

European Union Declaration of Conformity

MANUFACTURER:

Novaerus Ireland, Ltd.

Oyster Point, Temple Road Blackrock, Co Dublin, Ireland

EUROPEAN

PRODUCTS:

Novaerus Ireland, Ltd.

REPRESENTATIVE:

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.

STANDARDS APPLIED:

- IEC 60601: Medical electrical equipment, Part 1: General requirements for basic safety and essential performance;
- IEC/EN 61010-1: Electrical Equipment For Measurement, Control and Laboratory Use, Part 1: General Requirements;
- 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:

September 2018

SIGNATURE:

Quality Director

Declan Kiely

Novaerus Ireland Ltd.