Certificate of Registration of Quality Management System to I.S. EN ISO 13485:2016

The National Standards Authority of Ireland certifies that:

FUJIFILM Irvine Scientific, Inc.
2511 Daimler Street
Santa Ana, CA 92705
USA

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

The Design, Development, Manufacture, Contract Manufacture and Distribution of Medical Devices Consisting of Tissue Culture Products, In-Vitro Diagnostic Devices for use in Genetic Testing of Various Hematological Disorders, and Assisted Reproductive Products for In-Vitro Fertilization use.

Additional sites covered under this multi-site certification are listed on the Annex (File No. MD19.2686)

Approved by:
Geraldine Larkin
Chief Executive Officer

Approved by:
Caroline Dore Geraghty
Director of Medical Devices /
Head of Notified Body

Registration Number: MD19.2686
Certification Granted: April 29, 1998
Effective Date: August 2021
Expiry Date: August 28, 2024

National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland T +353 1 807 3800

Annex to Certificate Number: MD19.2686

Scope of Registration:

The Design, Development, Manufacture, Contract Manufacture and Distribution of Medical Devices Consisting of Tissue Culture Products, In-Vitro Diagnostic Devices for use in Genetic Testing of Various Hematological Disorders, and Assisted Reproductive Products for In-Vitro Fertilization use.

Activity	Location
Headquarters, Manufacturing	FUJIFILM Irvine Scientific, Inc. 2511 Daimler Street Santa Ana, CA 92705 USA File No.: MP19.2686 Facility ID: F001579
Administration, Warehouse, Distribution	FUJIFILM Irvine Scientific, Inc. 1830 Warner Street Santa Ana, CA 92705 USA File No.: MP19.2686/A Facility ID: F001579
Administration, Manufacturing, Warehouse, Distribution	FUJIFILM Irvine Scientific, Inc. 2601 Daimler Street Santa Ana, CA 92705 USA File No.: MP19.2686/B Facility ID: F001579
Design and Development	FUJIFILM Irvine Scientific, Inc. 17112 Armstrong Irvine, CA 92614 USA File No.: MP19.2686/D Facility ID: F001579

Annex to Certificate Number: MD19.2686

Scope of Registration:

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Activity	Location
Administration, Packaging,	FUJIFILM Irvine Scientific, Inc. 1800/1802 Carnegie Santa Ana, CA 92705 USA File No.: MD19.2686/E
Administration, Warehouse,	FUJIFILM Irvine Scientific, Inc. 1880 E St Andrew Pl Santa Ana, CA 92705 USA File No.: MD19.2686/F

Verified by:
Operations Manager

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 Recognized Auditing Organization and certifies that:

FUJIFILM Irvine Scientific, Inc.
2511 Daimler Street
Santa Ana, CA 92705
USA
Facility ID: F001579

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, Development, Manufacture and Distribution of Medical Devices Consisting of Tissue Culture Products, In-Vitro Diagnostic Devices for use in Genetic Testing of Various Hematological Disorders, and Assisted Reproductive Products for In-Vitro Fertilization use.

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Approved by:
Geraldine Larkin
Chief Executive Officer

Approved by:
Caroline Dore Geraghty
Director of Medical Devices /
Head of Notified Body

Certificate Number: MP19.2686 / Rev 1
Certification Granted: 2018/08/29
Effective Date: 2021/08/29
Expiry Date: 2024/08/28

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

Annex to Certificate number: MP19.2686 / Rev 1

Scope of Registration:

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Operations Manager