

NSAI

Certificate of Registration of Quality Management System to ISO 13485:2016

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,

21 CFR 821 - Device Tracking

The National Standards Authority of Ireland is an MDSAP Authorized Auditing Organization and certifies that:

Irvine Scientific
2511 Daimler Street
Santa Ana, CA 92705
USA

D-U-N-S: 057475246

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.

Additional sites covered under this multi-site certification are listed on the Annex (File No. MP19.2686)

Approved by:
Geraldine Larkin
Chief Executive
Officer

Approved by:
Eoin Banville
Operations Manager,
Medical Devices

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



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.nsa-inc.com
The continued validity of this certificate may be verified under "Approved Client Listing"



NSAI

Annex to Certificate number: MP19.2686/Rev 1

Scope of Registration:

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.

Activity

Location

Headquarters, Production

Irvine Scientific
2511 Daimler Street
Santa Ana, CA 92705
USA
File No: MP19.2686
D-U-N-S: 057475246

Management, RA, Storage,
Distribution

Irvine Scientific
1830 Warner Street
Santa Ana, CA 92705
USA
File No: MP19.2686/A
D-U-N-S: 057475246

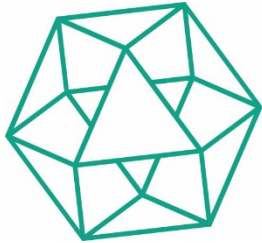
Purchasing, Production, Storage,
Distribution

Irvine Scientific
2601 Daimler Street
Santa Ana, CA 92705
USA
File No: MP19.2686/B
D-U-N-S: 057475246

Design, Development, Marketing,
Sales

Irvine Scientific
17112 Armstrong
Irvine, CA 92614
USA
File No.: MP19.2686/D
D-U-N-S: 057475246

**Verified by:
Operations Manager**



NSAI

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

The National Standards Authority of Ireland certifies that:

Irvine Scientific
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:
Susan Murphy
European Medical Device
Operations Manager

Registration Number: MD19.2686
Certification Granted: Apr 29, 1998
Effective Date: Aug 29, 2018
Expiry Date: Aug 28, 2021



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



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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

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

Administration, Distribution

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

Manufacturing, Distribution

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

Design, Development

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

**Verified by:
Operations Manager**