

Certificate of Registration

Certificate number

235428.260622

File number

A29365

Initial issue date

2017-12-27

Cycle start date

2023-12-27

Effective date

2026-06-22

Expiry date

2026-12-26

**Bunnell Inc.**330 North Cutler Drive
North Salt Lake, Utah 84054 UNITED STATES

Facility ID: F009176

UL LLC, UL Solutions medical and regulatory services issues this certificate to the Firm named above, after assessing the Firm's quality system and finding it in conformance per the defined scope with respect to:

ISO 13485:2016
EN ISO 13485:2016/A11:2021

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

The design, manufacture, and service of neonatal high frequency jet ventilator systems that include the neonatal high frequency ventilator, patient box, patient circuit kit and adapters; and provision of related training services for hospital personnel.

Certificate with Addendum(s) totals 3 pages.

Authorized by:

A handwritten signature in black ink, appearing to read 'P. Daysh'.

Paul Daysh

Operations manager – Medical Regulatory

Check certificate status: [here](#)

This quality system registration is included in UL's Product iQ directory and applies to the provision of goods and/or services as specified in the scope of registration from the address(es) shown. By issuance of this certificate, the firm represents that it will maintain its registration in accordance with the applicable requirements. This certificate is not transferrable and remains the property of UL Solutions.

UL LLC, UL Solutions medical regulatory services
is an MDSAP Recognized Auditing Organization

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

Addendum 1

Site	Company Name	Location	Performing
1-1	Bunnell Inc.	330 North Cutler Drive North Salt Lake Utah 84054 UNITED STATES Facility ID: F009176	Management, quality, purchasing, design and manufacturing of breathing circuits and adapters used in conjunction with high frequency jet ventilator systems.
1-2	Bunnell Inc.	360 North Cutler Drive North Salt Lake Utah 84054 UNITED STATES Facility ID: F009176	Receiving of raw materials, manufacturing, distribution and service of neonatal high frequency jet ventilator systems as well as the patient box accessories.

Additional Regulatory Requirements

Bunnell Inc.

330 North Cutler Drive
North Salt Lake, Utah 84054 UNITED STATES

Facility ID: F009176

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

United States:

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