

## Certificate of Registration of Quality Management System to I.S. EN ISO 13485:2016

The National Standards Authority of Ireland certifies that:

Aerogen Limited Galway Business Park Dangan Galway Ireland

has been assessed and deemed to comply with the requirements of the above standard in respect of the scope of operations given below:

The Design and Development and Manufacturing of Aerosol Delivery Systems for Systemic Treatment and Drug Delivery.

Additional sites covered by this multi-site certification are listed on the Annex (File No. MD19.3129)

Approved by: Geraldine Larkin Chief Executive Officer, NSAI Approved by: Caroline Dore Geraghty Director of Medical Devices / Head of Notified Body

Certificate Number: MD19.3129 Certification Granted: 07 June 2000 Effective Date: 06 April 2021 Expiry Date: 27 February 2022



All valid certifications are listed on NSAI's website – <u>www.nsai.ie</u>. The continued validity of this certificate may be verified under "Certified Company Search"

NSAI (National Standards Authority of Ireland), 1 Swift Square, Northwood, Santry, Dublin 9, Ireland T +353 1 807 3800 E: <a href="mailto:info@nsai.ie">info@nsai.ie</a> www.nsai.ie NSAI Inc. 20 Trafalgar Square, Suite 603, Nashua, New Hampshire, NH 03063, USA T +1 603 882 4412 E: <a href="mailto:info@nsaiinc.com">info@nsaiinc.com</a> www.nsaiinc.com



Annex to Certificate Number: MD19.3129

## Scope of Registration:

The Design and Development and Manufacturing of Aerosol Delivery Systems for Systemic Treatment and Drug Delivery.

| Activity | Location |
|----------|----------|
| ACTIVITY | Location |

Headquarters, Administration, Design Aerogen Ltd.

Galway Business Park

Dangan Galway Ireland

File No.: MD19.3129

Manufacturing Aerogen Ltd.

M&M Qualtech Ltd.

Parkmore Business Park West

Ballybrit Co. Galway Ireland

File No.: MD19.3129/A

Administration, Design Aerogen Ltd.

Galway Business Park

Building 2 Dangan Galway Ireland

File No.: MD19.3129/B

Manufacturing Aerogen Ltd.

Shannon Industrial Estate

Shannon Co. Clare Ireland

File No.: MD19.3129/C

Verified by:

Operations Manager