

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Bunnell Incorporated

(F000762)

Main Site: 436 Lawndale Drive

Salt Lake City, Utah 84115 United States

has been registered by Intertek, an MDSAP recognized auditing organization, as conforming to the requirements of:

ISO 13485:2016

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6)

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)

The management system is applicable to:

The design, manufacture, installation, 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 Number:

0070398-04

Initial Certification Date:

2017-12-27

Date of Certification Decision:

2023-12-07

Certification Effective Date:

2023-12-26

Certification Expiry Date:

2026-12-26



intertek

Calin Moldovean

President, Business Assurance

Intertek Testing Services NA, Inc.
900 Chelmsford Street
Lowell, MA, USA 01851

