Gas Control Equipment

PREMIUM CYLINDER REGULATOR SERIES

ProControl®

"We challenged our skilled engineers to develop follower of our top-seller Dincontrol which has been presented in the market already for 18 years and has become a leader among the premium cylinder regulators in terms of ***Accuracy, Safety,*** *and* ***Reliability.*** *We made a few modifications to ensure keeping the focus on these three main features. From customer feedback, we have seen the weakest part of the regulator has been the gauges. We are now adding* ***Durability*** *to the features of GCE ProControl® by* ***protecting the gauges*** *to minimise the risk of breakdown and user productivity interruption. The investment in gauge protection is paid back in a very short time."*

GCE Team

HIGHLY DURABLE REGULATOR

Mechanical damages are the most frequent and most costly reason for regulator failure. It happens usually during transport of the installed oxy-fuel sets, during cylinder exchange or when transporting heavy parts and constructions on the cranes in the welding areas. The improved, robust gauge protection minimizes production breaks, service, and replacement cost and saves the gas leaking through broken gauges.

HIGH OPERATION SAFETY

GCE ProControl® has been designed for use with all common technical gases up to 300bar cylinder pressure. All safety-related specifics of the oxygen and flammable gases, as well as high-pressure hazards, have been considered in product design. It has passed a full set of type tests conforming to ISO 2503. The product safety has been also proven by long-term field test with selected users making various applications.

PRECISE ADJUSTMENT

Gas pressure and flow accuracy are the main parameters which the user requires from the pressure regulator. But GCE ProControl® users do not need to know that. They just use the gas for the application they are working with.

ERGONOMIC DESIGN

9 of 10 users have confirmed they like to work with GCE ProControl®. When fitted on the cylinder valve the position of the pressure adjusting mechanism makes setting easy. Outlet shut-off valve in the right position gives the chance to switch off the gas flow without depressurising the regulator. This also increases the lifetime of the internal parts and saves cost with operation breakdowns and related services. Pressure gauges with three main unit high-contrast scales allow reading the set value also in difficult light conditions. The Instruction for Use can be scanned from the QR code present on the product label during all its lifetime.

SUITS TO APPLICATION

GCE ProControl® fits users of common technical gases because product variants specific for all markets, gases, and pressures are available.

GCE ProControl®

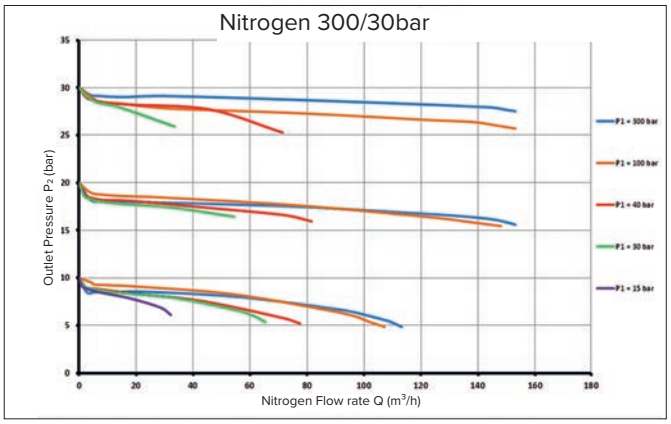
FEATURES

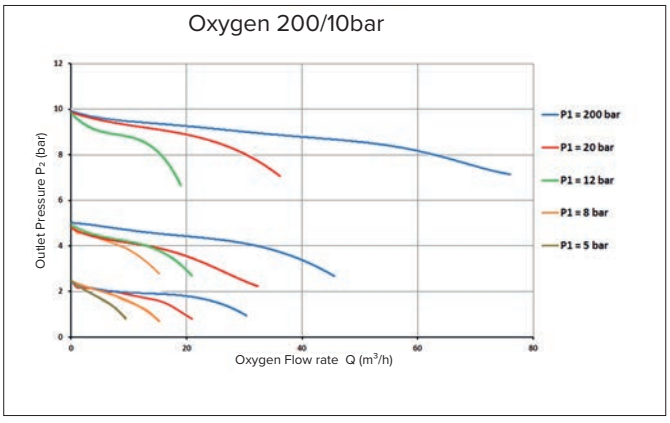
- **High-performance** regulator following all common technical gas applications needs
- **Safety** focused design following ISO 2503
- **Robust** rubber gauge **protection** with back lid preventing damages and impurities
- Prolonged lifetime **saving costs** related to services, spares, and replacements
- Encapsulated regulating technology for **precise** parameters **stability**
- Easy handling for the operator by **ergonomic** arrangement
- Three scale pressure gauges acc. to ISO 5171 with high contrast pointer for **better** gas pressure **clarity**

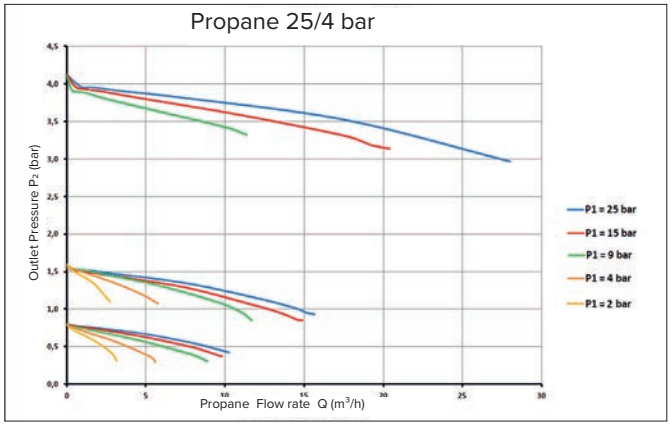
TECHNICAL DATA

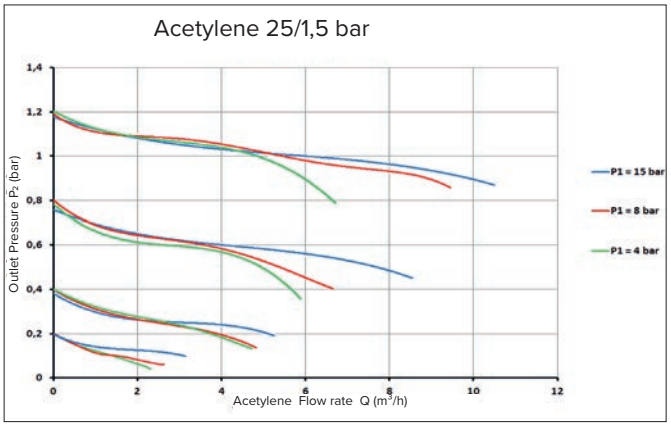
Gas	O_2, N_2, H_2, He	Ar, Ar/CO_2, F. G. *	CO_2	Acetylene	Propane
Body	Brass forged				
Bonnet	Zn/Al alloy Die Cast				
Stems, nuts and fittings	Brass				
Diaphragm	EPDM				NBR
Seat sealing	PA			CR	
Inlet/ Outlet connection	Gas specific connection				
Maximal inlet pressure	200 or 300 bar		200 bar	25 bar	
Outlet pressure/ flow range	0-10 bar	0-16l/min 0-24l/min 0-30l/min F. G. : 0-50 l/min		1,5 bar	4 bar
	0-20 bar				
	0-30 bar				
	0-50 bar				
Temperature range	From -20°C to 60°C				
Weight	Approx. according to gas variant: 1,9 kg				
Pressure relief valve	Used in all variants				

** F.G. ... Forming gas*

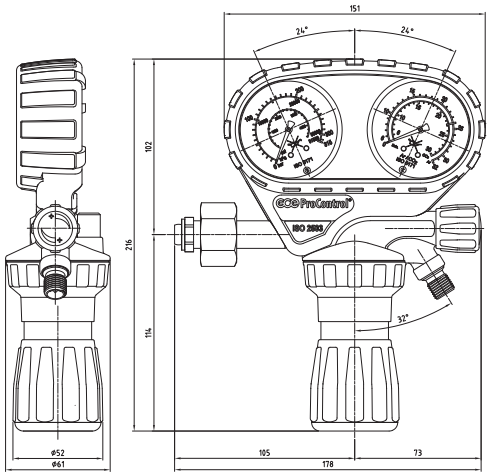








ECE ProControl®



Pressure gauges are precise measuring instruments. They are the most sensitive regulator components exposed fully to the industrial environment. Robust rubber cap gives optimal protection against potentially rough handling. ***Consumption of the spare pressure gauges is three times lower*** *in the markets where using gauge protections is a common habit already today, compared to markets with not protected regulators. The savings are even more significant if customer changes regulator completely.*

- *Increased product lifetime and operation safety*
- *Decreased operation shutdowns and gas lost and safety risk when leaking through damaged gauges.*

Exact gas pressure measurement. Easy reading of the gas parameters with a three-unit scale and contrast pointer.

The back lid closes the rubber protection cap to eliminate dust and other impurities.

Outlet shut- off valve for contemporary operation breaks.

On-line instructions for use directly on the body stay available for entire regulator lifetime.

Stabile gas outlet pressure and optimal flow performance for the gas application. Encapsulated regulating valve technology.

Accurate parameter setting with an optimized pressure adjusting mechanism.

Protection against humidity for the toughest conditions.

Safe operation with pre-adjusted pressure relief valve.

Ergonomic handwheel for easier handling.

GCE Group
www.gcegroup.com

Gas Control Equipment

EU Quality Management System Certificate

Certificate no.:	Initial certification date:	Valid Until:
C671184	18 April 2024	18 April 2029

This is to certify that the quality system of

GCE, s.r.o.

Žižkova 381
583 01 Chotěboř
Czech Republic

SRN: CZ-MF-000019708

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

Pressure Regulator Integrated with Cylinder Valve

Has been assessed and found to comply with respect to:

The conformity assessment procedure described in Annex IX, (Chapter I & III) of Regulation (EU) 2017/745 on Medical Devices

Place and date:
Høvik, 18 April 2024

For the issuing office:
DNV Product Assurance AS – Notified Body 2460
Veritasveien 1, 1363 Høvik, Norway

Sholeh Gheissar

Sholeh Gheissar
Management Representative

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

NOTIFIED BODY 2460: DNV Product Assurance AS, Veritasveien 1, 1363 Høvik, Norway, Tel +47 67 57 88 00, www.dnv.com

MCR-CO-078-A V0.5

Certificate no.: C671184
Place and date: Høvik,18 April 2024

Jurisdiction

Application of Regulation 2017/745 on medical devices, adopted as “Forskrift om Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Report No.	Issue Date
0.0	Original Certificate	2927737	18 April 2024

Products covered by this Certificate:

Product Description (and intended purpose for class IIb	Product Name	Class*
Pressure regulators integrated with cylinder valves (so called medical combination valves) are designed to be fitted to gas cylinders used for medical gases up to 300 bar. Medical combination valves are used to reduce high cylinder pressure to lower pressure or to specific outlet flow suitable for the administration of medical gases in the treatment of patients.	MediVital, MediVital E, MediVitop, Ministar 2	IIb

* Class III and class IIb devices referred to in the second subparagraph of Article 52(4): Technical documentation assessment is covered by a separate EU Technical Documentation Assessment Certificate No.: NA

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 the Notified Body of any intended updating of the quality system and the Notified Body 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. Notified Body reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.
- For the class III devices covered this certificate is dependent on the continued validity of the EU Technical Documentation Assessment Certificate, covering the devices.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window

Specific conditions - Class I devices, Systems and Procedure Packs:

- For class I device being placed on the market in a sterile condition, Class I devices with a measurement function and class I devices being reusable surgical instruments covered by this certificate the audit by the notified body of the quality management system was limited to the aspects required under article 52(7) of the regulation.
- For system and procedure packs being placed on the market in a sterile condition, covered by this certificate the audit by the notified body of the quality management system was limited to the aspects required under article 22(3) of the regulation.
- For Custom Made Class III implantable device the certification only relates to the Quality management system. Technical documentation assessment and issuance of EU Technical Documentation Assessment Certificate does not apply.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EU declaration of conformity and legally affix the CE mark followed by the Notified Body identification number.

APPENDIX TO EC CERTIFICATE

Appendix to Certificate no.:
10000321467-PA-NA-CZE Rev.2.0

Valid Until:
27 May 2024

This is an Appendix issued to EC Certificate issued for manufacturer:
Gas Control Equipment Ltd.

originally issued in compliance with:
the Council Directive 93/42/EEC on Medical Devices, as amended

Based on assessment performed, the following changes to the certification has been accepted as compliance with Council Directive 93/42/EEC on Medical Devices has been established.

A new EU representative, replacing the one stated on the certificate, has been accepted.

EU Representative
GCE, s.r.o., Žižkova 381, 583 01 Chotěboř, Czech Republic

Appendix History -		
Revision	**Description**	**Issued Date**
0.0	A new EU representative has been accepted	12 October 2022

Place and date:
Høvik, 12 October 2022

For the issuing office:
DNV Product Assurance AS - Notified Body 2460
Veritasveien 1, 1363 Høvik, Norway

Hazem Tinawi
Technical Reviewer

EU DECLARATION OF CONFORMITY

Document ID:	DoC ZP 22-044 Pressure regulators integrated with cylinder valves, ver. 1.03
Manufacturer´s Name:	GCE, s.r.o.
Manufacturer´s Address:	Žižkova 381, 583 01 Chotěboř, Czech Republic
SRN (Single Registration Number):	CZ-MF-000019708
Name of the Device(s):	**Pressure regulators integrated with cylinder valves**
Name of the Model(s):	**MediVital®, MediVital® E, Ministar 2, MediVitop®**

Intended purpose:

Pressure regulators integrated with cylinder valves (medical combination valves) are designed to be fitted to gas cylinders used for medical gases up to 300 bar. These combination valves together with gas cylinders form gas packages used as gas supply points for medical devices and allow management of the medical gases and their mixtures supply. Medical combination valves are used to reduce high cylinder pressure to lower pressure or to specific outlet flow suitable for the administration of medical gases in the treatment of patients.

Basic UDI-DI:	**8592346ZP22044XF**
Risk Class:	**IIb, rule 12**
EMDN code:	**Z120309**

Standards/Common specifications:

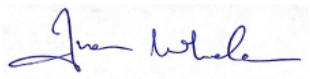
EN ISO 9001:2015	EN ISO 13485:2016+A11:2021
EN ISO 14971:2019+A11:2021	EN ISO 15223-1:2021
EN ISO 20417:2021	EN 62366-1:2015+A1:2020
EN ISO 18562-1:2020	EN ISO 10993-1:2020
EN ISO 15001:2011	EN ISO 10524-3:2019
EN ISO 10297:2014+A1:2017	EN ISO 11114-2:2021
EN ISO 15996:2017	EN ISO 11117:2019
EN 1789:2020	EN 60601-1-2:2015
EN 60601-1-11:2015+A1:2021	EN 60529:1991+A1:2000+A2:2013
EN 62304:2006+A1:2016	EN 60601-1:2006+A1:2013+A11:2011+A2:2021

Notified Body Name:	DNV Product Assurance AS
Notified Body Address:	Veritasveien 1, 1363 Høvik, Norway
Notified Body Identification Number:	2460
Certificate Identification:	C671184

Conformity assessment procedure:

This declaration of conformity is issued under the sole responsibility of GCE, s.r.o. as manufacturer of the medical device. The manufacturer hereby declares that the medical device(s) specified above meet the provision of the Regulation (EU) 2017/745 on medical devices and the Conformity Assessment Procedure was performed according to Annex IX of the Regulation (EU) MDR 2017/745 on medical devices. Technical documentation is established, is maintained and is in compliance with Annex II and III. The manufacturer has established, implemented, documented, and maintained a quality management system that is conformed with the Quality Management System standard: ISO 13485:2016 (see 262513-2018-AQ-CZS-NA-PS). All supporting documentation is retained at the premises of the manufacturer.

Signature: **Place and date of issue:**



…… Chotěboř 18/04/2024

On behalf of the manufacturer signed by Ivan Whelan

Person responsible for regulatory compliance

Note: The list of configurations is in the attachment of this document.

LIST OF CONFIGURATIONS

Attachment of EU Declaration of conformity

Document ID: DoC ZP 22-044 Pressure regulators integrated with cylinder valves, ver. 1.03

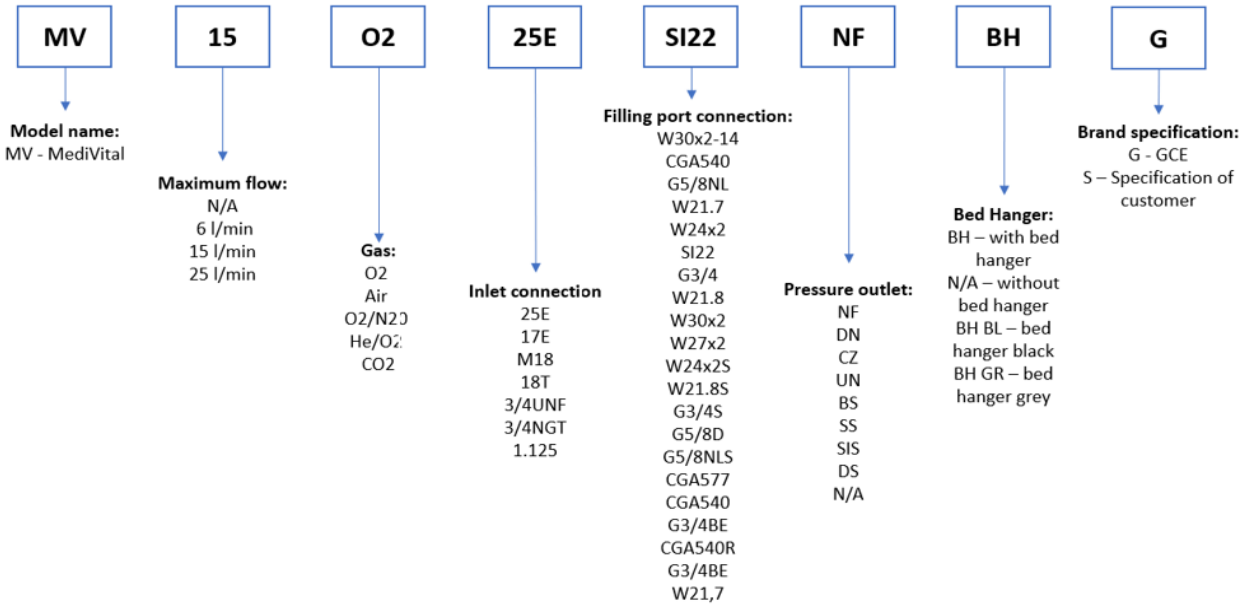
Name of the Device(s): **Pressure regulators integrated with cylinder valves**

Name of the Model: **MediVital®**

List of configurations:

Configuration REF number / order number		**Description**
Model REF number	**Configuration ordering identifier***	
07180	xx	Explanatory description of the configuration
07181	xx	Explanatory description of the configuration
07182	xx	Explanatory description of the configuration

*xx – every X represent digit in the range 0-9



Legend:	example: MV15 O2 25E SI22 NF G	When some information is mentioned as N/A is not visible in the configuration name.
	MV	MediVital Product specification abbreviation
	15	Maximum flow
	O2	Gas specification for example O2, CO2, …
	25E	Inlet connection – information about inlet connection thread
	SI22	Filling port – information about filling port thread or connection
	NF	Pressure outlet - information about pressure outlet connection
	N/A	Bed Hanger; BH - with bed hanger, N/A - without bed hanger
	G	Brand specification G – GCE, S – Specification of customer, or another letter of alphabet connects to specific customer

LIST OF CONFIGURATIONS

Attachment of EU Declaration of conformity

Document ID: DoC ZP 22-044 Pressure regulators integrated with cylinder valves, ver. 1.03

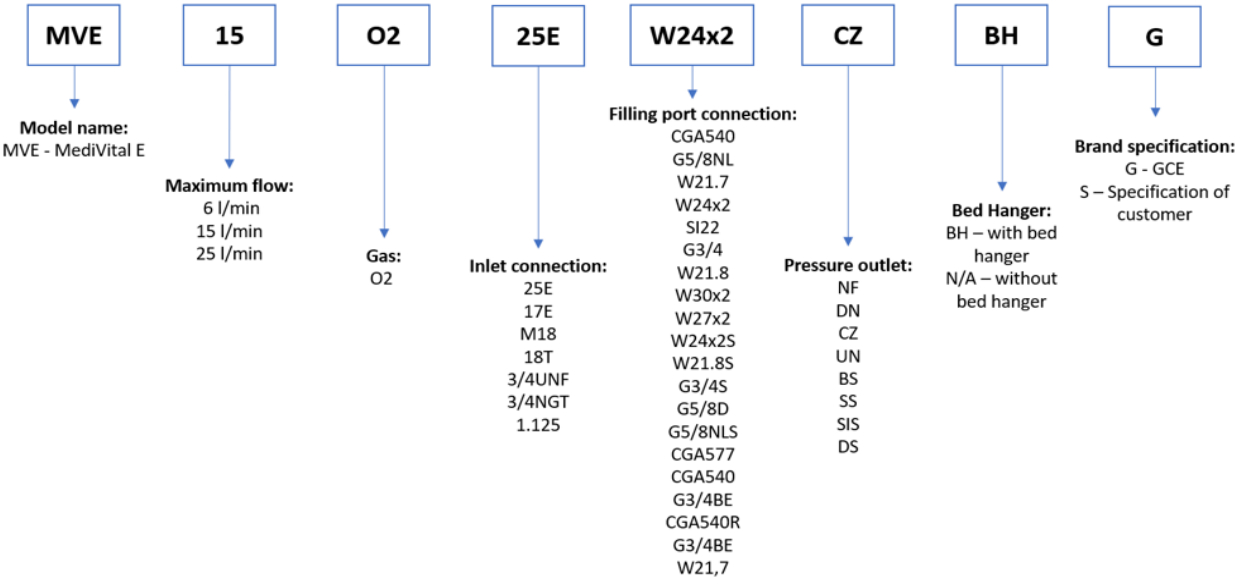
Name of the Device(s): **Pressure regulators integrated with cylinder valves**

Name of the Model: **MediVital® E**

List of configurations:

Configuration REF number / order number		**Description**
Model REF number	**Configuration ordering identifier***	
07185	xx	Explanatory description of the configuration

*xx – every X represent digit in the range 0-9



Legend:	example: MVE15 O2 25E W24x2 CZ G	When some information is mentioned as N/A is not visible in the configuration name.
	MVE	MediVital E Product specification abbreviation
	15	Maximum flow
	O2	Gas specification for example O2
	25E	Inlet connection – information about inlet connection thread
	W24x2	Filling port – information about filling port thread or connection
	CZ	Pressure outlet - information about pressure outlet connection
	N/A	Bed Hanger; BH - with bed hanger, N/A - without bed hanger
	G	Brand specification G – GCE, S – Specification of customer, or another letter of alphabet connects to specific customer

LIST OF CONFIGURATIONS

Attachment of EU Declaration of conformity

Document ID: DoC ZP 22-044 Pressure regulators integrated with cylinder valves, ver. 1.03

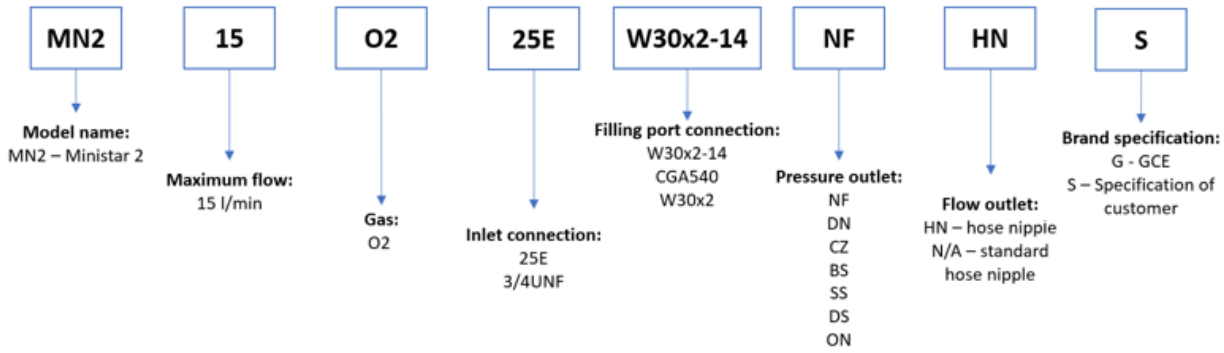
Name of the Device(s): **Pressure regulators integrated with cylinder valves**

Name of the Model: **Ministar 2**

List of configurations:

Configuration REF number / order number		**Description**
Model REF number	**Configuration ordering identifier***	
07121	xx	Explanatory description of the configuration

*xx – every X represent digit in the range 0-9



Legend:	example: MN2 15 O2 25E W30x2-14 NF HN S	When some information is mentioned as N/A is not visible in the configuration name.
	MN2	Ministar 2 Product specification abbreviation
	15	Maximum flow
	O2	Gas specification for example O2
	25E	Inlet connection – information about inlet connection thread
	W30x2-14	Filling port – information about filling port thread or connection
	NF	Pressure outlet - information about pressure outlet connection
	HN	Flow outlet: HN – Hose nipple N/A – Standard hose nipple
	S	Brand specification G – GCE, S – Specification of customer, or another letter of alphabet connects to specific customer

LIST OF CONFIGURATIONS

Attachment of EU Declaration of conformity

Document ID: DoC ZP 22-044 Pressure regulators integrated with cylinder valves, ver. 1.03

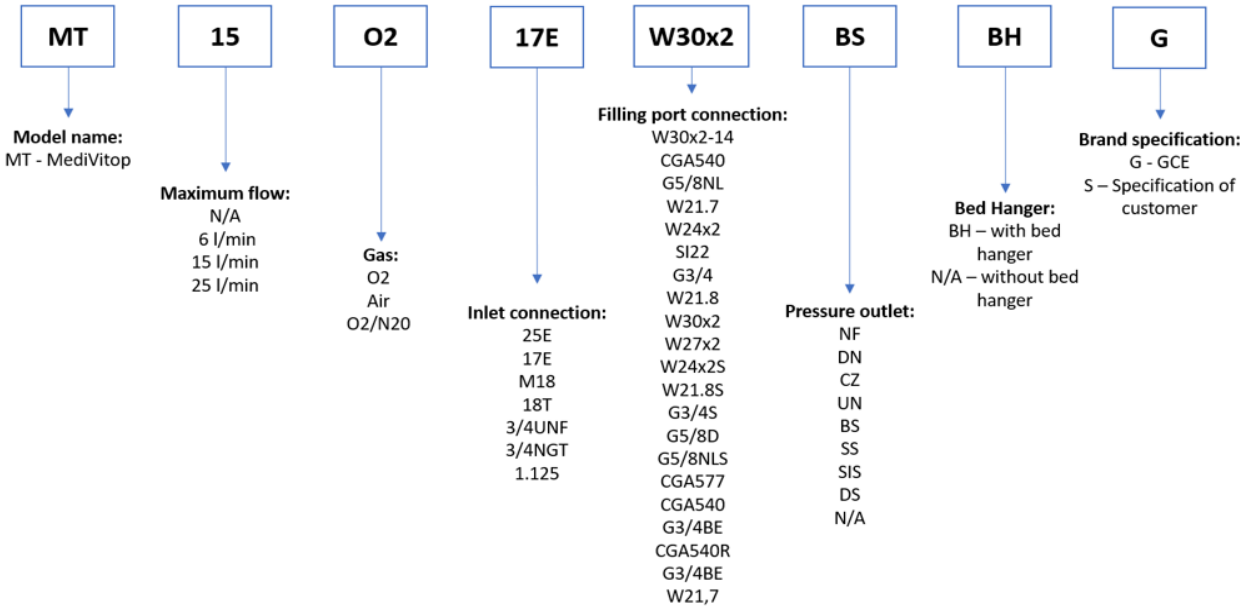
Name of the Device(s): **Pressure regulators integrated with cylinder valves**

Name of the Model: **MediVitop®**

List of configurations:

Configuration REF number / order number		Description
Model REF number	**Configuration ordering identifier***	
07123	xx	Explanatory description of the configuration
07124	xx	Explanatory description of the configuration
07126	xx	Explanatory description of the configuration

*xx – every X represent digit in the range 0-9



Legend:	example: MT15 O2 17E W30x2 BS G	When some information is mentioned as N/A is not visible in the configuration name.
	MT	MediVitop Product specification abbreviation
	15	Maximum flow
	O2	Gas specification for example O2
	17E	Inlet connection – information about inlet connection thread
	W30x2	Filling port – information about filling port thread or connection
	BS	Pressure outlet - information about pressure outlet connection
	N/A	Bed Hanger; BH - with bed hanger, N/A - without bed hanger
	G	Brand specification G – GCE, S – Specification of customer, or another letter of alphabet connects to specific customer

EC CERTIFICATE

Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
10401-2017-CE-CZS-NA-PS Rev. 6.0	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,16 March 2021

For the issuing office:
Notified Body 2460
DNV Product Assurance AS

Sholeh Ghelssar

Sholeh Ghelssar
Principal assessor