MDD 93/42/EEC Declaration of Conformity

MANUFACTURER:	Novaerus Ireland, Ltd. DCU Innovation Campus, Old Finglas Road Glasnevin, Dublin 11, Ireland Phone: +35319072750
PRODUCTS:	Novaerus Infection Control Unit Model NV800
CLASSIFICATION & ANNEX:	Class I under Medical Device Directive (MDD) 93/42/EEC Rule 1 and Rule 12. The conformity assessment procedure per Article 11 for a Class I device is Annex II of the MDD 93/42/EEC.
DECLARATION:	We herewith declare that the above mentioned products meet the provisions of the Medical Device Directive (MDD) 93/42/EEC for medical devices. All supporting documentation is retained under the premises of the manufacturer.

STANDARDS APPLIED:	• ISO 14971: Medical Devices: Application of Risk Management to Medical Devices
	• IEC 60601: Medical electrical equipment
	  • Part 1: General requirements for basic safety and essential performance;
	  • Part 1-2: Collateral standard: Electromagnetic compatibility – requirements and tests
	• ISTA Procedure 2A Partial-Simulation Performance Test Procedure: Packaged Products 150lb (68 kg) or Less
	• UL 867: UL Standard for Safety for Electrostatic Air Cleaners, Section 40, Ozone Test, Fifth Edition
	• ISO 15223-1: Medical devices: Symbols to be used with medical device labels, labeling and information supplied – Part 1: General requirements.

START OF CE-MARKING:	JULY 2017
SIGNATURE:	Felipe Soberon Chief Technology Officer Felipe Soberon Novaerus, Inc.