



# CERTIFICATE OF REGISTRATION

## Flotec, Inc.

7625 West 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.

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	1435.211028	Effective Date	October 28, 2021
Initial Issue Date	October 15, 2018	Expiry Date	October 27, 2022

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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### 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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