ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 15 06 20809 035

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, Respiratory Monitoring Devices, Sleep Apnea and Humidifier Systems**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713063789

Valid from: 2015-10-28
Valid until: 2020-10-27

Date, 2015-08-06

Hans-Heiner Junker

· 672830

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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