EU Quality Management System Certificate

Certificate no.:
C659279

Initial certification date:
26 January 2024

Valid Until:
26 January 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:

Medical gas equipment and devices for use with medical gases

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, 08 July 2025

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

Tone Kolpus

Tone Kolpus
Management Representative

Digitally signed by Grabazei Alexandru
Date: 2025.10.31 11:00:14 EET
Reason: MoldSign Signature
Location: Moldova

MOLDOVA EUROPEANA

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

Jurisdiction

Application of Regulation 2017/745 on medical devices, implemented in Norway by Act 7 May 2020 no. 37 on medical devices and Regulation 9 May 2021 no.1476 on medical devices by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Report No.	Issue Date
0.0	Original Certificate	2688262	26 January 2024
1.0	Admin Change	2688262	29 January 2024
2.0	Added Diamond Flowmeter variant to Tube Flowmeter	3156432	10 January 2025
3.0	Extension in scope – new product Low Pressure Connections added	3250954	30 June 2025
4.0	Certificate combined with C536876, C664967, C671184, C646764, C692946, C685278, C709705, C710348	3276606	08 July 2025

Products covered by this Certificate:

Product Description (and intended purpose for class IIb)	Product Name	Class
Low Pressure Regulators for use with medical gases Low pressure regulator (MediFlow® Ultra II) are designed to be connected directly at terminal units of a medical gas pipeline system or gas-specific connection points of devices such as medical high pressure regulaors. Low pressure regulators fitted with the flow-selector device are used to select specific outlet flow suitable for administering medical gases in the treatment and management of patients. Low pressure regulators are designed to deal with fluctuating inlet pressure which causes the medical device to deliver accurate and stable flow consistently. Low pressure regulators are not intended to be used with gasses for driving surgical tools.	MediFlow Ultra II Trade name: HOSPIQUICK, Debistar+, DUOSTAR, MULTISTAR	IIb
Pressure Regulator Integrated with Cylinder Valve for use with medical gases 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	MediVital, MediVital E, MediVitop, Ministar 2	IIb

pressure or to specific outlet flow suitable for the administration of medical gases in the treatment of patients.		
Cylinder Valves for use with medical gases Cylinder valves are designed to be fitted to gas cylinders used for medical gases up to 300 bar. These valves together with a gas cylinder, forms gas packages used as gas supply point for medical devices and allows opening and closing of the medical gases and their mixtures supply.	Cylinder Valve	IIb
Pin-Index Valve for use with medical gases Pin-index valves are designed to be fitted to gas cylinders used for medical gases up to 200 bar. These valves together with a gas cylinder, forms gas packages used as gas supply point for medical devices and allows opening and closing of the medical gases and their mixtures supply.	Pin-Index Valve (Pin-index)	IIb
Line Stabilizers for use in medical gas pipeline system Line stabilizers are medical gas manifolds for use in medical gas pipeline systems. They are used as a regulating and stabilizing manifold to stabilize the pressure of the flowing gas and to compensate gas pressure and gas flow fluctuations. The result is a stable correct pressure of provided medical gas. The Line stabilizer is designed for distribution of medical gases and gases to drive surgical instruments. The Line stabilizer is a secondary reduction unit where the primary gas supply is provided by the high pressure gas manifold or possibly by a cryogenic tank. Line stabilizers are intended for use in healthcare facilities and hospitals.	Line Regulator, MM40 Stabilizer, MC80 Stabilizer, MC150 Stabilizer	IIb
High Pressure Regulators for use with medical gases High pressure regulators (MediSelect® II / MediReg® II / MediTec™) are designed to be fitted to gas cylinders equipped with medical cylinder valves or as an integral part of medical equipment that is used for medical gases up to 300 bar. High pressure regulators are used for reducing high cylinder pressure to lower pressure or to specific outlet flow suitable for the administration of medical gases in the treatment of patients.	MediSelect II, MediReg II, MediTec	IIb

Terminal Units Terminal units are intended to be used as outlet points at hospital pipeline systems. Terminal units are intended to provide pressurised gases or vacuum for medical purposes. Terminal units can be used in medical emergency ambulances. Terminal unit is an outlet point where operators connect and disconnect an inlet of other gas specified medical devices, such as medical hoses, flowmeters, etc. The Terminal units are designed to be gas specific which means that they cannot be connected to a medical device that is for a different type of gas.	Mediunit, Mediunit AFNOR	IIb
Flow Selectors	MediFlow II, MediFlowTec, MediFlow+	IIa
Tube Flowmeter for use with medical gases	Medimeter	IIa
	Diamond Flowmeter	
Low Pressure Connections	MediConnect	IIa
	Duoline	

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 and IIb devices falling under Article 52 (4) 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.