

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Nox Medical
Katrínartúni 2
Reykjavík
IS-105
Iceland

Facility ID Number: F000342

Holds Certificate No:

MDSAP 688545

Statement of Conformity: The company listed on this certificate has been audited and found to conform with the following criteria: ISO 13485:2016 and 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; Japan - MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

The design and manufacture of pediatric and adult sleep diagnostic devices.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2019-04-04

Effective Date: 2022-04-04

Expiry Date: 2023-04-03



BSI Group America Inc. is an MDSAP authorized auditing organization

Page: 1 of 1

...making excellence a habit.™