

# DECLARATION OF CONFORMITY

**Certificate Number:** ZP 03-006 High Pressure Regulators\_09-02

This declaration of conformity is issued under the sole responsibility of the

**Manufacturer:** GCE, s.r.o.  
Žižkova 381, 583 01 Chotěboř  
CZECH REPUBLIC

We hereby declare that the medical device specified below is in conformity with applicable Regulation MDD 93/42/EEC for medical devices. This declaration is supported by the Quality System approval to ISO 13485:2016 issued by DNV GL PRESAFE AS, valid until May 11, 2021.

**Product group:** Medical devices for use with Medical Gases

**Product name:** High Pressure Regulators

**Model:** MEDISELECT II

**Risk Classification:** IIb

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.

**Notified Body:** DNV GL PRESAFE AS  
Veritasveien 3, N-1363 Høvik  
Norway

**Notified Body No.:** 2460

**EC Certificate number:** 10401-2017-CE-CZS-NA-PS Rev. 3.0

**Valid until:** May 27, 2024

**Name:** Tomáš Janeček

**Function:** Managing Director

**Signature:** 

**Place and date of issue:** Chotěboř, May 27, 2020



Gas Control Equipment

GCE, s.r.o., Žižkova 381, 583 01 Chotěboř, Česká republika, tel.: +420 569 661 111, VAT: CZ27110991,  
e-mail: gce@gcegroup.com  
www.gcegroup.com