

DECLARATION OF CONFORMITY

for CE – marking according to Annex II of Medical Devices Directive 93/42/EEC – Amending 2007/47/EC

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

The GCE s.r.o. herewith declares under his sole responsibility that the product

Product group: Medical devices for use with Medical Gases

Product name: High pressure regulators

Model: **MEDISELECT**

Risk Classification: IIb

is in conformity with applicable regulation

Directive: MDD 93/42/EEC, Annex II – 2007/47/EC
Amending

Quality Assurance Standard: ISO 9001:2015
ISO 13485:2016

Standards Applied: EN ISO 10524-1:2006
EN ISO 15001:2011
EN 62366:2008+A1:2015
EN ISO 9170-1:2008

Product is in compliance with the essential requirements of Annex I the MDD 93/42/EEC and is safe for to be declared using in standard conditions.

Any modification to the product, not authorized by us, will invalidate this declaration.

EC Certificate No. 10401-2017-CE-CZS-NA-PS Rev. 2.0 issued by DNV GL NEMKO PRESAFE AS – Veritasveien 3, N-1363 Høvik, Norway – Registered Enterprise No: NO 997 067 401 MVA Notified Body No. 2460.

Chotěboř, 2019-01-15



MARTIN ŠTEFAN
Quality Engineer