


**MDD 93/42/EEC Declaration of Conformity**

<b>MANUFACTURER:</b>	Novaerus Ireland, Ltd. DCU Innovation Campus, Old Finglas Road Glasnevin, Dublin 11, Ireland Phone: +35319072750
<b>PRODUCTS:</b>	Novaerus Infection Control Unit Model NV800
<b>CLASSIFICATION &amp; ANNEX:</b>	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.
<b>DECLARATION:</b>	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.
<b>STANDARDS APPLIED:</b>	<ul style="list-style-type: none"><li>• ISO 14971: Medical Devices: Application of Risk Management to Medical Devices</li><li>• IEC 60601: Medical electrical equipment<ul style="list-style-type: none"><li>• Part 1: General requirements for basic safety and essential performance;</li><li>• Part 1-2: Collateral standard: Electromagnetic compatibility – requirements and tests</li></ul></li><li>• ISTA Procedure 2A Partial-Simulation Performance Test Procedure: Packaged Products 150lb (68 kg) or Less</li><li>• UL 867: UL Standard for Safety for Electrostatic Air Cleaners, Section 40, Ozone Test, Fifth Edition</li><li>• ISO 15223-1: Medical devices: Symbols to be used with medical device labels, labeling and information supplied – Part 1: General requirements.</li></ul>
<b>START OF CE-MARKING:</b>	JULY 2017
<b>SIGNATURE:</b>	 <hr/> Chief Technology Officer Felipe Soberon Novaerus, Inc.