DECLARATION OF CONFORMITY

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

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:	**MEDIREG**
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 ISO 14971:2012 EN 62366:2008+A1:2015 EN ISO 15223-1:2016 EN 1041:2008+A1:2013 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, 2018-10-08

MARTIN ŠTEFAN
Quality Engineer