




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• 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:	DECEMBER 2017
SIGNATURE:	 _____ Chief Technology Officer Felipe Soberon Novaerus, Inc.