ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICA

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 11 08 60742 005

Manufacturer:

Inogen, Inc.
326 Bollay Drive
Goleta CA 93117
USA

EC-Representative:

HEALTHLINK EUROPE BV
Centaurusweg 123
5015 TC Tilburg
THE NETHERLANDS

Product Category(ies):

Oxygen Concentrators and Remote Oxygen Conservers

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.: DM1107285

Valid from: 2011-10-05
Valid until: 2016-10-04

Date, 2011-09-29

Hans-Heiner Junker

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

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