Certificate GB22/00000455

The quality management system of



Signifier Medical Technologies Ltd

5-17 Hammersmith Grove The Triangle 6th Floor Hammersmith Grove London W6 0LG United Kingdom Facility number: F006384

has been assessed and certified as meeting the requirements of

MDSAP (ISO 13485:2016)

Australia: Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 - Full Quality Assurance System; Therapeutic Goods (Medical Devices) Regulations 2002 Canada: Medical Devices Regulations – Part 1 SOR 98/282

United States: 21 CFR Part 803 - Medical Device Reporting; 21 CFR Part 806 - Reports of Corrections and Removals; 21 CFR Part 807 (Subparts A to D) - Establishment Registration and Device Listing; 21 CFR Part 820 - Quality System Regulation

For the following activities

Design, development, manufacture and distribution of neuromuscular tongue stimulator devices to alleviate sleep disordered breathing

This certificate is valid from Effective date 2022-10-07 until Expiry date 2024-11-26 and remains valid subject to satisfactory surveillance audits.

Issue 1. Certified since 2022-10-07

Authorised by Geofrey De Visscher Head of Notified Body 1639

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SGS UK LTD is recognised under the Medical Devices Single Audit Program. The validity of this certificate can be verified at www.SGS.com SGS United Kingdom Ltd

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