




NOVAERUS

LVD 2014/35/EU 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 NV200 |
| CLASSIFICATION & ANNEX: | Classified as a low voltage electrical equipment under Low Voltage Directive (LVD) 2014/35/EU Article 1. The conformity assessment procedure per Article 15 is Annex I of the LVD 2014/35/EU. |
| DECLARATION: | We herewith declare that the above mentioned products meet the provisions of the Low Voltage Directive (LVD) 2014/35/EU for products. All supporting documentation is retained under the premises of the manufacturer. |
| STANDARDS APPLIED: | <ul style="list-style-type: none">• ISO 14971: Medical Devices: Application of Risk Management to Medical Devices• IEC 61010: Safety requirements for electrical equipment for measurement, control, and laboratory use,<ul style="list-style-type: none">○ Part 1: General requirements• IEC 60601: Medical electrical equipment<ul style="list-style-type: none">○ 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, labelling and information supplied – Part 1: General requirements. |
| DATE OF ISSUE: | 31 March 2021 |
| SIGNATURE: |  Declan Kiely, Quality Director, Novaerus Ireland Ltd. |