

Aerogen®

Regulatory Affairs
Aerogen Ltd.

Title	Aerogen Solo Declaration of Conformity
Document No.	RA015

Revision	DCR No.	Effectivity Date
N	DCR15099	5 th August 2015
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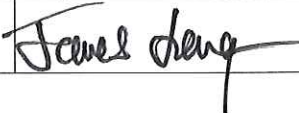
Aerogen Solo Declaration of Conformity

Legal Manufacturer: Aerogen Limited,
Galway Business Park,
Dangan,
Galway,
Ireland.

Manufacturer Site: Parkmore Business Park West,
Ballybrit,
Galway,
Ireland.

Marketing Reference Number	Product Description
AG-AS3000-UK	Solo Starter Kit (UK)
AG-AS3000-IN	Solo Starter Kit (IN)
AG-AS3000-NE	Solo Starter Kit (NE)
AG-AS3000-SE	Solo Starter Kit (SE)
AG-AS3000-SC	Solo Starter Kit (SC)
AG-AS3000-CN	Solo Starter Kit (CN)
AG-AS3000-JP-MQ	Solo Starter Kit (JP)
AG-AS3000-JP-PH	Solo Starter Kit (JP)
AG-AS3000-JP-CV	Solo Starter Kit (JP)
AG-AS3000-DK	Solo Starter Kit (DK)
AG-AS3000-RB	Solo Starter Kit (RB)
AG-AS3000-CE	Solo Starter Kit (CE)
AG-AS3000-EE	Solo Starter Kit (EE)
AG-AS3450	Solo T-Piece Plug (FRU)
AG-AS3500	Aerogen Solo Nebulizer
AG-AS3020	Solo Pediatric T-Piece 15mm
AG-AS3025	Solo Pediatric T-Piece Adapter Kit
AG-AS3300	Solo Convenience Kit (5 Pack)
AG-AS3350	Solo Convenience Kit (10 Pack)
AG-AS3010	Solo Adult T-Piece 22mm (FRU)
AG-AS3035	Solo Pediatric T-Piece 12mm (FRU)
AG-AS3036	Solo Pediatric T-Piece 10mm (FRU)
AG-AS3100	Solo Nebuliser (5 Pack)
AG-AS3200	Solo Nebuliser (10 Pack)
AG-AS5000-MQ	Aerogen Solo Nebulizer
AG-PX1050-IN	Pro-X Controller (IN)
AG-AS1075	Solo Mask Kit (Intl)
AG-AS1055	Solo Vented Elbow
AG-AS3075	Solo Continuous Nebulization Tube Set (5 Pack)
AG-AS3085	Solo Continuous Nebulization Syringe (5 Pack)

AG-AS3095	Solo Continuous Nebulization Syringe (50 Pack)
AG-AS7500-EU	Aerogen Ultra Starter Kit
AG-AS7000-EU	Aerogen Ultra
AG-PX1000-UK	Pro-X Controller Kit (UK)
AG-PX1000-NE	Pro-X Controller Kit (NE)
AG-PX1000-SE	Pro-X Controller Kit (SE)
AG-PX1000-SC	Pro-X Controller Kit (SC)
AG-PX1000-IN	Pro-X Controller Kit (IN)
AG-PX1000-RB	Pro-X Controller Kit (RB)
AG-PX1000-CE	Pro-X Controller Kit (CE)
AG-PX1000-EE	Pro-X Controller Kit (EE)
1079421	NIVO Pro-X Controller Kit – Eng EU
1079422	NIVO Pro-X Controller Kit – UK/IE
1079424	NIVO Pro-X Controller Kit – Eng INTL
1082693	NIVO Pro-X Controller Kit – Northern EU
1082694	NIVO Pro-X Controller Kit – Southern EU
1082695	NIVO Pro-X Controller Kit – Scand EU
1082696	NIVO Pro-X Controller Kit -INTL
1076302	NIVO Nebuliser (5 Pack)
AG-AP1040-UK	Aerogen AC/DC Adapter (UK)
AG-AP1040-EU	Aerogen AC/DC Adapter (EU)
AG-UC1040-UK	Aerogen USB Controller AC/DC (UK) FRU
AG-UC1040-EU	Aerogen USB Controller AC/DC (EU) FRU
AG-UC1000-UK	Aerogen USB Controller (UK)
AG-UC1000-NE	Aerogen USB Controller (NE)
AG-UC1000-SE	Aerogen USB Controller (SE)
AG-UC1000-SC	Aerogen USB Controller (SC)
AG-UC1000-RB	Aerogen USB Controller (RB)
AG-UC1000-CE	Aerogen USB Controller (CE)
AG-UC1000-EE	Aerogen USB Controller (EE)
AG-UC1000-IN	Aerogen USB Controller (IN)
AG-UC1500-UK	Aerogen Solo USB Controller Starter Kit (UK)
AG-UC1500-NE	Aerogen Solo USB Controller Starter Kit (NE)
AG-UC1500-SE	Aerogen Solo USB Controller Starter Kit (SE)
AG-UC1500-SC	Aerogen Solo USB Controller Starter Kit (SC)
AG-UC1500-RB	Aerogen Solo USB Controller Starter Kit (RB)
AG-UC1500-CE	Aerogen Solo USB Controller Starter Kit (CE)
AG-UC1500-EE	Aerogen Solo USB Controller Starter Kit (EE)
AG-UC1500-IN	Aerogen Solo USB Controller Starter Kit (IN)
AG-UC2000	Replacement Aerogen USB Controller
AG-UC2500-NE	Aerogen Solo USB Controller Starter Kit (NE)
AG-UC2500-SC	Aerogen Solo USB Controller Starter Kit (SC)
AG-UC2500-SE	Aerogen Solo USB Controller Starter Kit (SE)
AG-UC2500-UK	Aerogen Solo USB Controller Starter Kit (UK)
AG-UC2500-RB	Aerogen Solo USB Controller Starter Kit (RB)
AG-UC2500-CE	Aerogen Solo USB Controller Starter Kit (CE)
AG-UC2500-EE	Aerogen Solo USB Controller Starter Kit (EE)

Document Number:	Title:	Date of Issue / Edition	
252.509	Quality System Approval Certificate Medical Devices Directive 93/42/EEC	16 June 2015 /Cert-114: EC Annex II-NL-A4 (5)	
MD19.3129	Quality Management System - EN ISO 13485:2012	07 April 2016/13485 2012 NL A4	
CM19.3129	Quality Management System - ISO 13485:2003	07 April 2016/CMDCAS 13485 2003 SCC A4 (5)	
MD19.3129	Quality Management System - EN ISO 13485:2012		
CM19.3129	Quality Management System - ISO13485:2003		
Classification:	Class IIa (based on Rule 11 of Annex IX of MDD 93/42/EEC).		
GMDN Code	35457 (Nebuliser System, non-heated)		
Conformity Assessment Route:	Annex II		
Start of CE-Marking	August 2007		
Products Standards Applied: Reference RA018 Aerogen Solo Technical File Notified Body: National Standards Authority of Ireland (NSAI) 1 Swift Square, Northwood, Santry, Dublin 9, Ireland. (Notified Body No. 0050)			
Declaration: We, the manufacturer, declare that the stated medical devices meet the transposition into national law, the relevant provisions of the Council Directive 93/42/EEC of 14 June 1993 concerning Medical Devices. All supporting documentation is retained by the manufacturer.			
Place of Issue	Galway, Ireland	Signed for and on behalf of:	Aerogen Limited
Name	Function	Signature	Date
James Langan	QA/RA Manager		18-Apr-2016