

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 13 08 33935 012

Manufacturer: **SleepNet Corporation**
5 Merrill Industrial Drive
Hampton NH 03842
USA

EC-Representative: **MPS Medical Product Service GmbH**
Borngasse 20
35619 Braunfels
GERMANY

Product Category(ies): **Disposable and Re-usable
Respiratory Care and
Sleep Apnea Products**

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.: DM1201356

Valid from: 2013-10-22

Valid until: 2018-10-21




Date, 2013-09-19

Hans-Heiner Junker

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

Page 1 of 2



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 13 08 33935 012

Facility(ies):

SleepNet Corporation
5 Merrill Industrial Drive, Hampton NH 03842, USA