

EC DECLARATION OF CONFORMITY

according to Annex II to Council Directive 93/42/EEC of June 14, 1993

Manufacturer AGA Gas AB
Address 181 81 Lidingö, Sweden
Medical device Carbon dioxide (CO₂) in cylinder with valve
Product identification See appendix 1
Classification Class IIa (rule 7 and 9))

We declare the compliance of the above medical device with the relevant provisions of the Council Directive 93/42/EEC of June 14, 1993 (amended by Directive 2007/47/EEC) and LVFS 2003:11, the Swedish implementation of the same directive, and their amendments. Any modification of the medical device not authorized by us will invalidate this declaration.

The conformity in accordance of Directive 93/42 Annex V is certified with CE Certificate No. 44760-2008-CE-NOR by the following Notified Body:

DNV
Det Norske Veritas Certification AS
Veritasveien 1
1322 Høvik
Norway


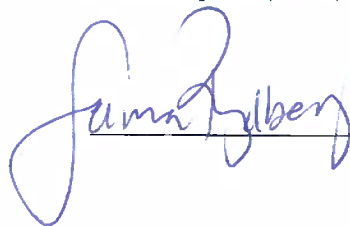
The identification number of the notified body for implementation of the procedure set out in Annex II to the above Directive is 0434.

Place and date Lidingö, 2015-02-16

Name Sanna Rydberg
(Head of Healthcare
Healthcare Region Europe North)

Veija Pellikka
(Head of Quality & Regulatory Affairs
Healthcare-Regional Continental)

Signature



Appendix 1

CO₂ products covered

Size	Package	Country	Article No (SAP)
2,5L	Steel cylinder + valve	SE/NO	107650
	Steel cylinder + valve	FI	107652
	Steel cylinder + pin index valve	DK	107651
5L	Aluminium cylinder + valve	SE/NO	107653
	Steel cylinder + valve	FI	107654
10L	Steel cylinder + valve	SE/NO/DK	107658
	Steel cylinder + valve	FI	107659
	Steel cylinder + valve	Balticum	112631
20L	Steel cylinder + valve	SE/DK	107660
40L	Steel cylinder + valve	NO/SE	107661
	Steel cylinder + valve	FI	107662