NSAI

Quality System Approval Certificate

Medical Devices Directive 93/42/EEC

*The National Standards Authority of Ireland as a duly designated Notified Body, (identification number **0050**), for the purposes of the European Communities (Medical Devices) Regulations (S.I. No. 252 of 1994)*

APPROVES THE QUALITY SYSTEM APPLIED BY

AeroGen Ltd

Galway Business Park
Dangan
Galway
Ireland

to the Product Family

Nebulizer System (Aeroneb)

on the basis of examination under the requirements of Annex II, Section 3.2 of Directive 93/42/EEC.
*The use of the NSAI Notified Body identification number **0050** in conjunction with CE Marking of Conformance for this product family is hereby authorised.*

Registration Number:	**252.509**
Original Approval:	**24 October 2001**
Last Amended on:	**22 June 2011**
Remains valid until:	**30 December 2011**

Signed:

Approved by:
Kevin D. Mullaney
Chief Executive Officer - NSAI Inc.

Approved by:
John O'Dwyer
European manager

This certificate remains valid on condition that the Approved Quality System is maintained in an adequate and efficacious manner.
Details of the current product range and operational locations included within the scope of this approval can be obtained from NSAI

National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland.

Aerogen®

Regulatory Affairs
Aerogen Ltd.

Title	**Aeroneb Go Declaration of Conformity**
Document No.	**RA014**

Revision	DCR No.	Effectivity Date	Training Effectiveness
A	DCR09135	27th Aug 2009	N/A
B	DCR10059	5th March 2010	No Training Required
C	DCR10299	20th October 2010	No Training Required
D	DCR10303	20th October 2010	No Training Required

Martin Heneghan
20th October 2010

DECLARATION OF CONFORMITY

(In accordance with ISO/IEC 17050-1:2004(E))

Issuers Name / EU Representative Aerogen Limited,

Issuers Address: Galway Business Park, Dangan, Galway, Ireland.

Object of the Declaration: Aeroneb Go Product Family.	
AG-AG4070 Aeroneb Go Twist: Battery Controller Cable	AG-AG4300 Aeroneb Go Twist Handset
AG-AG 4200-UK Aeroneb Go Twist Complete System (UK)	AG-AG4100-IN Aeroneb Go Twist Battery Controller System (IN)
AG-AG 4200-IN Aeroneb Go Twist Complete System (IN)	AG-AG4100-NE Aeroneb Go Twist Battery Controller System (NE)
AG-AG 4200-NE Aeroneb Go Twist Complete System (NE)	AG-AG4100-SE Aeroneb Go Twist Battery Controller System (SE)
AG-AG 4200-SE Aeroneb Go Twist Complete System (SE)	AG-AG4100-SC Aeroneb Go Twist Battery Controller System (SC)
AG-AG 4200-SC Aeroneb Go Twist Complete System (SC)	AG-AG4060 Aeroneb Go Twist: Control Module & Cable
AG-AG3200-UK Aeroneb Go Nebulizer System, UK	AG-AG3200-IN Aeroneb Go Nebulizer System, International
AG-AG3200-AU Aeroneb Go Nebulizer System, Australia	AG-AG3200-NE Aeroneb Go Nebulizer System, Northern Europe
AG-AG3200-SE Aeroneb Go Nebulizer System, Southern Europe	AG-AG3100-UK Aeroneb Go Nebulizer System – Convenience Unit, UK
AG-AG3200- SC Aeroneb Go Nebulizer System, Scandinavia	AG-AG3100-NE Aeroneb Go Nebulizer System – Convenience Unit, Northern Europe
AG-AG3100-SE Aeroneb Go Nebulizer System – Convenience Unit, Southern Europe	AG-AG3100-SC Aeroneb Go Nebulizer System – Convenience Unit, Scandanavia
AG-AG3300 Aeroneb Go Nebulizer Handset	AG-AG3300 Aeroneb Go Handset
AG-AG3040 Mouthpiece	AG-AG3080 Mask Adaptor(22mm M)
AG-AG3410-XX AC/DC Adaptor	AG-AG3090 Mask Adaptor (22mm F)
AG-AG3060 Control Module	AG-AG3020 Go Medication Cup Assembly
AG-AG2070 Control Module Cable	AG-AG2120-XX Instruction Manual
AG-ACG1000-EU Aeroneb Go Filtered Nebuliser System EU (Europe)	

Declaration:

We, Aerogen Limited, of Galway Business Park, Dangan, Galway, Ireland, declare under our sole responsibility that the above listed products and accessories meet the provisions of the Medical Device Directive MDD93/42/EEC and the following standards:

Documents No.	Title	Edition/Date of Issue
EN 980:2008	Graphical symbols for use in the labelling of medical devices	2008
I.S.ENISO 13485:2003	Medical Devices: Quality Management System	2003
EN 1041:2008	Information supplied by the manufacturer with medical devices	2008
EN ISO 10993-1:2009	Biological evaluation of medical devices - Part 1: Evaluation and testing	2009
EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	2009
EN ISO 10993-10:2009	Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity	2009
ISO 14971:2009	Medical Devices: Application of Risk Management	2009
EN 13544-1:2007	Respiratory therapy equipment - Part 1: Nebulizing systems and their components	2007 + A1:2009
EN 14155-1: 2009	Clinical investigation of medical devices for human subjects - Part 1: General requirements	2009
ISO 60601-1	Medical Electrical Equipment: Safety	1990 and all amendments to A13:1996
ISO 60601-1-2	Medical Electrical Equipment: EMC	2002

This declaration is supported by the certification information listed below.

Document No.	Title:	Edition/Date of Issue
252.509	Quality System Approval Certificate	09 December 2004

Classification:	Class IIa (based on rule 11 of Annex IX of MDD 93/42/EEC).
Conformity Assessment Route:	Annex II.
Notified Body:	National Standards Authority of Ireland (NSAI), 1 Swift Square, Northwood, Santry, Dublin 9, Ireland. (Notified Body No. 0050).
Start of CE-Marking:	26 June 2002
Signed for and on behalf of:	Aerogen Limited

Signature: Brendan Hogan	**Date:** 20 Oct. 2010.	**Place of issue:** Galway, Ireland
Name/Function:	Brendan Hogan, Engineering Director	

Certificate of Registration of Quality Management System to I.S. EN ISO 13485:2003

The National Standards Authority of Ireland certifies that:

Aerogen Ltd
Galway Business Park
Galway,
Ireland

has been assessed and deemed to comply with the requirements of the above standard in respect of the scope of operations given below:

The design, development and manufacture of Medical Devices and Systems for Systemic Diagnosis, treatment and drug delivery.

Approved by:
Kevin D. Mullaney
Chief Executive Officer

Approved by:
John O'Dwyer
Medical Devices Manager , EU

Registration Number: MD19.3129

Certification Granted: Nov 05, 2004

Effective Date: Apr 07, 2010

Expiry Date: Apr 06, 2013

National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland T +353 1 807 3800