CERTIFICATE OF REGISTRATION

Sunset Healthcare Solutions

180 N Michigan Ave
Suite 2000
Chicago, Illinois 60601 UNITED STATES

Facility ID: F005491

UL Medical Regulatory Services of UL LLC®(UL) issues this certificate to the Firm named above, after auditing the Firm's quality management system and finding it in conformance per the defined scope with respect to:

ISO 13485:2016

with additional regulatory requirements listed on final page of this certificate.

Design and manufactures of respiratory filters.

The contract manufacture and distribution of CPAP masks, tubing, TENS electronic pulse stimulators, handheld compressor nebulizers, nasal pillow cap masks, CPAP cleaners.

With additional locations listed on Addendum: 1

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Authorized by

Paul Hilgeman
Director & Global Industry Leader, Medical
CMIT – Medical Regulatory

Check Certificate Status:
here

File Number	A28936	Cycle Start Date	March 8, 2022
Certificate Number	3414.220308	Effective Date	March 8, 2022
Initial Issue Date	March 8, 2022	Expiry Date	March 7, 2025

This quality system registration is included in UL's Directory of Registered Firms and applies to the provision of goods and/or services as specified in the scope of registration from the address(es) shown above. By issuance of this certificate the firm represents that it will maintain its registration in accordance with the applicable requirements. This certificate is not transferable and remains the property of UL Medical and Regulatory Services of UL LLC.
Certificates may be verified by visiting the Online Certifications Directory on UL.com.

UL Medical and Regulatory Services UL, LLC is an MDSAP Recognized Auditing Organization

UL LLC
333 Pfingsten Road
Northbrook, IL 60062-2096 USA

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180 N Michigan Ave
Suite 2000
Chicago, Illinois 60601 UNITED STATES

Facility ID: F005491

Addendum 1

1-1
Facility ID: **F005491**

Sunset Healthcare Solutions
180 N Michigan Ave, Suite 2000
Chicago, Illinois 60601 UNITED STATES

Performing: Corporate headquarters, accounting, sales, customer service.

2-1
Facility ID: **F005898**

Sunset Healthcare Solutions
279 Madsen Drive, Suite 101
Bloomingdale, Illinois 60108 UNITED STATES

Performing: Design, manufacturing, repackaging, relabeling, distribution.

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Additional Regulatory Requirements

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

United States:
- 21 CFR 820
- 21 CFR 803
- 21 CFR 806
- 21 CFR 807 – Subparts A to D
- 21 CFR 821 (where applicable)

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