



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.

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:

Medical Predictive Science Corporation

1233 Cedars Court

Suite 201

Charlottesville, VA 22903

USA

Facility ID: F002853

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 Automated Systems for the Monitoring and Evaluation of Neonatal and Paediatric Heart Rate Variability.

Approved by:
Kevin Mullaney
Director of Certification

Certificate Number: MP19.4577 / Rev 2

Certification Granted: 2019/06/05

Effective Date: 2023/06/05

Expiry Date: 2025/06/04



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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"