

GCE, s.r.o.

DECLARATION OF CONFORMITY

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

Batch No.:

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: Regulators for Medical Gases

Model :

Risk Classification : IIb

is in conformity with applicable regulation

Directive : MDD 93/42/EEC, Annex II

Quality Assurance Standards : EN ISO 9001
EN 13485

Procedural Standards : EN 10524-1 EN 980
EN ISO 14971 EN 1041

Product is in compliance with the requirements of Annex I the MMD 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.

Date of Issue:

Place of Issue : Chotěboř

Signature: 

Quality Manager: