DECLARATION OF CONFORMITY

Certificate Number: *ZP 05-009 Low Pressure Regulators_09-01*

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: *Low Pressure Regulators*

Model: **MEDIFLOW ULTRA II (HOSPIQUICK 25 AIR, HOSPIQUICK 25 O2, DEBISTAR+ 2, DEBISTAR+ 6, DEBISTAR+ 15, DEBISTAR+ 25)**

Risk Classification: IIa

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. 5.0

Valid until: May 27, 2024

Name: Tereza Šnapková

Function: Regulatory Specialist

Signature: Ing. Tereza Šnapková
Digitálně podepsal Ing. Tereza Šnapková
Datum: 2020.09.29 15:22:57 +02'00'

Place and date of issue: *Chotěboř, September 22, 2020*