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. 16/2013 RDC ANVISA n. 23/2012 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 System Regulation

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

ClearFlow, Inc.
1630 S. Sunkist Street
Suite E
Anaheim, CA 92806
USA
D-U-N-S: 827428223

has been assessed and deemed to comply with the requirements of the above standard and regulations in respect of the scope of operations given below:

The design, manufacture and distribution of sterile, disposable chest drainage catheters and systems.

Approved by:
Geraldine Larkin
Chief Executive Officer

Approved by:
Eoin Banville
Operations Manager,
Medical Devices

Certificate Number: MP19.4770/Rev 1
Certification Granted: 2018/07/06
Effective Date: 2018/07/06
Expiry Date: 2021/07/05

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
The continued validity of this certificate may be verified under "Approved Client Listing