



NSAI

Certificate of Registration of Quality Management System to ISO 13485:2016

Australia -Therapeutic Goods (Medical Devices) Regulations, 2002,

Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

Brazil - RDC ANVISA n. 665/2022 RDC ANVISA n. 551/2021 RDC ANVISA n. 67/2009

Canada - Medical Devices Regulations – Part 1- SOR 98/282

United States- 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A to D,

21 CFR 820 – Quality Management System Regulation

The National Standards Authority of Ireland is an MDSAP Recognized Auditing Organization and certifies that:

ClearFlow, Inc.
16 Technology Drive
Suite 150
Irvine, CA 92618
USA
Facility ID: F001017

The quality management system has been audited against stated criteria above and found to conform to the criteria for the scope listed below:

**The Design, Manufacture and Distribution of Sterile,
Disposable Chest Drainage Catheters and Systems.**

Approved by:
Pamela Burdette Miller
Certification Manager

Certificate Number: MP19.4770 / Rev 2

Certification Granted: 2018/07/06

Effective Date: 2026/04/03

Expiry Date: 2027/07/05



National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland T +353 1 807 3800
National Standards Authority of Ireland, 20 Trafalgar Square, Nashua, New Hampshire, NH 03063, USA T +1 603 882 4412

All valid certifications are listed on NSAI's website – www.nsaiinc.com and may be verified under "Approved Client Listing"