THE LINDE GROUP

AGA

EC DECLARATION OF CONFORMITY

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

Manufacturer	AGA Gas AB
Address	181 81 Lidingö, Sweden
Medical device	Liquid nitrogen (medical device)
Product identification	See appendix 1
Classification	Class IIa (according to Annex IX rule 2 and 9 to Council Directive 93/42/EEC)

We declare the compliance of the above medical device with the requirements of the Council Directive 93/42/EEC of June 14, 1993 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 of the quality assurance system ISO 13485 (production) and the conformity of the assessment procedure in Art. 11.2.b and Annex V (Module D) Council Directive 93/42/EEC, as amended, is certified with Certificate No. 69604-2010-CE-NOR-NA, dated 2010-01-14, by the following Notified Body:

DNV
Det Norske Veritas Certification AS
Veritasveien 1
1322 Hövik
Norway

The identification number of the notified body for implementation of the procedure is **0434**.

Place and date	Lidingö, 2010-03-02	
Name	Marcus Lindroos (Regional Manager IBD REC)	Veija Pellikka (Regional Director Quality & Regularory Affairs)
Signature		

For conditions of guarantee and liability please refer to our General Conditions of Sale

Appendix 1

Products covered

Article No.	Name
(SE) 113873 (SAP)	Flytande nitrogen (medicinteknisk produkt)
(FI) 113873 (Movex)	Nestemäinen typpi (lääkinnällinen laite)