# CERTIFICATE OF REGISTRATION

## Flotec, Inc.

7625 W. New York St.
Indianapolis, Indiana 46214 UNITED STATES

REPs Facility ID: F001756

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.

The design, manufacture and servicing of compressed gas delivery systems, medical gas valves and mass casualty assemblies for the area of respiratory/pulmonary medicine and anaesthesiology.

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Authorized by

**Deborah Jennings-Conner**
**Global Regulatory Director**
UL Life and Health Sciences
UL LLC

Check Certificate Status: here

| | | | |
|---|---|---|---|
| File Number | A12714 | Cycle Start Date | October 28, 2020 |
| Certificate Number | 1435.210326 | Effective Date | March 26, 2021 |
| Initial Issue Date | October 15, 2018 | Expiry Date | October 27, 2021 |

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 REGISTERED FIRM

**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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## Flotec, Inc.

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**Additional Regulatory Requirements**

**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)

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