



NSAI

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:
Kevin Mullaney
Director of Certification

Registration Number: MD19.2686
Certification Granted: April 29, 1998
Effective Date: August 29, 2024
Expiry Date: August 28, 2027





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Annex to Certificate Number: MD19.2686

Facility Locations, Scope and Activities

2511 Daimler Street, Santa Ana, CA 92705, USA
File No.: MD19.2686

Scope:

The Manufacture 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.

1830 Warner Street, Santa Ana, CA 92705, USA
File No.: MD19.2686/A

Scope:

The Storage 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.

2601 Daimler Street, Santa Ana, CA 92705, USA
File No.: MD19.2686/B

Scope:

The Storage, Distribution, and Manufacturing 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.

17112 Armstrong Avenue, Irvine, CA 92614, USA
File No.: MD19.2686/D

Scope:

The Design and Development 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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Annex to Certificate Number: MD19.2686 / Rev 1

Facility Locations, Scope and Activities

1800/1802 Carnegie Avenue, Santa Ana, CA 92705, USA
File No.: MD19.2686/E

Scope:

The Label Printing 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.

1880 E St Andrew Pl, Santa Ana, CA 92705, USA
File No.: MD19.2686/F

Scope:

The Storage 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.

1700 Carnegie Avenue, Santa Ana, CA 92705, USA
File No.: MD19.2686/G

Scope:

The Inspection 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.

**Verified by:
Director of Certification**