Gas Control Equipment

Intrebati

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

Client Inregistrat?
Suport Tehnic si post-vanzare

MEDIREG® II

Cod produs: 3221

Whole medical range is available on gcehealthcare.com

NOUA GENERATIE DE REGULATOARE DE INALTA PRESIUNE MEDICALE

- Regulator cu debitul de iesire reglat constant sau cu debitmetru
- Manometru de presiune rotativ care permite intotdeauna o citire confortabila
- Design ergonomic
- Suprafata usor de curatat
- Compact si usor de folosit

735100000403 MediReg II leaflet RO

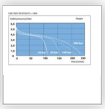
DATE TEHNICE

Gaz:	O_2, Aer, N_2O, CO_2, O_2/N_2O, Xe, Ar
Presiune intrare:	Pana la300 bar
Presiune iesire:	4 bar
Racord intrare:	conform standardelor nationale
Pressure outlet:	DIN, AFNOR, SS, CZ etc.
Material corp:	Alama nichelata
Buton control:	Poliamida
Garnituri O:	EPDM
Filtru:	Bronz sinterizat
Protectie manometru:	TPE (elastomer termoplastic)
Certificare regulatoare:	Conform cu Medical Devices Directive 93/42/EEC Conform cu EN 10524-1 (Regulatoare de presiune pentru utilizarea gazelor medicale) Conform cu Standard EN 1789:2000 (Vehicule medicale si echipamentele lor – Ambulante rutiere)
Clasificare:	Clasa IIb
Producător:	GCE, s.r.o, Žižkova 381, 583 81 Chotěboř, CZ

Informatii tehnice

Sus

Descarcati informatiile tehnice




Produse similare

Sus

EU DECLARATION OF CONFORMITY

Certificate Number:	*ZP 03-006 High Pressure Regulators_09-07*
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):	**MEDIREG II**
Product code:	7085
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 13:44:08 +02'00'

…… ……Chotěboř

Tereza Šnapková

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

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

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**

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

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