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 ISO 15223-1:2012

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: *2015-04-14*
Place of Issue : *Chotěboř*

Signature:
Quality Engineer: Vít Leszkow

GCE, s.r.o.
Žižkova 381
583 81 Chotěboř
Czech Republic
Tel. 00 420 569 661 111
Fax. 00 420 569 661 138
E-mail: gce@gcegroup.com
http:// www.gcegroup.com
VAT number: CZ27110991