

Certificate US19/81841351

The quality management system of

RhythmLink International, LLC

SGS

1140 1st Street South, Columbia, SC, 29209, United States Of America
Facility number: F001596

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

Brazil: RDC ANVISA n. 665/2022 - Good Manufacturing Practices; RDC ANVISA n. 551/2021 - Field Actions; RDC ANVISA n. 67/2009 - Vigilance

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

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 Sterile Subdermal Needle Electrodes, EEG Electrode Template, EEG Electrode Headset, Electrode Cable, EMG Electrodes, Stimulating Probes, and Non-Sterile Cutaneous Electrodes in the area of Electromyography (EMG), Electroencephalograph (EEG) and Nerve Potential Signals.

This certificate is valid from Effective date 2025-01-10 until Expiry date 2028-01-10 and remains valid subject to satisfactory surveillance audits.

Issue 5. Certified since 2019-01-15

Certified activities performed by additional sites are listed on subsequent pages.

L. Henderson

Authorised by

Lynn Henderson

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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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Certificate US19/81841351, continued

Rhythmlink International, LLC



MDSAP (ISO 13485:2016)

Issue 5

Sites

Campus:

1130 First Street South, Unit B and C, Columbia, SC, 29209, United States Of America



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