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 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

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:
Kevin Mullaney
Director of Certification

Certificate Number: MP19.4770 / Rev 1
Certification Granted: 2018/07/06
Effective Date: 2024/07/06
Expiry Date: 2027/07/05

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