Intrebati

Pentru mai multe detalii despre acest produs, contactati echipa de vanzari din regiune.

Cautare Produs
Apasati pentru a mari

Client Inregistrat?
Suport Tehnic si post-vanzare

MEDISELECT® II

Cod produs: 3211

Vizualizati mai multe imagini

Regulator de presiune pentru utilizarea cu butelii de gaze medicale prevazute cu robinet de butelie medical.

- Regulator cu selector de debit. Manometru de presiune rotativ care permite intotdeauna o citire confortabila
- Iesirea cu posibilitatea rotatiei la 360° – asigura o orientare mai buna catre canula nazala sau masca de oxigen inspre pacient, prevenind indoirea sau rasucirea furtunului
- Dispozitiv inovator de setare a debitului cu o curgere continua intre setari. In cazul putin probabil al deteriorarii mecanismului zimtat, pacientul va fi aprovizionat in continuare cu gaz medical.
- Citirea setarilor de debit laterala si frontala
- Numarul marit de orificii in discul de debit creste numarul optiunilor de tratament. Posibilitatea setarii la
  25 l/min, spre deosebire de variant traditionala cu 15 l/min variant, permite folosirea in resuscitari.
- Cei 7 l/min aditionali sunt destinati pentru nebulizare.

DATE TEHNICE

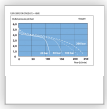
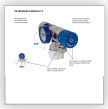
Gaz:	O_2, Aer, N_2O, CO_2, O_2/N_2O
Presiune intrare:	Pana la 300 bar
Presiune iesire:	3,6 - 5,5 bar
Gama de presiune*:	
de la 0 la 2 l/min:	0/ 0,1 / 0,2 / 0,3 / 0,4 / 0,5 / 0,6 / 0,7 / 0,8 / 1 / 1,5 / 2
de la 0 la 6 l/min:	0/ 0,25 / 0,5 / 0,75 / 1 / 1,5 / 2 / 2,5 / 3 / 4 / 5 / 6
de la 0 la 25 l/min:	0 / 1 / 2 / 3 / 4 / 5 / 6 / 7 / 9 / 12 / 15 / 25
Conexiune intrare:	In concordanta cu standardele nationale
Conexiune iesire:	9/16 UNF, M12×1,25, G3/8, G1/4 + stut furtun
Materialul corpului:	Alama nichelata
Robinetul de control:	Poliamida
Garnituri:	EPDM
Filtru:	Bronz sinterizat
Aparatoarea manometrului:	TPE (elastomer termoplastic)
Reglementari:	In conformitate cu Directiva Dispozitivelor Medicale 93/42/EEC In conformitate cu EN ISO 10524-1 In conformitate cu EN 1789 Produs in concordanta cu EN ISO 9001 si EN ISO 13485
Clasificare:	Clasa IIb

* Debitele sunt valabile la 23°C si 101,3 kPa

Informatii tehnice

Sus

Descarcati informatiile tehnice

Descarcarile

Sus

Informatii suplimentare pentru acest produs

EU DECLARATION OF CONFORMITY

Certificate Number:	*ZP 03-006 High Pressure Regulators_09-01*
Manufacturers Name:	GCE, s.r.o.
Manufacturers Address:	Žižkova 381, 583 01 Chotěboř, Czech Republic
SRN (Single Registration Number):	003172 RZPRO
Product Group:	*High Pressure Regulators*
Name of the Device (s):	**MEDISELECT**
Product code:	7114
Risk Classification:	IIb
GMDN code:	43438
Other used standards:	**EN ISO 10524-1:2018**
Notified Body name:	DNV Product Assurance AS
Notified Body Address:	Veritasveien 3, N-1363 Høvik, Norway
Notified Body Identification number:	2460
EC Certificate Number:	10401-2017-CE-CZS-NA-PS

Conformity assessment route:

This declaration of conformity is issued under the sole responsibility of GCE, s.r.o. We hereby declare that he medical device(s) specified above meet the provision of the Regulation MDD 93/42/EEC for medical devices. This declaration is supported by the Quality System approval to ISO 13485:2016 issued by DNV Product Assurance AS.

The product is in accordance with Annex II (excluding section 4) of the MDD 93/42/EEC and is safe for declared purpose of use under standard conditions. Any modification to the product, not authorized by us, will invalidate this declaration.

All supporting documentation is retained at the premises of the manufacturer.

Signature: Place and date (dd.mm.yyyy) of issue:

Ing. Tereza Šnapková
Digitálně podepsal Ing. Tereza Šnapková
Datum: 2021.05.28 13:47:05 +02'00'

……. ……Chotěboř

Tereza Šnapková

Regulatory Specialist, On behalf of Tomáš Janeček, managing director.

Note: List of variants is in attachment of this docoment.

EC Certificate
Full Quality Assurance System

A DNV GL & NEMKO COMPANY

Certificate No.:	Project No.:	Valid Until:
10401-2017-CE-CZS-NA-PS Rev. 0.0	**PRJC-189266-2009-PRC-CZE**	**30 MARCH 2020**

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 Article 11.3.a and Annex II excluding section 4 (Module H2) 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, 1 November 2017

NORWEGIAN ACCREDITATION
PROD 021
Notified Body No.: 2460

For:
DNV GL-NEMKO PRESAFE AS

Alessandra Rinna

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.: **10401-2017-CE-CZS-NA-PS Rev. 0.0**
Project No.: **PRJC-189266-2009-PRC-CZE**
Valid Until: **30 MARCH 2020**

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	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

Products covered by this Certificate:

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

The complete list of devices is filed with the Notified Body

EC Certificate
Full Quality Assurance System

A DNV GL & NEMKO COMPANY

Certificate No.:	Project No.:	Valid Until:
10401-2017-CE-CZS-NA-PS Rev. 0.0	**PRJC-189266-2009-PRC-CZE**	**30 MARCH 2020**

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