Quality System Approval Certificate
Medical Devices Directive 93/42/EEC

*The National Standards Authority of Ireland as a duly designated Notified Body, (identification number **0050**), for the purposes of the European Communities (Medical Devices) Regulations (S.I. No. 252 of 1994)*

APPROVES THE QUALITY SYSTEM APPLIED BY

FUJIFILM Irvine Scientific, Inc

2511 Daimler Street
Santa Ana
CA 92705
USA

to the Product Family

IVF Medium

GMDN Code: 44046

on the basis of examination under the requirements of Directive 93/42/EEC on Medical Devices, Annex II, excluding (4)

*The use of the NSAI Notified Body identification number **0050** in conjunction with CE Marking of Conformance for this product family is hereby authorised.*

Registration Number:	**252.802**
Original Approval:	**9 March 2010**
Last Amended on:	**15 October 2019**
Remains valid until:	**8 March 2024**

Signed:

Approved by:
Geraldine Larkin
Chief Executive Officer, NSAI

Approved by:
Elaine Darcy
European Medical Device Operations Manager

This certificate remains valid on condition that the Approved Quality System is maintained in an adequate and efficacious manner.
Details of the operational locations included within the scope of this approval can be obtained from NSAI

In the case of a Class III device, this certificate must be supported by a valid design examination certificate

National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland.

Attachment to Certificate 252.802 dated 09 March 2010

This Certificate covers 1 model(s)

Model Reference	Detail
9305	Oil for Embryo Culture

Last Amended Date: 09 March 2010
Date of Printing: 15 March 2010