



MEDICAL HIGH PRESSURE REGULATORS

MEDISELECT[®] II

MEDIREG[®] II

MEDISELECT[®]

- Regulator with flow selector
- Rotating pressure gauge which allows convenient reading
- 360° swivelling outlet – it enables better orientation of the nasal cannula or oxygen mask towards the patient (preventing from twisting)
- Innovative self centering flow setting device with continuous flow between settings. In the unlikely event of indent mechanism failure, the patient will still be supplied by medicinal gas
- Lateral and frontal reading of flow settings
- Higher number of flow disc holes increases treatment options. Extra flow setting of 25 l/min on the traditional 15 l/min variant, allows use in resuscitation
- The additional 7 l/min is intended for nebulization



MEDIREG[®]

- Regulator with pressure outlet, constantly adjusted flow or with flowmeter
- Rotating pressure gauge which allows convenient reading.
- Ergonomic and streamlined design
- Easy cleaning surface
- Compact and user friendly

THE ADVANTAGES OF MEDISELECT® II

Rotating pressure gauge which allows convenient reading

Continuous flow between settings, in the unlikely event of mechanism failure

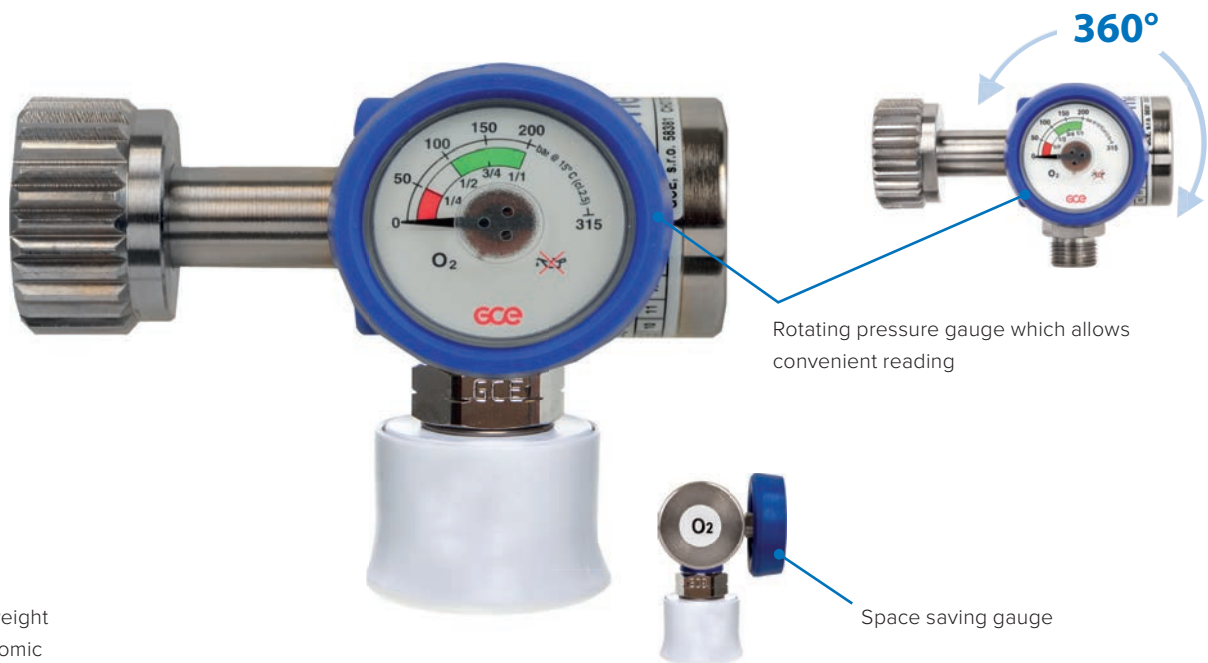


THE ADVANTAGES OF MEDIREG® II

Low weight
Ergonomic
Compact

Rotating pressure gauge which allows convenient reading

Space saving gauge

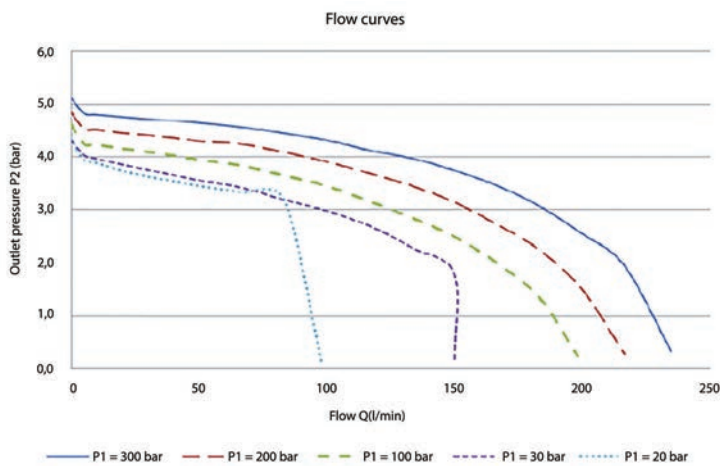


TECHNICAL DATA

Gas:	O ₂ , Air, N ₂ O, CO ₂ , O ₂ /N ₂ O	
Inlet pressure range:	Up to 300 bar	
Nominal outlet pressure:	4 bar	
Flow ranges*:	0 to 2 lpm	0;0,1;0,2;0,3;0,4;0,5;0,6;0,7;0,8;1,1,5;2
	0 to 3 lpm	0, 1/64, 1/32, 1/16, 1/8, 1/4, 1/2, 3/4, 1, 1,5, 2, 3
	0 to 6 lpm	0;0,25;0,5;0,75;1,1,5;2;2,5;3;4;5;6
	0 to 25 lpm	0;1;2;3;4;5;6;7;9;12;15;25
Inlet connection:	According to national standards	
Outlet connection:	9/16 UNF, M12x1,25, G3/8, G1/4 with hose nipple	
Body material:	Nickel-plated brass	
Control knob:	Polyamide	
O-rings:	EPDM	
Filter:	Sintered bronze	
Gauge cover:	TPE (thermoplastic elastomer)	
Regulatory status:	Complies with Medical Devices Directive 93/42/EEC	
	Complies with EN ISO 10524-1 (Pressure regulators for use with medical gases)	
	Complies with EN 1789 (Medical vehicles and their equipment - Road ambulances)	
Classification:	Class IIb	
Manufacturer:	GCE, s.r.o., Žižkova 381, 583 81 Chotěboř, CZ	

* Flowrates expressed at 23°C and 101,3 kPa

FLOW CURVE FOR OXYGEN (P2 = 4 BAR)



REGIONAL OFFICES

EUROPE

CZECH REPUBLIC
FRANCE
GERMANY
HUNGARY
ITALY
POLAND
PORTUGAL
ROMANIA
SPAIN
SWEDEN
UNITED KINGDOM & IRELAND

AMERICA

LATIN AMERICA
MEXICO
USA

ASIA

CHINA
INDIA
RUSSIA



visit: www.gcegroup.com

МЕДИЦИНСКИЕ РЕДУКТОР ВЫСОКОГО
ДАВЛЕНИЯ

MEDISELECT® II MEDIREG® II



ВЫПУСК 1/2016

MEDISELECT®

Регулятор давления и расхода.

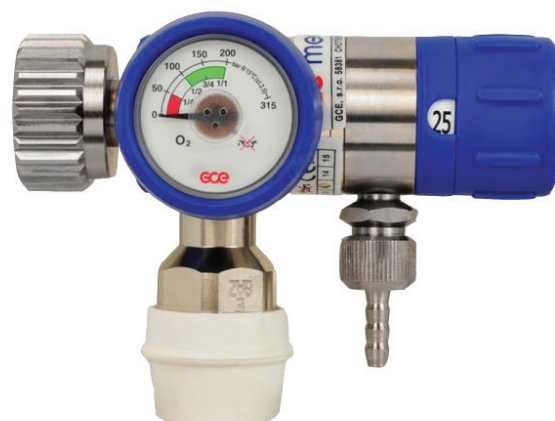
Поворотный манометр позволяет легко контролировать давление газа в баллоне.

Поворотный на 360° выходной штуцер позволяет лучше подсоединить канюлю или маску (позволяет предотвратить скручивание трубочки)

Новое самоцентрирующееся устройство регулятора расхода с плавным расходом в положении между отдельными значениями. В случае повреждения механизма не происходит остановка подачи медицинского газа.

Простота контроля настроенных значений расхода газа – переднее и боковое контрольное окошко.

Большой диапазон расходов увеличивает число способов применения. Значение 25 л/мин. Может использоваться для реанимации, а значение 7 л/мин. предназначено для небулизации

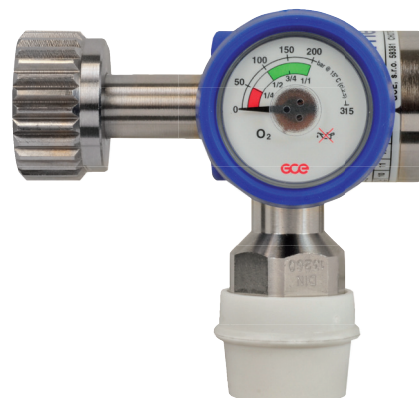


MEDIREG®

Редукционный клапан с предустановленным давлением на выходе.

Поворотный манометр позволяет легко контролировать давление газа в баллоне.

Поворотный на 360° вывод потока позволяет лучше подсоединить канюлю или маску (позволяет предотвратить скручивание трубочки).



ПРИЕМУЩЕСТВА MEDISELECT® II

Поворотный манометр позволяет легко контролировать давление газа в баллоне.

Плавность потока в положении между отдельными значениями. В случае повреждения механизма подача медицинского газа не прекращается.



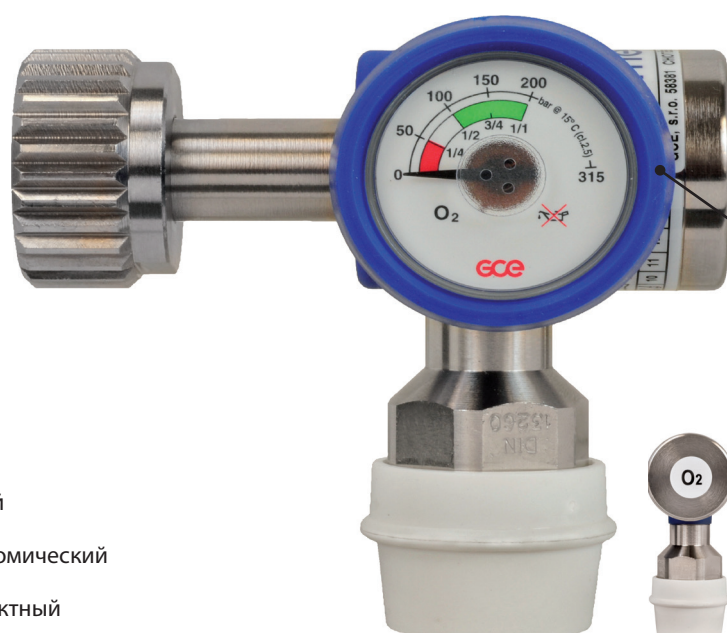
Вывод потока с поворотом на 360° обеспечивает удобное подсоединение

Простота контроля настроенных значений расхода газа – переднее и боковое оконце для считывания

ПРИЕМУЩЕСТВА MEDIREG® II

Поворотный манометр позволяет легко контролировать давление газа в баллоне

Легкий
Эргономический
Компактный

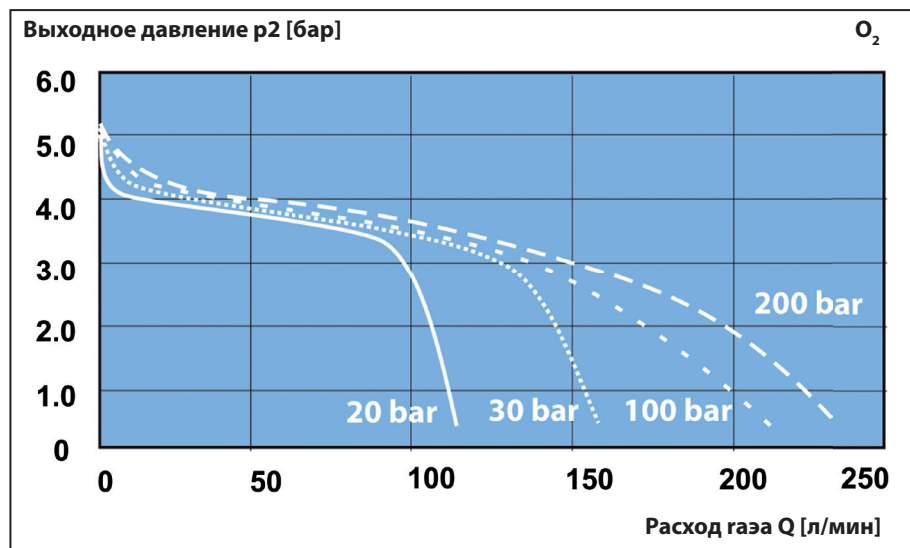


Вывод потока с поворотом на 360° обеспечивает удобное подсоединение

Компактный манометр

ТЕХНИЧЕСКАЯ ИНФОРМАЦИЯ О MEDISELECT® II И MEDIREG® II

FLOW CURVE FOR OXYGEN (P2 = 4 BAR)



ТЕХНИЧЕСКИЕ ДАННЫЕ

Газ:	O ₂ , Воздух, N ₂ O, CO ₂ , O ₂ /N ₂ O
Входное давление:	До 300 бар
Выходное давление:	3,6 - 5,5 бар
Диапазоны расхода*:	
от 0 до 2 л/мин:	0 / 0,1 / 0,2 / 0,3 / 0,4 / 0,5 / 0,6 / 0,7 / 0,8 / 1 / 1,5 / 2
от 0 до 6 л/мин:	0 / 0,25 / 0,5 / 0,75 / 1 / 1,5 / 2 / 2,5 / 3 / 4 / 5 / 6
от 0 до 25 л/мин:	0 / 1 / 2 / 3 / 4 / 5 / 6 / 7 / 9 / 12 / 15 / 25
Входное соединение:	В соответствии с нац. стандартами
Выходное соединение:	9/16 UNF, M12×1,25, G3/8, G1/4 + ниппель рукава
Материал корпуса:	Никелированная латунь
Ручка управления:	Полиамид
Кольцевые зажимы:	Этилен-пропиленовый каучук
Фильтр:	Спечённая бронза
Корпус индикатора давления:	Термопластичный каучук
Соответствие нормам и директивам:	Соответствует Директиве 93/42/ЕЕС о медицинских изделиях
	Соответствует EN ISO 10524-1
	Соответствует EN 1789
	Произведено в соответствии с EN ISO 9001 и EN ISO 13485
Классификация:	Класс IIb

*Расход при 23°C и 101,3 кПа

GCE Group – одна из лидирующих компаний в мире в сфере оборудования для газового контроля. Главный офис располагается в Мальме (Швеция), а два основных снабженческих подразделения – в Европе и Азии. Холдинг управляет 15 дочерними компаниями по всему миру и является работодателем для более чем 900 человек.

GCE Group работает в четырех различных направлениях – оборудование для сварки и резки, промышленное, медицинское оборудование и оборудование для чистых газов. В настоящее время ассортимент продукции компании включает в себя большое количество наименований: от простейших регуляторов давления, газосварочного и газорезательного оборудования до сложнейших систем подачи газов для применения в здравоохранении и в производстве электронных компонентов.



ООО "ГСЕ Красс"

194100, г. Санкт-Петербург, ул. Кантемировская, 12А

129343, Москва, ул. Уржумская, д. 4

Бесплатный номер: 8-800-5000-423,

e-mail: officespb@gcegroup.com

www.gcegroup.com

russia.gcegroup.com



Gas Control Equipment



EC CERTIFICATE

Full Quality Assurance System

Certificate No.:

10401-2017-CE-CZ0-NA-PS Rev. 6.0

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:
Havik, 16 March 2021



For the issuing office:
Notified Body 2480
DNV Product Assurance AS

Sholeh Ghelssar

Sholeh Ghelssar
Principal assessor

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

NOTIFIED BODY 2480: DNV Product Assurance AS, Veitavæien 5, 1365 Havik, Norway, Tel +47 87 87 88 00, www.dnv.com

ICP-4-S-11-MDD-02, rev. 0



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

Cecilie Gudesen Torp

Cecilie Gudesen Torp
Management 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

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

Valid Until:
27 May 2024

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