



Chaussée de Vilvorde, 156
Vilvoordsesteenweg 156
B-1120 Bruxelles/Brussel
Tel.: 32 (0)2 264 03 60
Fax: 32 (0)2 268 89 58
<http://www.apragaz.com>
info@apragaz.com

Certificate N°: 07/DK/1281-3-Rev.0

APRAGAZ certifies that the Quality System developed by :

OXYMAT SLOVAKIA s.r.o.
part of
OXYMAT A/S

for the following activities :

Design, manufacture, service and market of oxygen and nitrogen PSA generators sold for appliances such as medical appliances, aquaculture, ozone generation, marine, fire and explosion safety systems...

carried out at the following location:

Vadovce, 87
SK – 91613 VADOVCE
SLOVAKIA

has been assessed and found to perform to the requirements of the standard :

ISO 9001:2008

Under the condition the quality system of the company is working satisfactorily,
this certificate is valid for a three years period until :

03/11/2019

Date of issue : 07/11/2016

The General Manager

on behalf of the company

Ch. Leplat, ir





APRAGAZ

Quality Assurance

Member of
CEOC
INTERNATIONAL

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Certificate N°: 07/SK/1282-3-Rev.0

APRAGAZ certifies that the Quality System developed by :

OXYMAT – SLOVAKIA s.r.o.
part of
OXYMAT A/S

for the following activities :

Design, manufacture, service and market of oxygen PSA generators , line assembly and filling ramps sold for medical appliances

carried out at the following location:

Vadovce, 87
SK – 91613 VADOVCE
SLOVAKIA

has been assessed and found to perform to the requirements of the standard :

ISO 13485:2012

(with exclusion of the following items: 7.5.1.2.1 a) b) and c), 7.5.1.3., 7.5.2.2, 7.5.3.2.2 and 8.2.4.2.)

Under the condition the quality system of the company is working satisfactorily,
this certificate is valid for a three years period until :

03/11/2019

Date of issue : 07/11/2016

The General Manager

on behalf of the company

Ch. Leplat, ir





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Certificate N°: 11/SK/2424-2-Rev. 0

APRAGAZ certifies that the Management System developed by :

OXYMAT SLOVAKIA s.r.o., part of OXYMAT A/S

for the following activities :

Design, manufacture, service and market of oxygen and nitrogen PSA generators sold for medical appliances, aquaculture, ozone generation, marine, fire and explosion safety systems.

carried out at the following locations:

**Vadovce, 87
SK – 91613 VADOVCE
SLOVAKIA**

has been assessed and found to perform to the requirements of the standard :

ISO 14001:2004 + AC 2009

Original Certification date : 04/04/2011

Under the condition the Environmental Management of the company is working satisfactorily,
this certificate is valid for a three years period until :

01/06/2017

Date of issue : 02/06/2014

The General Manager

on behalf of the company

Ch. Leplat, ir





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APRAGAZ certifies that the Management System developed by :

OXYMAT SLOVAKIA s.r.o., part of OXYMAT A/S

for the following activities :

Design, manufacture, service and market of oxygen and nitrogen PSA generators sold for medical appliances, aquaculture, ozone generation, marine, fire and explosion safety systems.

carried out at the following locations:

**Vadovce, 87
SK – 91613 VADOVCE
SLOVAKIA**

has been assessed and found to perform to the requirements of the standard :

OHSAS 18001: 2007

Original Certification date : 13/04/2015


Under the condition the Safety Management System of the company is working satisfactorily,
this certificate is valid for a three years period until :

12/04/2018

Date of issue : 13/04/2015

The General Manager

on behalf of the company


Ch. Leplat, ir



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CERTIFICATE OF CONFORMITY In accordance with module B of the Pressure Equipment Directive 2014/68/EU: EU TYPE EXAMINATION - PRODUCTION TYPE		Certificate N° 16/DK/3934-1-REV 0 Page 1/2
Manufacturer	Name	OXYMAT A/S
	Address	Fasanvej 18-20 DK – 3200 Helsingø DANEMARK
Manufacturing Location	Name	OXYMAT SLOVAKIA s.r.o
	Address	Vadovce 87 SK – 91613 Vadovce SLOVAKIA
Description: See Annex Equipment:/ Assembly: Yes Module: B		
Drawing Numbers: See Technical Files		
Maximum Allowable Pressure (PS): 10.5 barg (product buffer)/230 barg (filling ramp) NB: N2 filling ramp not covered by this module B		
Min/Max Allowable Temperature (TS): See files		
Safety valves		
Capacity: Various/See files		
Set pressure: Various/See files		
Hydrostatic Test		
Test Pressure (PT) /		
The undersigned certifies that the design of this Pressure Equipment conforms to the requirements of the Directive 2014/68/EU on the basis of the information supplied. The manufacturer is allowed to affix the "CE" mark followed with our notified body identification number 0029 to the approved equipment in the conditions described in the Directive.		
Date : 07/11/2016	Name : Ch. Leplat	Position General Manager
Notified body identification number :	0029	Signature
Notified body stamp :	APRAGAZ Belgium Inspecting Authority	
Notified body reference :	P17034-002/P8052 PED1 to PED6/P14967 1&2 – P17034-001 /P16158-001	



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CERTIFICATE OF CONFORMITY In accordance with module B of the Pressure Equipment Directive 2014/68/EU: EU TYPE EXAMINATION - PRODUCTION TYPE		Certificate N° 16/DK/3934-1-REV 0 Page 2/2
Manufacturer	Name	OXYMAT A/S
	Address	Fasanvej 18-20 DK – 3200 Helsingø DANEMARK
Manufacturing Location	Name	OXYMAT SLOVAKIA s.r.o
	Address	Vadovce 87 SK – 91613 Vadovce SLOVAKIA
<u>Concerned Equipment</u>		<u>Date of Validity</u>
<u>Nitrogen PSA:</u> N10, N20, N40, N70, N100, N190, N280, N430, N640, N880, N1250, N1500		06/06/2026
<u>Nitrogen PSA X version:</u> N280 X2, N430 X2, N640 X2, N880 X2, N1250 X2, N1500 X2, N1250 X3, N1500 X3, N1250 X4, N1500 X4, N1250 X5, N1500 X5		06/06/2026
<u>Nitrogen PSA Marine X Versions:</u> N40X2 MARINE, N60X2 MARINE, N70X2 MARINE, N100X2 MARINE, N190X2 MARINE, N280X2 MARINE, N430X2 MARINE, N640X2 MARINE, N880X2 MARINE, N1250X2 MARINE, N1250X3 MARINE, N1250X4 MARINE, N1500X2 MARINE, N1500X3 MARINE, N1500X4 MARINE,		04/08/2023
<u>Oxygen PSA:</u> O10, O20, O40, O60, O70, O100, O190, O280, O430, O640, O880, O1250, O1500		06/06/2026
<u>Oxygen PSA X versions:</u> O880 X2, O1250 X2, O1500 X2, O1250 X3, O1500 X3, O1250 X4, O1500 X4, O1250 X5, O1500 X5		06/06/2026
<u>Nitrogen purifier OPAS 1000</u>		16/07/2024
Date : 07/11/2016	Name : Ch. Leplat	Position General Manager
Notified body identification number :	0029	Signature
Notified body stamp :	APRAGAZ Belgium Inspecting Authority	
Notified body reference :	P17034-002/P8052 PED1 to PED6 /P14967 1&2 – P17034-001 /P16158-001	



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CERTIFICATE OF CONFORMITY		Certificate N° 07/DK/1179-5-REV 0
In accordance with module D of the Pressure Equipment Directive 2014/68/EU:		
CONFORMITY TO TYPE BASED ON QUALITY ASSURANCE OF THE PRODUCTION PROCESS		
Manufacturer	Name	OXYMAT A/S
	Address	Fasanvej 18-20 DK – 3200 Helsingø DANEMARK
Manufacturing Location	Name	OXYMAT SLOVAKIA s.r.o
	Address	Vadovce 87 SK – 91613 Vadovce SLOVAKIA
<p>Concerned Equipment : Nitrogen/Oxygen concentrators (PSA) covered by Module B (EU Type Examination – Production Type) Certificate N° : 16/DK/3934</p>		
<p>This is to certify that the Quality Management System of the above mentioned manufacturer has been assessed against the requirements of Module D of the Pressure Equipment Directive 2014/68/EU and conforms to the requirements for the equipment shown above. The approval is subject to the continued maintenance of the Quality Management System in accordance with the requirements of the above Directive. This shall be controlled by intermediate audits, inspections and surveys.</p>		
<p>The manufacturer is allowed to affix the “CE” mark followed with our notified body identification number 0029 to the approved equipment in the conditions described in the Directive.</p> <p>The approval is valid until 03/11/2019</p>		
Date : 07/11/2016	Name : Ch. Leplat	Position General Manager
Notified body identification number :	0029	Signature 
Notified body stamp :	APRAGAZ Belgium Inspecting Authority	
Notified body reference :	P8052/000	

EC Certificate

Full Quality Assurance System

Certificate No.:
9887-2017-CE-CZS-NA-PS 0.0

Project No.:
PRJC-543801-2016-PRC-SVK

Valid until:
18.04.2022

This is to certify that the quality system of:

OXYMAT – Slovakia, s.r.o.

Vaňovce 87, 916 13, Vaňovce, Slovakia (Slovak Republic)

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

Oxygen Generator and Filling Systems

Has been assessed with respect to:

The conformity assessment procedure described in Article 11.3.a and Annex II excluding section 4 (Module H) 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, 18 April 2017



For:
DNV GL NEMKO PRESAFE AS



Mariann Jeremiassen
Certification Manager

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.

EC Certificate

Full Quality Assurance System

Certificate No.:
9887-2017-CE-CZS-NA-PS 0.0

Project No.:
PRJC-543801-2016-PRC-SVK

Valid until:
18.04.2022

Jurisdiction

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

Certificate history:

Revision	Description	Issue Date
0.0	Original Certificate	2017-04-18

Products covered by this Certificate:

Product Description	Product Name	Class
PSA Oxygen generator	O10, O20, O40, O60, O70, O100, O190, O280, O430, O640, O880, O1250, O1500	IIb
PSA Oxygen generator X version	O880 X2, O1250 X2, O1500 X2	IIb
Oxygen filling systems	OFS I (4 cylinders), OFS II/OFS III (6 cylinders), OFS V (10 cylinders)	IIb

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Oxymat Slovakia, s.r.o., Vaďovce 87, 916 13 Vaďovce, Slovak Republic

EC Certificate

Full Quality Assurance System

Certificate No.:
9887-2017-CE-CZS-NA-PS 0.0

Project No.:
PRJC-543801-2016-PRC-SVK

Valid until:
18.04.2022

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