

Certificate GB22/00000455

The quality management system of

Signifier Medical Technologies Ltd

SGS

7th Floor 107 Leadenhall Street London EC3A 4AF 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

Canada: Medical Device Regulations SOR/98-282, Part 1

USA: 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 2024-11-26 until Expiry date 2027-11-26 and remains valid subject to satisfactory surveillance audits.

Issue 2. Certified since 2022-10-07

L. Henderson

Authorised by

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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.



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