



Solutions

CERTIFICATE OF REGISTRATION

Flotec, Inc.

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

Facility ID: F001756

UL Medical Regulatory Services of UL LLC® (UL Solutions) 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
EN ISO 13485:2016

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

The design, manufacture and servicing of medical gas pressure regulator, flow meter, and mass casualty gas delivery assemblies for use in respiratory/pulmonary medicine and anesthesiology.

Authorized by



Paul Hilgeman
Senior Business Manager - Medical
CMIT – Medical Regulatory



Check Certificate Status:
[here](#)

File Number	A12714	Cycle Start Date	October 28, 2023
Certificate Number	1435.231028	Effective Date	October 28, 2023
Initial Issue Date	October 15, 2018	Expiry Date	October 27, 2026

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® (UL Solutions). 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 Solutions
333 Pfingsten Road
Northbrook, IL 60062-2096 USA



Solutions

CERTIFICATE OF REGISTRATION

Flotec, Inc.

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

Facility ID: F001756

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)

File Number	A12714	Cycle Start Date	October 28, 2023
Certificate Number	1435.231028	Effective Date	October 28, 2023
Initial Issue Date	October 15, 2018	Expiry Date	October 27, 2026

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® (UL Solutions). 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 Solutions
333 Pfingsten Road
Northbrook, IL 60062-2096 USA