



Product Service

EC-CERTIFICATE

Full Quality Assurance System

(Annex II, section 3 of the Directive 93/42/EEC on Medical Devices)

No. G1 05 10 20809 025

Manufacturer: BREAS Medical AB

Företagsvägen 1
43533 Mölnlycke
SWEDEN

Facility(ies):

BREAS Medical AB
Företagsvägen 1, 43533 Mölnlycke, SWEDEN

**Product
Category(ies):**

**Respiratory Therapy Systems,
Sleep Apnea and Humidifier Systems**

The Certification Body of TÜV Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective products / product categories according to Annex II section 3 of the Directive 93/42/EEC on Medical Devices. This quality assurance system conforms to the provisions of this Directive and is subject to periodical surveillance. For marketing of class III products an additional Annex II.4 certificate is mandatory. See also notes overleaf.

Report No.: 70106351

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Reiner Krumme

TÜV Product Service GmbH is Notified Body according to Council Directive 93/42/EEC concerning medical devices with identification no. 0123.

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