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 Media/Devices

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:	**252.375**
Original Approval:	**14 November 2000**
Last Amended on:	**24 September 2019**
Remains valid until:	**13 November 2023**

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 252.375 dated 14 November 2000

This Certificate covers 7 model(s)

Model Reference	Detail
99264	ISolate® (2-layer kit)
99275	ISolate® (Stock Solution)
99306	Sperm Separation Concentrate
99252	Acidified Tyrode's Solution
99168	Modified Ham's F-10 Basal-HEPES
99175	Modified Ham's F-10 Basal
40709	CryoTip™

Last Amended Date: 23 November 2010
Date of Printing: 28 September 2011