10000500063-MSC-RvA-DEU

Initial certification date:
22 December 2021

Valid:
22 December 2021 – 21 December 2024

This is to certify that the management system of
Greggersen Gasetechnik GmbH
Bodestraße 27-29, 21031 Hamburg, Germany

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

This certificate is valid for the following scope:

Design and development, manufacture, final inspection, distribution, planning, installation and service of central gas supply systems, terminal units, medical gas devices and accessories, autogenous welding and cutting equipment, compressed gas technology

Place and date:
Barendrecht, 22 December 2021

For the issuing office:
DNV - Business Assurance
Zwolsseweg 1, 2994 LB Barendrecht,
Netherlands



Erie Koek
Management Representative



BUREAU
VERITAS

Bureau Veritas Certification

OMEGA AIR d.o.o. Ljubljana

Cesta Dolomitskega odreda 10, 1000 Ljubljana, Slovenia

OMEGA AIR d.o.o. Ljubljana, PE Logatec, Obrtna cona Logatec 20, 1370 Logatec, Slovenija

Bureau Veritas Certification Holding SAS – UK Branch certifies that the Management System of the above organisation has been audited and found to be in accordance with the requirements of the management system standards detailed below

ISO 9001:2015

Scope of certification

Development, design, production, sales and service of equipment and systems for compressed air and other gases, filtration and separation of gases and liquids.

Original Cycle Start Date:	16-09-2003
Expiry date of previous cycle:	15-09-2021
Certification / Recertification Audit date:	09-07-2021
Certification / Recertification cycle start date:	16-09-2021
Subject to the continued satisfactory operation of the organization's Management System, this certificate expires on:	15-09-2024

Certificate Number:	SI008842	Version:	1	Issue Date:	14-09-2021
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Certification Body Address: 5th Floor, 66 Prescott Street, London, E1 8HG, United Kingdom

Local office: Linhartova cesta 49a, SI - 1000 Ljubljana, Slovenia

Further clarifications regarding the scope and validity of this certificate, and the applicability of the management system requirements, please call: +386 1 47 57 670



0008



Certificate of Approval

This is to certify that the Management System of:

Walker Filtration Ltd

Birtley Road, Washington, NE38 9DA, United Kingdom

has been approved by Lloyd's Register to the following standards:

ISO 9001:2015

Approval number(s): ISO 9001 – 00005450

The scope of this approval is applicable to:

Design and manufacture of compressed air and gas filters, dryers and purification equipment, vacuum filters, autoclave filters for steam sterilizers and smoke evacuators for use in medical laser surgery.



David Derrick

Area Operations Manager UK & Ireland

Issued by: Lloyd's Register Quality Assurance Limited



001



MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:
262513-2018-AQ-CZS-NA-PS

Initial certification date:
11 May 2018

Valid:
02 July 2021 – 11 May 2024

This is to certify that the management system of

GCE Group AB

Murmansgatan 126, 212 25, Malmö, Sweden

and the sites as mentioned in the appendix accompanying this certificate

has been found to conform to the Quality Management System standard:

ISO 13485:2016

This certificate is valid for the following scope:

Design, production, sales, distribution and service of medical gas equipment and devices for usage of medical gases.

Place and date:
Høvik, 14 January 2022



For the issuing office:
DNV Product Assurance AS
Veritasveien 3, 1363 Høvik, Norway

Cecille Gudesen Torp

Cecille Gudesen Torp
Management Representative

Certificate

The Certification Body

**MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany**

herewith certifies that the company

**Greggersen Gasetechnik GmbH
Bodestraße 27-29
21031 Hamburg
Germany**

has introduced, applies and maintains a quality management system in the area of activities, products/services and locations listed in the appendix.

The conformity of this quality management system to the requirements of the following standard has been verified by an audit:

EN ISO 13485:2016

This certification is subject to surveillance by MEDCERT.

Effective date: 2021-12-19
Expiry date: 2024-12-18

Report No.: 0874FS27F
Procedure No.: QS – 0874
Certificate No.: 0874GB445211208

Hamburg, 2021-12-08



MEDCERT Certification Body
Markus Bianchi

The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

MEDCERT is a management systems certification body
accredited by DAkkS.

Appendix of certificate

Procedure No.: QS – 0874
Certificate No.: 0874GB445211208

Activities and products/services in the scope of certification

Design and development, manufacture, final inspection, distribution, installation, and servicing of

- Central gas supply systems
- Terminal units
- Medical gas devices and accessories

Locations in the scope of certification

Greggersen Gasetechnik GmbH
Bodestraße 27-29
21031 Hamburg
Germany

This appendix is integral part of the above-referenced certificate.
The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

MEDCERT is a management systems certification body
accredited by DAkkS.



BUREAU
VERITAS

Bureau Veritas Certification

OMEGA AIR d.o.o. Ljubljana

Cesta Dolomitskega odreda 10, 1000 Ljubljana, Slovenia

This is a multi-site certificate. Additional site details are listed in the appendix to this certificate.

Bureau Veritas Certification Denmark A/S certifies that the Management System of the above organization has been audited and found to be in accordance with the requirements of the management system standards detailed below.

Standard

DS/EN ISO 13485:2016

Scope of certification

DEVELOPMENT, DESIGN, PRODUCTION, SALES AND SERVICE OF EQUIPMENT AND SYSTEMS FOR COMPRESSED AIR AND OTHER GASES, FILTRATION AND SEPARATION OF GASES AND LIQUIDS.

Original cycle start date:	15-December-2020
Expiry date of previous cycle:	NA
Certification/Recertification Audit date:	NA
Certification/ Recertification cycle start date:	15-December-2020

Subject to the continued satisfactory operation of the organization's Management System, this certificate expires on: **14-December-2023**

Certificate No.: DNKFRC102175 Version: 1 Revision date: **15-December-2020**

Certification Office: Bureau Veritas Certification Denmark A/S
Oldenborggade 25-31, 7000 Fredericia, Denmark

Further clarifications regarding the scope of this certificate and the applicability of the Management System requirements may be obtained by consulting the organization. To check this certificate validity, please call **(+45) 77 311 000**. 1/2





BUREAU
VERITAS

Bureau Veritas Certification

OMEGA AIR d.o.o. Ljubljana

Standard

DS/EN ISO 13485:2016

Scope of certification

DEVELOPMENT, DESIGN, PRODUCTION, SALES AND SERVICE OF EQUIPMENT AND SYSTEMS FOR COMPRESSED AIR AND OTHER GASES, FILTRATION AND SEPARATION OF GASES AND LIQUIDS.

<u>Site Name/location:</u>	<u>Site Addition Date:</u>	<u>Site Address:</u>	<u>Site Scope:</u>
OMEGA AIR d.o.o. Ljubljana	15-December-2020	Cesta Dolomitskega odreda 10, 1000 Ljubljana, Slovenia	DEVELOPMENT, DESIGN, PRODUCTION, SALES AND SERVICE OF EQUIPMENT AND SYSTEMS FOR COMPRESSED AIR AND OTHER GASES, FILTRATION AND SEPARATION OF GASES AND LIQUIDS.
OMEGA AIR d.o.o. PE Logatec	15-December-2020	Obrtna cona Logatec 20, 1370 Logatec, Slovenia	DEVELOPMENT, DESIGN, PRODUCTION, SALES AND SERVICE OF EQUIPMENT AND SYSTEMS FOR COMPRESSED AIR AND OTHER GASES, FILTRATION AND SEPARATION OF GASES AND LIQUIDS.

Certificate No.: DNKFRC102175 Version: 1 Revision date: **15-December-2020**

Certification Office:

Rikke Jues
Bureau Veritas Certification Denmark A/S
Oldenborggade 25-31, 7000 Fredericia, Denmark

Further clarifications regarding the scope of this certificate and the applicability of the Management System requirements may be obtained by consulting the organization. To check this certificate validity, please call **(+45) 77 311 000**. 2/2



Reg.nr. 5005

Certificate of Approval

This is to certify that the Management System of:

Walker Filtration Ltd

Birtley Road, Washington, NE38 9DA, United Kingdom

has been approved by Lloyd's Register to the following standards:

ISO 13485:2016



David Derrick - Area Operations Manager UK & Ireland

Issued by: Lloyd's Register Quality Assurance Limited

Current issue date: 23 January 2020
Expiry date: 22 January 2023
Certificate identity number: 10246432

Original approval:
ISO 13485 – 23 January 2020

Product Approval number: ISO 13485 – 00023904

The scope of this approval is applicable to:

Manufacture of Medical Gas Products (Manifolds, Wallzones, Medical Plant, Hoses, PMGS Outlets, LBV and Global Dryer) for various OEM Brands and supply of associated service parts required for the product life.



001

ZERTIFIKAT

DIN EN ISO 14001

ÖKOZERT

BESCHEINIGT HIERMIT, DASS DIE FIRMA

BlitzRotary GmbH

D-78199 Bräunlingen

Für den Geltungsbereich:

Entwicklung, Herstellung und Vertrieb von Drucklufttechnik,
Fahrzeug-Hebetechnik, Reifenfülltechnik, Messtechnik,
Batterieservicetechnik, Sonderwerkzeuge

EIN
UMWELT - MANAGEMENT - SYSTEM
NACH
DIN EN ISO 14001 : 2015
EINGEFÜHRT HAT UND ANWENDET

Der Nachweis wurde im Rahmen des Zertifizierungsaudits
Bericht Nr. **ÖK 180425po01** erbracht.

Datum der
Erstzertifizierung: **27.08.2014**

Datum der
Rezertifizierung: **25.04.2018**

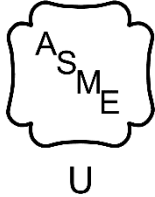
Zertifizierung-Nr.: **205372**

Gültig bis: **24.04.2021**



ÖKO - ZERT Gerhard Dischke
AKKREDITIERT DURCH
EURAS

D-72766 Reutlingen • Grüner Weg 60 • Tel (07121) 263 94 53



CERTIFICATE OF AUTHORIZATION

The named company is authorized by the American Society of Mechanical Engineers (ASME) for the scope of activity shown below in accordance with the applicable rules of the ASME Boiler and Pressure Vessel Code. The use of the ASME Certification Mark and the authority granted by this Certificate of Authorization are subject to the provisions of the agreement set forth in the application. Any construction stamped with the ASME Certification Mark shall have been built strictly in accordance with the provisions of the ASME Boiler and Pressure Vessel Code.

COMPANY:

Omega Air d.o.o.
Obrtna cona Logatec 20
Logatec, SI-1370
Slovenia

SCOPE:

Manufacture of pressure vessels at the above location only

AUTHORIZED: **November 18, 2019**

EXPIRES: **November 18, 2022**

CERTIFICATE NUMBER: **40270**

A blue ink signature of David E. Tuttle.

Board Chair, Conformity Assessment

A black ink signature of Joseph Lovcic.

Managing Director, Conformity Assessment



EC Certificate of Conformity

The Notified Body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany

herewith certifies that the company:

Greggersen Gasetechnik GmbH
Bodestraße 27-29
21031 Hamburg
Germany

has introduced, applies and maintains a quality assurance system for the products / product categories listed in the appendix.

The compliance of this quality assurance system with the below mentioned requirements of the **Council Directive 93/42/EEC** was verified by an audit:

Annex II without section 4

This certification is subject to surveillance by MEDCERT.

Effective date: 2020-06-03

Expiry date: 2023-12-18

Report No.: 0874PS25F
Process No.: QS – 0874
Certificate No.: 0874GB410200603

Hamburg, 2020-06-03

MEDCERT Certification Body
(Markus Bianchi)

The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

MEDCERT Identification Number: 0482

Form F10010005e EN / Rev. 11 / 2019.11.14



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-237.10.15

Appendix of EC Certificate of Conformity

Process No.: QS – 0874

Certificate No.: 0874GB410200603

List of products / product categories included in the scope of certificate

- **Central gas supply systems**
- **Terminal units**
- **Pressure reducers**
- **Flowmeters**
- **Compressed gas and vacuum regulators**
- **Low pressure hose assemblies**
- **Suction units**
- **Vaporizer and atomizer units**
- **Insufflation units**

– End of list –

This appendix is integral part of the above-referenced certificate.
The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

MEDCERT Identification Number: 0482

Form F10010005e EN / Rev. 11 / 2019.11.14



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-237.10.15



Type test Certificate

Evaluation of the solid particle removal efficiency of Atlas Copco DD+/DDp+ or PD+/PDp+ filter According to ISO12500-3:2009

Test report IBR JN: 12828A & 12828C

Report prepared for: Atlas Copco Airpower n.v.

Issue date of certificate: 26^h October, 2012

PN for DD+/DDp+: 1 624 1829 09

PN for PD+/PDp+: 1 624 1829 07

	0.01 µm	0.1µm	0.5 µm	1 µm	5µm
DD+/DDp+	99.93%	99.92%	99.95%	99.998%	>99.999%
PD+/PDp+	99.995%	99.992%	99.997%	>99.999%	>99.999%

	MPPS	Efficiency at MPPS
DD+/DDp+	0.1 µm	99.92%
PD+/PDp+	0.06 µm	99.98%

Report Authorized By:

Susan H Goldsmith Managing Director

Note: Full report available upon request

1. **DECLARATIE DE CONFORMITATE CE**

2 Noi, Atlas Copco Airpower n.v., declarăm pe proprie răspundere, ca produsul

3 Numele echipamentului: **Filtru de aer**

4 Tipul echipamentului: **DD/ DDp/ PD/ PDp/ QD (9-120)**

5 Seria echipamentului: **N/A**

6 ce cade sub incidența articolului 12.2 a al Directivei CE 2006/42/CE, respecta Cerințele de Siguranță și pe cele Fundamentale pentru Sănătate ale Directivei Consiliului anterior menționat, și amendamentele pentru armonizarea legislației Statelor Membre referitoare la Agregate.

7 Echipamentul este conform cu cerințele directivelor și a amendamentelor :

Directiva privind variațiile legilor Statelor Membre cu privire la	Standarde folosite	Comentarii
Echipament sub presiune	97/23/CE	X

8 Standardele tehnice folosite sunt menționate în atasament

9 **Conformitatea specificațiilor** **Conformitatea produsului**

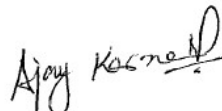
10 **cu directivele** **cu specificațiile**

11

12 Emitent Product engineering Fabricant

14 Nume Yves Goister Ajay Karnail

15 Semnatura

16 Data 26/04/2018

DIRECTIVA ECHIPAMENTELOR SUB PRESIUNE 97/23/CE

1 Estimari de conformitate urmarite: Vezi Tabelul. T1.

a. Categorie	b. Aplicabil	c. Modul	d. Org. Autorizat	e. Certificat de ref.
I	X	H	(1)	f:Ref: 0038/PED/2003004/A
II		H	(1)	
III		H	(1)	
IV		B	(2)	
		D	(1)	

(1) Notified body number 0038
Lloyd's Register Verification Ltd
71 Fenchurch street
EC3M – 4 BF London
United Kingdom

(2) Notified body number 0343
Lloyd's Register Stoomwezen
P.O. Box 701
3000 A 3 Rotterdam
Netherlands

2. Descrierea echipamentului sub presiune care constituie ansamblul : vezi tabelul T.2

a. Echipamentul, subiect al Directivei 87/404/CEE privind rezervoare sub presiune simple, este exclus din directiva 97/23/CE in concordanta cu articolul I, sectiunea 3.3			
b. Echipamentul face parte din categoria I, in concordanta cu directiva 97/23/CE, si este integrat in masina si este exclus din articolul I, sectiunea 3.6.			
c. Echipamentul din articolul 3.3 al 97/23/CE este subiectul unei practici si testari ingineresti			
h. Cat. II si mai sus	d. Echipament		g. Declaratie de conformitate atasat (include procedura de testare de conformitate urmata, identificarea standardelor)
	e. Descriere si/sau f. Componenta		
	Accesorii de siguranta	Supapa de siguranta	
	Rezervor	Separator de ulei	

3 Standarde estimate folosite: vezi Tabelul 2

4 Standarde tehnice nationale si specificari pentru utilizare: vezi Tabelul 2

Atlas Copco Airpower n.v.

A company within the Atlas Copco Group

Postal address
P.O. Box 100
B-2610 Wilrijk-Antwerp
Belgium
www.atlascopco.com

Visitors address
Boomsesteenweg 957
B-2610 Wilrijk-Antwerp
Belgium

Phone: +32 (0)3 870 21 11
Fax: +32 (0)3 870 24 43

Com. Reg. Antwerp 44651
V.A.T. 403.992.231

For info, please contact your local Atlas Copco representative

EC CERTIFICATE

Full Quality Assurance System

Certificate No.:
10401-2017-CE-CZS-NA-PS Rev. 5.0

Project No.:
PRJC-189266-2009-PRC-CZE

Valid Until:
27 May 2024

This is to certify that the quality system of:

GCE s.r.o.

Žižkova 381,583 01 Chotěboř, Czech Republic

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

MEDICAL DEVICES FOR USE WITH MEDICAL GASES

Has been assessed with respect to:

**THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN
ANNEX II EXCLUDING SECTION 4 OF COUNCIL DIRECTIVE
93/42/EEC ON MEDICAL DEVICES, AS AMENDED**

and found to comply.

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

Place and date:
Høvik, 15 September 2020



For:
DNV GL PRESAFE AS
Notified Body No.: 2460

Cathrine Wisbech

The certificate is digitally verified by blockchain technology. For more info, see www.dnvgl.com/assurance/certificates-in-the-blockchain.html



Certificate No.:
10401-2017-CE-CZS-NA-PS Rev. 5.0

Project No.:
PRJC-189266-2009-PRC-CZE

Valid Until:
27 May 2024

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Supersedes DNV GL (NB0434) certificate No. 73547-2010-CE-CZS-NA 7.0 following transfer of notified body function to DNV Nemko Presafe AS (NB2460)	2017-11-01
1.0	Correction pagination	2018-07-11
2.0	Scope extension – added new variants of Pressure regulators integrated with cylinder valves - MediVital A and MediVital E	2018-08-22
3.0	Re-certification	2020-03-30
4.0	Scope Extension – added new models in Bold High Pressure Regulators, model MEDITEC Flow-metering devices, model MediFlowTec As listed in the List of Models dated 11-09-2020	2020-09-11
5.0	Removing models – Gas Switch, Gas Alarm C44, Gas Alarm G4, Gas Alarm MC7701, Gas Alarm Touch, as per List of Models dated 14-09-2020	2020-09-15

Certificate No.:
10401-2017-CE-CZS-NA-PS Rev. 5.0

Project No.:
PRJC-189266-2009-PRC-CZE

Valid Until:
27 May 2024

Products covered by this Certificate:

Product Description	Product Name	Class
Medical devices for use with Medical Gases	Flow-metering devices (Ball flow meters, Flow selectors) Humidifiers Low pressure hoses Low pressure regulators Terminal Unit (for Anesthetic Gas Scavenging System) Suction equipment (Suction ejectors, Vacuum regulators) Demand Valve Gas Saver	IIa
Medical devices for use with Medical Gases	Pressure regulators integrated with cylinder valves Cylinder valves High Pressure Regulators Terminal Unit Ambulance Panel Central gas supply system Resuscitator Adjustable regulators	IIb

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
GCE s.r.o.	Žižkova 381, 583 01 Chotěboř, Czech Republic

Certificate No.:
10401-2017-CE-CZS-NA-PS Rev. 5.0

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Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate

TÜV Rheinland LGA Products GmbH • 51105 Cologne • Germany

Atlas Copco Airpower n.v.
P.O. Box 104
Boomsesteenweg 957
2610 Wilrijk
Belgium

Your correspondence
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Order-No.:3047714

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Customer Service Center
for Products
Phone +49 911 655-5225

Mail service@de.tuv.com

Cologne, 05th March 2012

Type Test certificate
Evaluation of the residual aerosol oil content after an
Atlas Copco PD+ filter
Test report No.: 3047714

The Atlas Copco PD+ filters are measured under the test conditions according to ISO 12500-1:2007, the compressed air samples are analyzed according to the ISO 8573-2:2007 test method.

	Maximum residual aerosol oil content	Average wet pressure drop
PD+-filter	0.008 mg/m ³	< 215 mbar

i. V.



Björn Koch

i. A.



Dr. rer. nat. Norbert Horlemann

TÜV Rheinland
LGA Products GmbH

Am Grauen Stein 29
51105 Cologne
Germany

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Board of Management

Dipl.-Ing.
Jörg Mähler, Spokesman

Dipl.-Kfm.
Dr. Jörg Schlösser

Nuremberg HRB 26013
VAT No.: DE811835490

Certificate of Approval

This is to certify that the Management System of:

Atlas Copco Airpower NV

Boomsesteenweg 957, 2610 Wilrijk, Belgium

has been approved by Lloyd's Register to the following standards:

ISO 13485:2016

Product approval number: ISO 13485 – 0010344

The scope of this approval is applicable to:

Manufacture of medical device components for compressors, vacuum pumps and air treatment products.



David Derrick

Area Operations Manager UK & Ireland

Issued by: Lloyd's Register Quality Assurance Limited



001



Valeriu Nastasiu
DataControl, Republic of Moldova

has been trained in June 2012 at company DataControl in Chisinau, Moldova

BASICS CENTRAL GAS SUPPLY UNITS

- **Pneumatic switch cabinets**
- **Ventus valve box**
- **AGSS outlet**
- **Forano outlet**

installation, assembling, function, maintenance
and spare parts

Mr Nastasiu took successfully part in the training of the above mentioned products.

Hamburg, 22.06.2012

GREGGERSEN
GASETECHNIK GmbH
Bodestr. 27-29 · 21031 Hamburg
Tel. 040/73 93 57-0 · Fax 73 93 57-39
email: info@greggersen.de

A handwritten signature in black ink, appearing to read "i. A. O. Koch".

Olaf Koch
- Trainer -

Certificate of Training

It is hereby certified, that

Mr. Valeriu Nastasiu
Data Control SRL, Republic of Moldova

has been trained in January 2018
at company DataControl SRL
in Chisinau, Republic of Moldova

Training Subjects :

- * *Medical Oxygen Plants (OGP);*
- * *Oil-injected, oil-free compressors (GA, ZT);*
- * *Refrigerant air dryers (FX, FD);*
- * *Compressed air filters (DD, PD, QD, QDT).*

Installation, assembling, function, maintenance
and spare parts.

Country Manager
Compressor Technique Equipment

Liviu Chelaru



A handwritten signature in blue ink, appearing to read 'Liviu Chelaru'.

