

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Neuromod Devices Limited
Rainsford Street
Dublin
D08R2YP
Ireland

Facility ID Number: F007532

Holds Certificate No:

MDSAP 810818

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure

Canada: Medical Devices Regulations - Part 1 - SOR 98/282

USA: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

The design, development, manufacture and servicing of nerve and auditory stimulation devices for the treatment of neurological disorders.

For and on behalf of BSI:



Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2025-02-12

Effective Date: 2025-02-12

Expiry Date: 2028-02-11



BSI Group America Inc. is an MDSAP recognised auditing organization

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