



NSAI

Certificate of Registration of Quality Management System to I.S. EN ISO 13485:2012

The National Standards Authority of Ireland certifies that:

Irvine Scientific
2511 Daimler Street
Santa Ana, CA 92705-5533
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 Attachment 1 (File No.MD19.2686)

Approved by:
Kevin D. Mullaney
Chief Executive Officer

Approved by:
Susan Murphy
Risk Management Officer

Registration Number: MD19.2686

Certification Granted: Apr 29, 1998

Effective Date: Aug 29, 2015

Expiry Date: Aug 28, 2018



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



NSAI

Attachment 1 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, Design,
Development and Distribution

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

Distribution

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

**Verified by:
Operations Manager**