EU DECLARATION OF CONFORMITY

Certificate Number:	*ZP 03-006 High Pressure Regulators_09-07*
Manufacturers Name:	GCE, s.r.o.
Manufacturers Address:	Žižkova 381, 583 01 Chotěboř, Czech Republic
SRN (Single Registration Number):	003172 RZPRO
Product Group:	*High Pressure Regulators*
Name of the Device (s):	**MEDIREG II**
Product code:	7085
Risk Classification:	IIb
GMDN code:	43438
Other used standards:	**EN ISO 10524-1:2018**
Notified Body name:	DNV Product Assurance AS
Notified Body Address:	Veritasveien 3, N-1363 Høvik, Norway
Notified Body Identification number:	2460
EC Certificate Number:	10401-2017-CE-CZS-NA-PS

Conformity assessment route:

This declaration of conformity is issued under the sole responsibility of GCE, s.r.o. We hereby declare that he medical device(s) specified above meet the provision of the Regulation MDD 93/42/EEC for medical devices. This declaration is supported by the Quality System approval to ISO 13485:2016 issued by DNV Product Assurance AS.

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.

All supporting documentation is retained at the premises of the manufacturer.

Signature: Place and date (dd.mm.yyyy) of issue:

Ing. Tereza Šnapková
Digitálně podepsal Ing. Tereza Šnapková
Datum: 2021.05.28 13:44:08 +02'00'

…… ……Chotěboř

Tereza Šnapková

Regulatory Specialist, On behalf of Tomáš Janeček, managing director.

Note: List of variants is in attachment of this docoment.