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
Japan - MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act (,as applicable)
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:

Alcor Scientific LLC
20 Thurber Boulevard
Smithfield, RI 02917
USA
Facility ID: F002399

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:

Design, Manufacture and Distribution of IVD Systems for Haematology.

Approved by:
Kevin Mullaney
Director of Certification

Certificate Number: MP19.4997 / Rev 2
Certification Granted: 2020/02/25
Effective Date: 2025/08/19
Expiry Date: 2026/02/24

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