DECLARATION OF CONFORMITY

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

Manufacturer*:* **GCE s.r.o.**
Žižkova 381
583 81 Chotěboř
CZECH REPUBLIC

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

Product name: Low Pressure Regulators

Model: MEDIFLOW ULTRA II

Risk Classification: IIa

is in conformity with applicable regulation

Directive: MDD 93/42/EC, Annex II

Quality Assurance Standards: EN ISO 9001:2008
EN ISO 13485:2012

Procedual Standards: EN ISO 10524-1:2006 EN 980:2008
EN ISO 14971:2012 EN 1041:2008

Product is in compliance with the requirements of Annex II 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. 73547-2010-CE-CZS-NA 6.0 issued by by Det Norska Veritas, Veritasveien 1, 1322 Høvik, Norway, Notified Body No. 0434

Date of Issue: 2016-09-29
Place of Issue: Chotěboř

Signature: Jana Jelínková
Quality Engineer: Jana Jelínková

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