# MDD 93/42/EEC Declaration of Conformity

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| **MANUFACTURER:** | Novaerus Ireland, Ltd.<br>DCU Innovation Campus,<br>Old Finglas Road<br>Glasnevin, Dublin 11, Ireland<br>Phone: +35319072750 |
| **PRODUCTS:** | Novaerus Infection Control Unit<br>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<br>• IEC 60601: Medical electrical equipment<br>  • Part 1: General requirements for basic safety and essential performance;<br>  • Part 1-2: Collateral standard: Electromagnetic compatibility – requirements and tests<br>• ISTA Procedure 2A Partial-Simulation Performance Test Procedure: Packaged Products 150lb (68 kg) or Less<br>• UL 867: UL Standard for Safety for Electrostatic Air Cleaners, Section 40, Ozone Test, Fifth Edition<br>• 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<br>Digitally signed by Chicu Natalia<br>Date: 2021.05.27 10:52:55 EEST<br>Reason: MoldSign Signature<br>Location: Moldova<br>Chief Technology Officer<br>Felipe Soberon<br>Novaerus, Inc. |