CE

bürkert
FLUID CONTROL SYSTEMS

EU Konformitäts-erklärung	EU Declaration of Conformity	Déclaration UE de Conformité

Hersteller / Manufacturer / Constructeur:

Bürkert Werke GmbH & Co. KG
Werk 10
Christian-Bürkert-Straße 13-17
74653 Ingelfingen
www.burkert.com

Hiermit erklären wir, dass das nachstehend bezeichnete Produkt in seiner Konzipierung und Bauart sowie in der von uns in Verkehr gebrachten Ausführung den Bestimmungen der genannten EU-Richtlinien entspricht.	We hereby declare that the product specified below complies in its design and construction, as brought by us into the market is in accordance with the listed EU directives.	Nous déclarons par la présente que le produit spécifié ci-dessous, dans son développement et sa fabrication tel que mis sur le marché par nous, est conforme aux dispositions des directives UE mentionnées.
Bei einer mit uns nicht abgestimmten Änderung des Produktes verliert diese Erklärung ihre Gültigkeit.	If any unauthorized modifications are made to the product, this declaration will lose its validity.	Toute modification non autorisée apportée au produit fait perdre la validité de cette déclaration.
Eine Technische Dokumentation ist vollständig vorhanden. Die zum Produkt gehörende Betriebsanleitung in der Landessprache des Anwenders liegt vor (wenn erforderlich).	A complete technical documentation is available. The operating manual in the local language of the user is present (if necessary).	Une documentation technique complète est disponible. Le manuel d'utilisation du produit est présent (si nécessaire) dans la langue locale de l'utilisateur.

Typ / Type / Type:

2000

Produktbezeichnung / Product Description / Appellation d'un produit:

2/2-Wege-Kolbensteuer-Schrägsitzventil
2/2-way-piston-operated angle-seat valve
Vanne à piston 2/2 siège incliné

2014/34/EU - ATEX	2014/34/EU - ATEX	2014/34/UE - ATEX
2014/68/EU - DGRL	2014/68/EU - PED	2014/68/UE - DESP
EU/2016/426 - GGVO	EU/2016/426 - GAR	UE/2016/426 - GAZR
2006/42/EG - MRL	2006/42/EG - MD	2006/42/EG - Machines

Die folgenden Seiten enthalten weitere Angaben zur Einhaltung dieser Richtlinien.	The following pages enclose detailed information concerning compliance to these Directives.	Les pages suivantes contiennent plus d'informations sur la conformité avec les lignes directrices.
Diese Erklärung beinhaltet keine Zusicherung von Eigenschaften.	This declaration does not guarantee any specifications.	Cette déclaration ne garantit pas les spécifications.

Ingelfingen, 04. April 2019

i.A.
A. Popp

Annegret Popp
Approval Management

i.A.
M. Schmeißer

Marc Schmeißer
Approval Management

Bürkert Werke GmbH & Co. KG
74653 Ingelfingen
Christian-Bürkert-Str. 13-17

ABD 1000186048 ML Version: F Status: RL (released | freigegeben) printed: 11.02.2021

Digitally signed by Grabazei Alexandru
Date: 2021.03.18 08:21:32 EET
Reason: MoldSign Signature
Location: Moldova

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FLUID CONTROL SYSTEMS

EU Konformitäts-erklärung	EU Declaration of Conformity	Déclaration UE de Conformité

2014/34/EU - ATEX	2014/34/EU - ATEX	2014/34/UE - ATEX
Reference in the Official Journal of the EU: L 96 dated 29.3.2014		

Typ / Type / Type (Geräteschlüssel / product specification key / clé de produit):

2000-*-*-****-**-**-****-*-* (1)

(1) Variabler Code / Variable code / Variable Code:
Gilt nur in Verbindung mit / Only valid in combination with / Est uniquement valable en lien avec: PX51

Der oben beschriebene Gegenstand der Erklärung erfüllt die Vorschriften der Richtlinie 2014/34/EU des Euro-päischen Parlaments und des Rates vom 26. Februar 2014 zur Harmonisierung der Rechtsvorschriften der Mitgliedstaaten für Geräte und Schutzsysteme zur bestimmungsgemäßen Verwendung in explosionsgefährdeten Bereichen.	The object of the declaration described above is in conformity with Directive 2014/34/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres.	L'objet de la déclaration décrit ci-dessus est conforme à la directive 2014/34/UE du Parlement européen et du Conseil du 26 février 2014 relative à l'harmonisation des législations des États membres concernant les appareils et les systèmes de protection destinés à être utilisés en atmosphères explosibles.
Nur gültig in Verbindung mit der EX-Kennzeichnung des Gerätes!	Only valid in combination with the EX-marking of the equipment!	Uniquement valable en liaison avec le marquage EX de l'appareil!
Das Gerät kann eingesetzt werden gemäß den auf dem Typschild und in der Betriebsanleitung angegebenen Daten.	The device can be used in accordance with the data given on the nameplate and in the operating instructions.	Le dispositif peut être utilisé conformément aux indications de la plaque signalétique et dans la notice d'utilisation.

Für die Bewertung wurden folgende Normen herangezogen (wenn anwendbar): EN 80079-37:2016, EN 80079-36:2016	For evaluation of the conformity, the following standards were consulted (if applicable):	Pour l'évaluation de la conformité, les normes suivantes ont été utilisées (le cas échéant):

Das genannte Produkt ist bescheinigt durch die Benannte Stelle:	The product is certified by the Notified Body:	Le produit est certifié par l'organisme notifié:
Name und Anschrift der Benannten Stelle:/ Name and Address of the notified body:/ Nom et adresse de l'organisme notifié: Bureau Veritas CPS Germany GmbH Businesspark 86842 Türkheim, Germany		
EU-Baumusterprüfbescheinigung Nr.:	EU Type Examination Certificate No.:	Attestation d'examen UE de type Non.:
	EPS 18 ATEX 2 008 X, 02.03.2018	

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FLUID CONTROL SYSTEMS

EU Konformitäts-erklärung	EU Declaration of Conformity	Déclaration UE de Conformité

Abweichend zu 2014/68/EU Artikel 1 Absatz 2 f) werden folgende Angaben gemacht.	Varying from 2014/68/EU, Article 1 (2) (f), the following information shall be provided.	Paragraphe 2 Contrairement à 2014/68/UE Article 1, f), les détails suivants ont été fournis.

2014/68/EU - DGRL	2014/68/EU - PED	2014/68/UE - DESP
Reference in the Official Journal of the EU: L 189 dated 27.6.2014		

Typ / Type / Type (Geräteschlüssel / product specification key / clé de produit):

2000-*-*-****-**-**-(1)-*-*

(1) Leitungsanschluss (LTA = DN) / port connection / raccord - category I:
DGRL gilt nur, wenn LTA > DN25 / PED valid only for LTA > DN25 / DESP valide de LTA > DN25
Maximaler Betriebsdruck PN 15 bar bei DN65 /max. working pressure PN 15 bar at DN65 / Pression de service maximale PN 15 bar pour DN65

Der oben beschriebene Gegenstand der Erklärung erfüllt die Vorschriften der Richtlinie 2014/68/EU des Europäischen Parlaments und des Rates vom 15. Mai 2014 zur Harmonisierung der Rechtsvorschriften der Mitgliedstaaten über die Bereitstellung von Druckgeräten auf dem Markt.	The object of the declaration described above is in conformity with Directive 2014/68/EU of the European Parliament and of the Council of 15 May 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment.	L'objet de la déclaration décrit ci-dessus est conforme à la directive 2014/68/UE du Parlement européen et du Conseil du 15 mai 2014 relative à l'harmonisation des législations des États membres concernant la mise à disposition sur le marché des équipements sous pression.

Für die Bewertung wurden folgende Normen herangezogen (wenn anwendbar): EN 13480-5:2017, EN 12266-1:2012	For evaluation of the conformity, the following standards were consulted (if applicable):	Pour l'évaluation de la conformité, les normes suivantes ont été utilisées (le cas échéant):

Angewandtes Konformitätsbewertungsverfahren: **Modul A** (Interne Fertigungskontrolle, inklusive Druckfestigkeitsprüfung auf statistischer Grundlage nach Anhang I Abschnitt 3.2.2)	Applied conformity assessment: **Module A** (Internal production control, including Compressive strength testing on a statistical basis as specified in Annex I, Section 3.2.2)	Examen de conformité appliqué: **Module A** (Vérification interne de la production, inclus les tests de résistance à la compression sur une base statistique comme spécifié à l'annexe I, section 3.2.2)
Einteilung nach Artikel 4 und Anhang II: Fluidklasse 1 (gasförmig oder flüssig), Diagramm 6, Kategorie I Instabile Gase sind ausgeschlossen. Max. Betriebsdruck PN 10 bar bei DN 100	Classification acc. to Article 4 and Annex II: Class 1 fluid (gaseous or liquid) Chart 6, Category I Unstable gases are excluded. Max. working pressure PN 10 bar at DN 100	Classification de l'article 4 et à l'annexe II: Classe 1 de fluide (gazeux ou liquide) Tableau 6, Catégorie I Gaz instables sont exclus. Pression de service maximale PN 10 bar pour DN 100

Das Produkt kann unter den folgenden Bedingungen verwendet werden (abhängig vom max Druck, dem LTA und dem Medium), ohne Kategorie		The product can be used under the following conditions (dependent of the maximum operating pressure, the LTA and the medium), without category		Le produit peut être utilisé dans les conditions suivantes (dépendante de la pression de service maximale, la LTA et le milieu), sans catégorie	
Medium	Bedingungen	Fluid	Conditions	Fluide	Conditions
Gruppe 1, §4.1.c.i	DN ≤ 25	Fluid group 1, §4.1.c.i	DN ≤ 25	Fluide groupe 1, §4.1.c.i	DN ≤ 25
Gruppe 2, §4.1.c.i	DN ≤ 32 oder PS*DN ≤ 1000	Fluid group 2, §4.1.c.i	DN ≤ 32 or PS*DN ≤ 1000	Fluide groupe 2, §4.1.c.i	DN ≤ 32 ou PS*DN ≤ 1000
Gruppe 1, §4.1.c.ii	DN ≤ 25 oder PS*DN ≤ 2000	Fluid group 1, §4.1.c.ii	DN ≤ 25 or PS*DN ≤ 2000	Fluide groupe 1, §4.1.c.ii	DN ≤ 25 ou PS*DN ≤ 2000
Gruppe 2, §4.1.c.ii	DN ≤ 200 oder PS*DN ≤ 5000	Fluid group 2, §4.1.c.ii	DN ≤ 200 or PS*DN ≤ 5000	Fluide groupe 2, §4.1.c.ii	DN ≤ 200 ou PS*DN ≤ 5000
DN (LTA) in mm and PS (PN) in bar					

Die Sicherheits- und Einbauhinweise der mitgelieferten Produktdokumentation sind zu beachten	The instructions for safety and installation of the enclosed product documentation have to be observed.	Les consignes de sécurité et d'installation décrites dans la documentation fournie avec le produit doivent être respectées.

ABD 1000186048 ML Version: F Status: RL (released | freigegeben) printed: 11.02.2021

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EU Konformitäts-erklärung	EU Declaration of Conformity	Déclaration UE de Conformité

EU/2016/426 - GGVO | EU/2016/426 - GAR | UE/2016/426 - GAZR

Reference in the Official Journal of the EU: L 81 dated 31.03.2016

Typ / Type / Type (Geräteschlüssel / product specification key / clé de produit):

2000-*-*-****-**-**-****-*-* (1)

(1) Variabler Code / Variable code / Variable Code:
Gilt nur in Verbindung mit / Only valid in combination with / Est uniquement valable en lien avec: PO19 oder PO20

Der oben beschriebene Gegenstand der Erklärung erfüllt die Vorschriften der Verordnung (EU) 2016/426 des Europäischen Parlaments und des Rates vom 9. März 2016 über Geräte zur Verbrennung gasförmiger Brennstoffe und zur Aufhebung der Richtlinie 2009/142/EG.	The object of the declaration described above is in conformity with Regulation (EU) 2016/426 of the European Parliament and of the Council of 9 March 2016 on appliances burning gaseous fuels and repealing Directive 2009/142/EC.	L'objet de la déclaration décrit ci-dessus est conforme à la Règlement (UE) 2016/426 du Parlement européen et du Conseil du 9 mars 2016 concernant les appareils brûlant des combustibles gazeux et abrogeant la directive 2009/142/CE.

Für die Bewertung wurden folgende Normen herangezogen (wenn anwendbar):	For evaluation of the conformity, the following standards were consulted (if applicable):	Pour l'évaluation de la conformité, les normes suivantes ont été utilisées (le cas échéant):

EN 13611:2015, EN 161:2011+A3:2013, EN 16678:2015

Das genannte Produkt ist bescheinigt durch die Benannte Stelle:	The product is certified by the Notified Body:	Le produit est certifié par l'organisme notifié:

Name und Anschrift der Benannten Stelle:/ Name and Address of the notified body:/ Nom et adresse de l'organisme notifié

DVGW Cert GmbH
Josef-Wirmer-Straße 1-3
53123 Bonn, Germany

EU-Baumusterprüfbescheinigung Nr.:	EU Type Examination Certificate No.:	Attestation d'examen UE de type Non.:

CE-0085BO6147, 12.03.2019

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FLUID CONTROL SYSTEMS

EU Konformitäts-erklärung	EU Declaration of Conformity	Déclaration UE de Conformité

2006/42/EG - MRL	2006/42/EG - MD	2006/42/EG - Machines
Reference in the Official Journal of the EU: L 157 dated 9.6.2006		

Hiermit erklären wir, dass die nachstehend bezeichnete Maschine in ihrer Konzeption und Bauart sowie in der von uns in Verkehr gebrachten Ausführung den grundlegenden Sicherheits- und Gesundheitsanforderungen der EG-Richtlinie 2006/42/EG entspricht.	We hereby declare that the machine indicated below in its conception and construction and in the version marketed by us is in accordance with the essential health and safety requirements of the EC Directive 2006/42/EC.	Nous déclarons par la présente que la machine indiquée ci-dessous, dans sa conception et sa construction dans la version que nous commercialisons, est conforme aux exigences de santé et de sécurité de la directive européenne 2006/42/CE.

Bevollmächtigter für die Zusammenstellung der technischen Dokumentation:	Authorized person for compiling the technical documentation: Bürkert Werke GmbH & Co. KG Werk 10 Christian-Bürkert-Straße 13-17 74653 Ingelfingen	Personne autorisée pour collecter la documentation technique:

Fertigungsstätten / manufacturing sites / sites de production:

Werk/Factory/Usine 3
Öhringen
Schleifbachweg 40
74613 Öhringen

Gerät oder Anlage / Equipment or installation / Appareil or installation:

Bezeichnung / Designation / La désignation suivante:	2000
Seriennummer / Serial number / Numéro de série:	diverse ID
Baujahr / Year of manufacture / Année de construction:	2019

Das Produkt erfüllt auch die Anforderungen der folgenden Richtlinie(n): siehe Seite 1	The product also meets the requirements of following directive(s): see page 1	Le produit est également conforme aux exigences de la directive(s) ci-dessous: voir page 1
Die Schutzziele der Niederspannungsrichtlinie 2014/35/EU wurden eingehalten (siehe Anhang I, Nr. 1.5.1 der Richtlinie 2006/42/EG).	The protection objectives of the Low Voltage Directive 2014/35/EU have been observed (see Annex I, point 1.5.1 of Directive 2006/42/EC).	Les objectifs de sécurité de la Directive Basse Tension 2014/35/UE ont été observés (voir annexe I, no. 1.5.1 de la directive 2006/42/CE).

Für die Bewertung wurden folgende Normen herangezogen (wenn anwendbar): EN 13861:2012, EN 349:2008, EN 12100:2011	For evaluation of the conformity, the following standards were consulted (if applicable):	Pour l'évaluation de la conformité, les normes suivantes ont été utilisées (le cas échéant):

CERTIFICATO CE

Certificato n. 1884/MDD

Dichiarazione di approvazione del sistema qualità

(Sistema completo di garanzia qualità)

Visto l'esito delle verifiche condotte in conformità all'Allegato II, con l'esclusione del punto 4, della direttiva 93/42/CEE e s.m.i., si dichiara che la ditta:

GCE, s.r.o.

58381 CHOTEBOR - ZIZKOVA 381 (CZE) - Czech Republic

mantiene negli stabilimenti di:

58381 CHOTEBOR - ZIZKOVA 381 (CZE) - Czech Republic

un sistema qualità che assicura la conformità dei seguenti prodotti:

Impianti per la distribuzione dei gas medicinali (ossigeno, aria) destinati all'installazione su mezzi di soccorso (ambulanze)

Mod. Ambulance Panel System
Marca GCE

ai requisiti essenziali della direttiva suddetta ad essi applicabili (in tutte le fasi dalla progettazione al controllo finale) ed è sottoposta alla sorveglianza prevista dal punto 5 dell'Allegato II.

Riferimento pratiche IMQ:
10AP00004.

Questa Dichiarazione di approvazione è rilasciata dall'IMQ S.p.A. quale organismo notificato per la direttiva 93/42/CEE e s.m.i.
Il numero identificativo dell'IMQ S.p.A. quale organismo notificato è: 0051.

Emesso il: 2016-09-02

Data Scadenza: 2021-09-01

IMQ

ISTITUTO ITALIANO DEL MARCHIO DI QUALITA'

IMQ S.p.A. - I-20138 Milano
Via Quintiliano 43
tel. + 39 0250731
www.imq.it

EC CERTIFICATE

Certificate No 1884/MDD

Full Quality Assurance System Approval Certificate

On the basis of our examination carried out according to Annex II, excluding section 4, of the Directive 93/42/EEC and its revised version, we hereby certify that:

GCE, s.r.o.

58381 CHOTEBOR - ZIZKOVA 381 (CZE) - Czech Republic

manages in the factories of:

58381 CHOTEBOR - ZIZKOVA 381 (CZE) - Czech Republic

a quality assurance system ensuring the conformity of the following products:

Medical gas pipeline systems (oxygen, air) for road ambulance
Type ref. Ambulance Panel System
Trade mark GCE

with the relevant essential requirements of the aforementioned directive (from design to final inspection and testing) and it is subject to surveillance as specified in section 5 of Annex II.

Reference to IMQ files Nos:
10AP00004.

This Approval Certificate is issued by IMQ S.p.A. as Notified Body for the Directive 93/42/EEC and its revised version.
Notified Body notified to European Commission under number: 0051.

Date: 2016-09-02

Expirying Date: 2021-09-01

IMQ

ISTITUTO ITALIANO DEL MARCHIO DI QUALITA'

IMQ S.p.A. - I-20138 Milano
Via Quintiliano 43
tel. + 39 0250731
www.imq.it

This Approval Certificate is subjected to the provisions laid down in the "Rules for managing the EC Certification of Medical Devices on the basis of the Directive 93/42/EEC".

This is a translation of the Italian text, which prevails in case of doubts

DNV·GL

EC CERTIFICATE

Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
10401-2017-CE-CZS-NA-PS Rev. 5.0	PRJC-189266-2009-PRC-CZE	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

NORWEGIAN ACCREDITATION

PROD 021

For:
DNV GL PRESAFE AS

Notified Body No.: 2460

Cathrine Wisbech

Cathrine Wisbech

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

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**

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

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

Management System Certificate

Certificate No.:	Project No.:	Initial Certification Date:	Valid Until:
262513-2018-AQ-CZS-NA-PS Rev. 0.0	**PRJC-358993-2012-MSC-CZE**	**11 May 2018**	**11 May 2021**

This is to certify that the management system of:

GCE Holding AB

Källvattengatan 9
200 21 MALMØ
Sweden

With sites as listed overleaf.

Complies with the requirements of:

ISO 13485:2016/NS-EN ISO 13485:2016

The Certificate is valid for the following scope:

Design, production, sales, distribution and service of medical devices to control flow and pressure as well as devices for usage of medical gases in health services in following product groups: Pressure regulators, Terminal units, Suction equipment, Hoses, Cylinder and combination valves, Flow meters, Central Gas Manifolds, Accessories.

Place and Date:
Høvik, 15 May 2018

NORWEGIAN ACCREDITATION
MSYS 018

For:
DNV GL NEMKO PRESAFE AS

Eugenie Winger Husebye

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

Management System Certificate

Certificate No.:	Project No.:	Initial Certification Date:	Valid Until:
262513-2018-AQ-CZS-NA-PS Rev. 0.0	**PRJC-358993-2012-MSC-CZE**	**11 May 2018**	**11 May 2021**

Site Name	Address	Site Scope
GCE s.r.o.	Žižkova 381,583 01,Chotěboř,Czech Republic	Design, production, sales, distribution and service of medical devices to control flow and pressure as well as devices for usage of medical gases in health services in following product groups: Pressure regulators, Terminal units, Suction equipment, Hoses, Cylinder and combination valves, Flow meters, Central Gas Manifolds, Accessories.
GCE GmbH	Weyherser Weg 8,36043,Fulda,Germany	Sales, distribution and service of medical devices to control flow and pressure as well as devices for usage of medical gases in health services
GCE Norden AB	Källvattengatan 9,SE-200 21,Malmö,Sweden	Sales, distribution, customization and service of medical devices to control flow and pressure as well as devices for usage of medical gases in health services
GCE SAS	70, Rue du Puits Charles,58403,LA CHARITE SUR LOIRE,France	Sales and distribution of medical devices to control flow and pressure as well as devices for usage of medical gases in health services. Service of concentrators.

End of Certificate

DNV·GL

MANAGEMENT SYSTEM CERTIFICATE

Certificate No:	Initial certification date:	Valid:
164429-2014-AQ-GER-DAkkS	20 January 2019	20 January 2019 - 19 January 2022

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, construction, manufacture, final inspection, distribution, planning, installation and service of central gas supply systems, outlets, medical gas devices and accessories, autogenous welding and cutting equipment, compressed gas technology

Place and date:
Essen, 17 July 2019

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-18453-01-00

For the issuing office:
DNV GL - Business Assurance
Schnieringshof 14, 45329 Essen, Germany

Thomas Beck
Management Representative

MED CERT®

Certification. Medical Only.

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:

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

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

The conformity of this quality management system to the requirements of the below mentioned standard was verified by an audit:

EN ISO 13485:2016

This certification is subject to surveillance by MEDCERT.

Effective date: **2020-06-03**
Expiry date: **2021-12-18**

Report No.: 0874PS25F
Procedure No.: QS – 0874
Certificate No.: 0874GB445200603

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 is a DAkkS accredited management systems certification body

DAkkS
Deutsche Akkreditierungsstelle
D-ZM-19630-04-00

MED CERT®

Certification. Medical Only.

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.

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

MEDCERT Identification Number: 0482

MED CERT®

Certification. Medical Only.

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

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

LIETUVOS NACIONALINIS AKREDITACIJOS BIURAS

VS SERTIFIKAVIMAS ISO/IEC 17021

Nr. LA.04.002

SERTIKA

CERTIFICATE

Certificate registration No. 18K.1520 6th of November, 2018

The quality management system is designed, implemented and maintained in the

UAB Medical Technologies LBI

Savanoriu av. 271, LT-50131 Kaunas, LITHUANIA

meets the requirements of the standard
ISO 9001:2015
(LST EN ISO 9001:2015)

Scope of certification:

Design, manufacturing and installation of hospital medical supply systems.

This certificate is valid up to 05th of November, 2021.

Director UAB Ingrida Kusiene

LIETUVOS RESPUBLIKA UAB SERTIKA REPUBLIC OF LITHUANIA

"Sertika" Ltd.
Savanoriu av. 271-255,
LT-50131 Kaunas, Lithuania

sertika@sertika.lt
www.sertika.lt

SERTIKA

CERTIFICATE

Certificate registration No. 18M.1521 6th of November, 2018

Medical devices. The quality management system is designed, implemented and maintained in the

UAB Medical Technologies LBI

Savanoriu av. 271, LT-50131 Kaunas, LITHUANIA

meets the requirements of the standard
ISO 13485:2016
(LST EN ISO 13485:2016)

Scope of certification:

Design, manufacturing and installation of hospital medical supply systems.

This certificate is valid up to 05th November, 2021.
Medical devices. The quality management system is certified since 17th of January, 2013.

Director Ingrida Kusiene

LIETUVOS RESPUBLIKA UAB SERTIKA REPUBLIC OF LITHUANIA

"Sertika" Ltd.
Savanoriu av. 271-255,
LT-50131 Kaunas, Lithuania

sertika@sertika.lt
www.sertika.lt

SAFETY DATA SHEET

SUNOCO VP 68

Lubricants
United States

Section 1 - Identification

1.1 Product Identifiers

Product Name : SUNOCO VP 68
Product Code(s) : 9373

1.4 Supplier Information

SUNOCO LUBRICANTS
Philadelphia, PA 19154
United States

Phone : 800-660-0761
Fax : 215-352-0140

1.2 Product Usage

Recommended Usage : Specialized Usage Lube Oil
Restricted Usage : Not Intended for any other usage

1.3 Emergency Support

Emergency Support : CHEMTREC
United States/Canada +1(800) 424-9300

Section 2 - Hazards Identification

2.1 Classification of the Substance or the Mixture

GHS Rating(s) : **No Classified Hazards**
Signal Word : **Not Applicable**

2.2 Label Elements

No Classified Hazards.

Precautionary : **P201** Obtain Special Instructions Before Use.
P202 Do Not Handle Until All Safety Precautions Are Understood.
P281 Use Personal Protective Equipment As Required.
Response : **P308** If Exposed Or Concerned: Get Medical Advice/attention.
Storage : **P405** Store Locked Up.
Disposal : **P501** Dispose Of Container According To Regional Regulations.

2.3 Other Hazards

Section 3 - Composition / Information on Ingredients

3.1 Substance Details

Chemical Name	CAS #	%Weight
RESIDUAL OILS, PETROLEUM, SOLVENT-DEWAXED	64742-62-7	8.0
BASE OIL SEVERELY REFINED	64742-65-0	92.0

Products containing mineral oil with less than 3% DMSO extract as measured by IP-346.

Section 4 - First Aid Measures

4.1 First Aid Measures

Eye Contact : Immediately flush eyes with plenty of water occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for atleast 20 minutes. Get Medical Attention.

Inhalation : Remove victim to fresh air and keep at rest in a position comfortable for breathing. If breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth to mouth resuscitation. Maintain an open airway. Get medical attention if symptoms occur.

Ingestion : Wash out mouth with water. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Never give anything by mouth to an unconscious person. get medical attention if symptoms occur.

4.2 Symptoms & Effects

To Physician : Treat symptomatically. Contact poison specialist if product has been ingested.

Specific Treatment : No Specific Treatment.

4.3 Medical Attention

Protection of First Aiders : No action should be taken involving any personal risk or without suitable training. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation.

Note To Doctor : Aspiration during swallowing or vomiting may severely damage the lungs. If evacuation of stomach contents is necessary, use method least likely to cause aspiration.

Section 5 - Fire Fighting

5.1 Extinguishing Media

Suitable Media
Unsuitable Media : CO_2, Dry chemical, or Foam. Water can be used to cool and protect product. Do not use water jet as an extinguisher, it will spread the fire.

Specific hazards arising from this product : When heated, hazardous gases may be released including: sulfur dioxide. A solid stream of water will spread the burning material. Material creates a special hazard because it floats on water. This material creates a special hazard because it floats on water. This material is harmful to aquatic life. Any fire water contaminated with this material must be contained and prevented from being discharged to any waterway, sewer or drain.

5.3 Firefighters Advice

Special protective equipment : Fire Equipment Information: Fire-fighters should wear appriovirate protective equipment and sel contained breathing apparatus(SCBA) with a full face -piece operated in positive pressure mode.

Section 6 - Accidental Release Measures

6.1 Personal precautions, protective equipment

General Measures : No health affects expect from the cleanup of this material if contact can be avoided. Follow personal protect equipment recommendations found in section 8 of this SDS.

6.2 Environmental Precautions

Non-Emergency Personnel : Avoid dispersal of spilled material and runoff and contact with soil , waterways, drains and sewers. Inform authorities if the product has caused environmental pollution Water Polluting Material may be harmful to the environment if released in large quantities.

6.3 Materials & Methods to Contain and Cleanup

Reference Section 8 : Follow all protective equipment recommendations provided in Section 8.

Spill Control Measures : Prevent the spread of any spill to minimize harm to human health and the environment if safe to do so. Wear complete and proper personal protective equipment following the recommendation of Section 8 at a minimum. Dike with suitable absorbent material like granulated clay. Dispose of according to Federal, State, Local, or Provincial regulations. Used fluid should be disposed of at a recycling center.

Containment and Cleanup : Stop leak if without risk. Move containers from spill area. Approach release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Wash spillage's with noncombustible, absorbent material e.g. sand earth vermiculite or diatomaceous earth and place in container for disposal according to local regulations. Dispose of via licensed waste disposal contractor. Contaminated absorbent material may pose the same threat hazard as the spilled product.

Section 7 - Handling & Storage

7.1 Safe Handling

Personal Protective Equipment : Put on appropriate personal protective equipment (see section 8). Do not ingest. Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. Avoid release to the environment. Keep in the original container or an approved alternative made from a compatible material, keep lid tightly closed when not in use. Empty containers retain product residue and can be hazardous. Do not reuse container.

7.2 Safe Storage

Required conditions : Odorous and toxic fumes may form from the decomposition of this product if stored at temperatures in excess of 113 deg F (45 deg C) for extended periods of time or if heat sources in excess of 250 deg F (121 deg C) are used. Store away from incompatible materials. See section 10 for incompatible materials.

7.3 Specific End Use

Designed Purpose : This product is designed for use as a Specialized Usage Lube Oil

Section 8 - Exposure Control

8.1 United States Exposure Limits

CAS	Chemical Name	Exposure Limits	Source

8.2 Exposure Controls

Engineering Controls : Material should be handled in enclosed vessels and equipment, in which case general room ventilation should be sufficient. Local exhaust ventilation should be used at points where dust, mist, vapors or gases can escape into the room air. No special requirements under ordinary conditions of use and with adequate ventilation.

Enviromental Exposure Controls : General room ventilation should be satisfactory. Local exhaust ventilation may be necessary if misting is generated.

Hygeine Measures : Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing to remove contaminants. Discard contaminated footwear that cannot be cleaned.

Eye / Face Protection : If contact is likely, safety glasses with side shields are recommended.

Skin / Hand Protection : Butyl rubber. Use nitrile or neoprene gloves. Use good industrial hygiene practices. In case of skin contact, wash hands and arms with soap and water. Use caution when opening manway covers of storage and transportation containers. 3-nitroaniline crystals may be present on the interior surface of these openings. 3-nitroaniline is toxic by dermal exposure.

Respiratory Protection : Use a properly fitted air purifying or supplied air respirator complying with an approved standard if a risk assessment indicates this a necessary. Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the selected respirator.

Section 9 - Physical & Chemical Properties

9.1 Information On Basic Physical and Chemical Properties

Physical state	: Liquid
Color	: B&C
Odor	: Characteristic of Petroleum
Odor threshold	: No Data Available
pH	: No Data Available
Freezing Point	: No Data Available
Boiling Point / Range	: No Data Available
Flash Point COC	: 248C
Evaporation rate:	: No Data Available
Upper Explosive Limits (% air)	: No Data Available
Lower Explosive Limits (% air)	: No Data Available
Flammability (solid, gas)	: Not Applicable
Vapor pressure	: <1 mm Hg
Vapor density (air=1)	: > 1
Relative Density	: <Field Missing>
Auto-ignition temperature	: Not Determined
Decomposition temperature	: Not Determined
Solubility in water	: Negligible, 0-1%
Partition coefficient, n-octanol/water	: No Data Available

Section 10 - Stability & Reactivity

10.1 Material Analysis

Reactivity	: No Data Available
Chemical stability	: Stable Under Normal Circumstances.
Possibility of hazardous reactions	: Hazardous polymerization will not occur.

10.2 Environmental

Conditions to avoid	: Temperatures above the high flash point of this combustible material in combination with sparks, open flames, or other sources of ignition.
Incompatible materials	: Strong oxidizing agents
Hazardous decomposition products	: Carbon monoxide, Smoke, Carbon monoxide, sulfur oxides, aldehydes, and other petroleum decomposition products in the case of incomplete combustion. Oxides of nitrogen, phosphorus, calcium, copper, magnesium, sodium, and hydrogen sulfide may also be present

Section 11 - Toxicological Information

11.1 Toxicological Effects

Ingestion Toxicity	: No hazard with normal usage.
Skin Contact	: This material is likely to be slightly irritating to skin based on animal data.
Inhalation Toxicity	: No data available.
Eye Contact	: The material is likely to be irritating to eyes based on animal data.

11.2 Inhalation Toxicity Data

CAS	Chemical Name	Test	Value		Species	Source
64742-62-7	Residual oils, petroleum, solvent-dewaxed	Inhalation	2.18mg/L	4h	Rat	NLM_CIP

Section 11 - Toxicological Information Continued

Sensitizer : No data available to indicate product or components may be a skin sensitizer.

Mutagenicity : No data available to indicate product or any components present at greater than 0.1% is mutagenic or genotoxic.

Carcinogenicity : Not expected to cause cancer. This product meets the IP-346 criteria.

Reproductive Toxicity : No data available if components greater than 0.1% may cause birth defects.

Section 12 - Ecological Information

12.1 Aquatic Toxicity

Persistence and degradability : No Data Available.

Bioaccumulative potential : Bioconcentration may occur. No Data Available.

Mobility in soil : No Data Available.

Results of PBT and vPvB assessment : Not Determined.

Other adverse effects : No Data Available.

12.2 LC50 Toxicity Data

CAS	Chemical Name	Test	Value	Species	Source
64742-62-7	Residual oils, petroleum, solvent-dewaxed	LC50	5000.0mg/L 96h	Oncorhynchus	IUCLID

12.3 Other Toxicity Data

CAS	Chemical Name	Test	Value	Species	Source
64742-62-7	Residual oils, petroleum, solvent-dewaxed	EC50	1000.0mg/L 48h	Daphnia magna	IUCLID

Section 13 - Disposal Considerations

13.1 Waste treatment

Waste treatment methods : Dispose of according to Federal, State, Local, or Provincial regulations.

Disposal Methods : Recycle used oil.

Waste Disposal : Use material is non-hazardous according to environmental regulations.

Contaminated packaging : Recycle containers whenever possible!

Section 14 - Transportation Information

14.1 U.S. Department of Transportation (DOT)

14.2. Shipping Description : If shipped by land in a packaging having a capacity of 3,500 gallons or more, the provisions of 49 CFR, Part 130 apply. (Contains oil) International Maritime Dangerous Goods (IMDG)

14.2. DOT Compliance Note : U.S. DOT compliance requirements may apply. See 49 CFR 171.22, 23 & 25. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable International Civil Aviation Org. / International Air Transport Assoc. (ICAO/IATA)

14.2. DOT Compliance Requirement : U.S. DOT compliance requirements may apply. See 49 CFR 171.22, 23, 24

Section 15 - Regulatory Information

Agency		Inventory Status
(TSCA) Toxic Substance Control Act	: All components are either listed or not regulated US TSCA Inventory.	64742-62-7

WHMIS Hazard Class : None

Canada CPR : This product has been classified in accordance with the hazard criteria Controlled Products Regulations (CPR) and the SDS contains all the information required by the Regulations.

CERCLA Sections

302, 313, 372 : This material does not contain reportable chemicals.

311, 312 :

Acute Health Hazard	No	Pressure Hazard	No	Fire Hazard	No
Chronic Health Hazard	No	Reactive Hazard	No		

New Jersey Right to Know (NJ RTK) This material does not contain reportable chemicals.

Massachusets Right to Know (MA RTK) This material does not contain reportable chemicals.

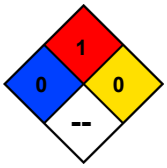
Pennsylavania Right to Know (PA RTK) This material does not contain reportable chemicals.

Rhode Island Right to Know (RI RTK) This material does not contain reportable chemicals.

Section 16 - Other Information

ACGIH	American Conference of Governmental Industrial Hygienists
CFR	Code of Federal Regulations
DOT	United States Department of Transportation
GHS	Globally Harmonized System of Classification and Labeling of Chemicals
NIOSH	National Institute for Occupational Safety and Health
OSHA	Occupational Safety and Health Administration
PEL	Permissible Exposure Limit
RTK	Right-to-Know
SARA	Short-term Exposure Limit
TSCA	Toxic Substances Control Act
WHMIS	Workplace Hazardous Materials Information System

NFPA:		
	HEALTH	**0**
	FLAMMABILITY	**1**
	INSTABILITY	**0**
	SPECIAL	**-**



Disclaimer: This safety data sheet and the information it contains is offered to you in good faith as accurate. We have reviewed any information contained in the data sheet which we have received from outside sources and we believe the information to be correct, but cannot guarantee its accuracy or completeness.
Health and safety precautions in this data sheet may not be adequate for all individuals and/or situations. It is the user's obligation to evaluate and use this product in a safe manner and to comply with all applicable laws and regulations. No statement made in this data sheet shall be construed as permission or recommendation for the use of any product in a manner that might infringe existing patents. No warranty is made, either expressed or implied.

LIMITED WARRANTY

Advanced Lubrication Specialties warrants that it's Sunoco branded lubricants meet or exceed the standards and specifications stated on the product, packaging or product data sheets. In the event the product fails to conform to the warranty, Advanced Lubrication Specialties will pay for reasonable costs of repairs for damages which are caused solely and directly by a breach of warranty. The warranty protects your equipment against lubricant related failure provided the following steps are performed:

- The product was used in accordance with the operating instructions of the manufacturer of the equipment.
- The equipment is used under normal operating conditions and maintained according to the manufacturers recommendations
- The product was changed as specified by the engine or equipment manufacturer maintenance schedule and the proper lubricant level has been maintained in the engine or equipment through documentation of frequency of oil make up.
- Written notice of such failures is provided to Advanced Lubrication Specialties within thirty (30) days of discovery of such failure or damages resulting therefrom. Notice should be sent to:

  V. P. Sales & Marketing
  Advanced Lubrication Specialties
  420 Imperial Court East
  Bensalem, PA 19020

- Advanced lubrication Specialties is provided a sample of the used product from the failed equipment and a sample of the unused product if it is available.
- Documentation that the equipment has been maintained in a preventive maintenance program which meets the equipment manufacturer's recommendations is provided.

Advanced Lubrication Specialties is not responsible for any consequential or indirect damages or losses. The foregoing warranty is exclusive and in lieu of all other warranties, whether written, oral or implied, including but not limited to those of merchantability and fitness for a particular purpose.

SUNOCO VACUUM PUMP OILS

OVERVIEW

SUNOCO VACUUM PUMP OILS are high quality, high boiling range, low vapor pressure oils specifically designed for use in vacuum pump applications. These fluids are mineral based petroleum fluids. They have excellent oxidation resistance and thermal stability as well as low moisture contents and low volatility to insure excellent performance characteristics in high vacuum pump applications.

FEATURES & BENEFITS

SUNOCO VACUUM PUMP OILS are low in volatility, offer good air release and prevent pump cavitation. In addition to promoting rapid water separation and resistance to emulsion formation, SUNOCO VACUUM PUMP OILS provide very good lubrication and wear resistance at startup and during boundary lubrication regimes. Due to their oxidation and thermal stability, SUNOCO VACUUM PUMP OILS promote long oil service life and a minimum of deposit formation.

APPLICATIONS

SUNOCO VACUUM PUMP OILS are recommended for the lubrication of vacuum pumps and are suitable for applications involving absolute pressures from 50 microns of mercury down to the highest vacuum level achieved by commercially available vacuum pumps. They are also suitable for use in pump rings and sealing glands.

SPECIFICATIONS

SUNOCO VP 46 is a lower viscosity vacuum pump oil designed for direct drive vacuum pumps from the following manufacturers, EDWARDS, PRECISION, WELCH, YELLOW.
SUNOCO VP 68 is designed for belt driven vacuum pumps from the following manufacturers; CENCO, WELCH.

TYPICAL PROPERTIES

Product Code	9133	9373
ISO Viscosity Grade	46	68
Viscosity, cSt @ 40°C	45	64
Viscosity, cSt @ 100°C	6.9	8.25
Vicosity Index	109	
CCS Viscosity -10°C mPa/sec	-	2550
CCS Viscosity -25°C mPa/sec	1550	-
Flash Point, °C	204	222
Pour Point, °C	-18	-9
NOACK, wt%	10	8
Vapor Pressure, Torr., @ 100°F	<0.01	<0.01

GMED
GROUPE LNE

ATTESTATION / *CERTIFICATE* **N° 28577 rev. 5**
Délivrée à Paris le 11 février 2019
Issued in Paris on February 11th, 2019

ATTESTATION CE / *EC CERTIFICATE*

Approbation du Système Complet d'assurance Qualité/ *Approval of full Quality Assurance System*
ANNEXE II excluant le point 4 Directive 93/42/CEE relative aux dispositifs médicaux
ANNEX II excluding section 4 Directive 93/42/EEC concerning medical devices
Pour les dispositifs de classe III, un certificat CE de conception est requis
For class III devices, a EC design certificate is required

Fabricant / *Manufacturer*

TECHNOLOGIE MEDICALE
101 rue Vaillant Couturier
93130 NOISY-LE-SEC FRANCE

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

Détendeurs et produits pour l'oxygénothérapie et l'aspiration

Pressure regulators and products for oxygen therapy and suction

Voir détails sur addendum / See attachment for additional information

GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé P181091-1, le système d'assurance qualité - pour la conception, la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe II excluant le point 4 de la Directive 93/42/CEE.

GMED certifies that, on the basis of the results contained in the file referenced P181091-1, the quality system - for design, manufacturing, and final inspection - of medical devices listed here above complies with the requirements of the Directive 93/42/EEC, annex II excluding section 4

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

Début de validité / *Effective date :* **February 11th, 2019 (included)**
Valable jusqu'au / *Expiry date :* **March 11th, 2022 (included)**

GMED SAS GMED SAS

On behalf of the President
Béatrice LYS
Technical Director

GMED_b2p3-F-V0-07-2018

GMED - 28577 rev. 5
Renouvelle le certificat 28577-4

GMED
GROUPE LNE

Addendum au certificat n° 28577 rev. 5 **page 1/1**
Addendum of the certificate n° 28577 rev. 5
Dossier / *File* N° P181091-1

Identification des dispositifs / *Identification of devices*

Désignation du dispositif / Accessoires marqués CE *Device designation / CE marked accessories*	**Réf commerciale du dispositif ou code article** *Device commercial reference or article code*	**Classe du DM** *MD class*
Détendeurs et produits pour l'oxygénothérapie et l'aspiration *Pressure regulators and products for oxygen therapy and suction*	**Switch et Flow-Switch** / *Switch and Flow-switch* **Rampe et Dédoubleur de prise** / *Ambulance panel and Y connector* **Flexible** / *Hosepipes* **Robinet direct** / *Direct valve* **RTM3** / *RTM3* **RVTM3** / *RVTM3* **Soupape de Jeanneret** / *Water manometer* **Vanne de vide** / *Direct vacuum valve* **Vanne de vide Australie** / *Direct vacuum valve (Australia)* **Venturi TM2** / *Venturi TM2* **Debflo et Debplus** / *Debflo and Debplus* **Debson TM2** / *Debson TM2* **Humidificateur** / *Humidifier*	**IIa**
	DetregTM / *DetregTM* **Minireg** / *Minireg* **RegflowTM** / *RegflowTM* **RegsonTM2** / *RegsonTM2*	**IIb**

Identification du site couvert et des activités
Identification of location and activities

TECHNOLOGIE MEDICALE – 101 rue Vaillant Couturier – 93130 NOISY-LE-SEC – FRANCE
Conception, fabrication et contrôle final
Design, manufacture and final control

GMED 0459

On behalf of the President
Béatrice LYS
Technical Director

Certificat de Conformitate si Calitate

Noi, Atlas Copco Romania SRL,
Sos. Bucuresti – Ploiesti, nr. 135, sector 1, Bucuresti.

Declaram pe propria raspundere ca produsele la care declaratia face referire sunt proiectate, produse si testate in conformitate cu prevederile aplicabile ale directivelor si standardelor:

1. Directive

89/392/EEC/,91/368/EEC,93/44/EEC,93/68/EEC:	echipamente
87/404/EEC,90/488/EEC,93/68/EEC:	echipamente sub presiune
89/336/EEC,89/68/EEC:	compatibilitate electro-magnetica
73/23/EEC,89/68/EEC:	joasa tensiune

2. Standarde EN

EN 292:	Siguranta echipamentelor
EN 1012-1	Compresoare si pompe de vid: masuri de siguranta
EN 60 204-1	Instalatiile electrice ale echipamentelor
EN 60439-1	Aparatura comanda pentru tensiune joasa
EN 286-1	Vase sub presiune simple
Pr EN 294	Siguranta echipamentelor; distanta de siguranta
Pr EN 1034	Siguranta echipamentelor; izolatia si pierderea de energie
Pr EN 1050	Siguranta echipamentelor; evaluarea riscului
Pr EN 983	Cerintele de siguranta pentru sisteme hidraulice si componentele lor pneumatice
Pr En 12189-1	Evaluarea si reducerea riscului rezultat in urma emisiei de radiatii a echipamentului

3. Standarde internationale

IEC 34,IEC 38,IEC 72,IEC 85	Motoare electrice
IEC 364-4	Instalatii electrice
IEC 364-5-523	Cablaje

Atlas Copco Romania SRL ,

Atlas Copco Romania

Atlas Copco Romania SRL	Visitors address:	Telephone:	+40 21 352 36 23	Reg. No: J40/8495/2010
Sos. Bucuresti-Ploiesti,	Sos. Bucuresti-Ploiesti,	Telefax:	+40 21 351 37 64	VAT no: R17479588
nr.135,Corp1,et1,Sector 1,Bucuresti	nr.135,Corp1,et1			IBAN:RO14INGB0001008165048910
Romania	Sector 1,Bucuresti	www.atlascopco.com		ING Bank Bucharest- Central

1. **DECLARATIE DE CONFORMITATE CE**

2 Noi, Atlas Copco Airpower n.v., declaram pe proprie raspundere, ca produsul

3 Numele echipamentului: **Filtru de aer**

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

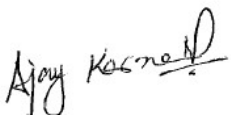
5 Seria echipamentului: **N/A**

6 ce cade sub incidenta articolului 12.2 a al Directivei CE 2006/42/CE, respecta Cerintele de Siguranta si pe cele Fundamentale pentru Sanatate ale Directivei Consiliului anterior mentionat, si amendamentele pentru armonizarea legislatiei Statelor Membre referitoare la Agregate.

7 Echipamentul este conform cu cerintele directivelor si a amendamentelor :

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

8 Standardele tehnice folosite sunt mentionate in atasament

9	**Conformitatea specificatiilor**		**Conformitatea produsului**
10	**cu directivele**		**cu specificatiile**
11			
12	Emitent	Product engineering	Fabricant
14	Nume	Yves Goister	Ajay Karnail
15	Semnatura		
16	Data	26/04/2018	

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

For info, please contact your local Atlas Copco representative

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

Lloyd's Register

Current issue date:	2 September 2020	Original approval(s):
Expiry date:	31 December 2022	ISO 14001 - 1 January 2005
Certificate identity number:	10294956	ISO 45001 - 11 September 2007
		ISO 9001 - 9 December 2002

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

UKAS MANAGEMENT SYSTEMS
001

Certificate identity number: 10294956

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.

UKAS MANAGEMENT SYSTEMS
001

Issued by: Lloyd's Register EMEA, Jan Van Gentstraat 7 (bus 202) 2000 Antwerp Belgium for and on behalf of: Lloyd's Register Quality Assurance Limited, 1 Trinity Park, Bickenhill Lane, Birmingham B37 7ES, United Kingdom

Certificate identity number: 10294956

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.

UKAS MANAGEMENT SYSTEMS
001

Issued by: Lloyd's Register EMEA, Jan Van Gentstraat 7 (bus 202) 2000 Antwerp Belgium for and on behalf of: Lloyd's Register Quality Assurance Limited, 1 Trinity Park, Bickenhill Lane, Birmingham B37 7ES, United Kingdom

Certificate identity number: 10294956

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.

UKAS MANAGEMENT SYSTEMS
001

Issued by: Lloyd's Register EMEA, Jan Van Gentstraat 7 (bus 202) 2000 Antwerp Belgium for and on behalf of: Lloyd's Register Quality Assurance Limited, 1 Trinity Park, Bickenhill Lane, Birmingham B37 7ES, United Kingdom

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

Management Service

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 Druckluftechnik, 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

DAkkS Deutsche Akkreditierungsstelle D-ZM-14143-01-00

TÜV SÜD Management Service GmbH • Zertifizierungsstelle • Ridlerstraße 65 • 80339 München • Germany

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**

Zertifizierung-Nr.: **205372**

Datum der Rezertifizierung: **25.04.2018**

Gültig bis: **24.04.2021**

Umwelt-Management-System ÖKOZERT DIN EN ISO 14001

ÖKO - ZERT Gerhard Dischke

AKKREDITIERT DURCH EURAS

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

CERTIFICATE

EN ISO 14001

ÖKOZERT

certifies that the company

BlitzRotary GmbH

D-78199 Bräunlingen

Re the area of applicability:

Development, production and sales of compressed air technology, vehicle lifting technology, tire inflation technology, measurement technology, battery service technology, special toolsComplete company

has established and applies a environment system according to

EN ISO 14001:2015

The proof was furnished by certification audit and written in report - no.**ÖK 180425po1**

Date of the first certification: **2014-08-27**

Date of the recertification: **2018-04-25**

Registrations-no.: **205372**

Valid until: **2021-04-24**

Umwelt-Management-System ÖKOZERT DIN EN ISO 14001

ÖKO - ZERT Gerhard Dischke

ACCREDITED THROUGH EURAS

D-72766 Reutlingen • Grüner Weg 60 • Tel 0049 7121 263 94 53