NOVAERUS

European Union Declaration of Conformity

MANUFACTURER:	Novaerus Ireland, Ltd. Oyster Point, Temple Road Blackrock, Co Dublin, Ireland
EUROPEAN REPRESENTATIVE:	Novaerus Ireland, Ltd.
PRODUCTS:	Novaerus Air Purifier Defend NV1050
DECLARATION:	We herewith declare that the above-mentioned product has been successfully tested and meets the provisions of the following standards. All supporting documentation is retained under the premises of the manufacturer. The above-mentioned product has been prepared for submission for meeting the provisions of the Medical Device Directive (MDD) 93/42/EEC for medical devices. Once certified by the HPRA the above-mentioned product is anticipated to meet 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 VII of the MDD 93/42/EEC. The functionality and intended purpose for the NV1050 is similar to that of the Novaerus's previously certified Class I device, the NV800. Novaerus anticipates certification for the NV1050 to meet Class I under Medical Device Directive (MDD) 93/42/EEC Rule 1 and Rule 12.
STANDARDS APPLIED:	• IEC 60601: Medical electrical equipment, Part 1: General requirements for basic safety and essential performance; • ISO 14971: Medical Devices: Application of Risk Management to Medical Devices; • ISO 15223-1: Medical devices: Symbols to be used with medical device labels, labelling and information supplied – Part 1: General requirements
PLACE OF ISSUE:	Dublin, Ireland
DATE OF ISSUE:	27 March 2019
SIGNATURE:	

Declan Kiely
Quality Director, Novaerus Ireland Ltd.

NOVAERUS
Airborne Infection Control
Registered office: Oyster Point, Temple Road, Blackrock, Co. Dublin, Ireland
Company Registeration No: 509993 VAT Registration No: IE9820131Q