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

Reproductive Laboratory Products containing Gentamicin Sulphate and Human tissues/plasma (Complete ECM®, Complete Multiblast®, Blastocyst Thaw, Embryo Thaw, Vit Kit® Freeze/Thaw, Continuous Single Culture™ Medium Complete, Continuous Single Culture™ -NX Complete, Multipurpose Handling Medium™ Complete, Embryo Biopsy 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:	**252.794**
Original Approval:	**15 December 2009**
Last Amended on:	**11 October 2019**
Remains valid until:	**14 December 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.

EC Design Examination Certificate

2000/70/EC

*The National Standards Authority of Ireland as a duly designated Notified Body, (identification number **0050**), for the purposes of the European Communities (Medical Devices incorporating stable derivatives of human blood or plasma) Regulations (S.I. No. 576 of 2002)*

HAS EXAMINED THE DESIGN DOSSIER
Submitted by

FUJIFILM Irvine Scientific, Inc

2511 Daimler Street
Santa Ana
CA 92705
USA

For Product Family

Reproductive Laboratory Products containing Gentamicin Sulphate and Human tissues/plasma (Complete ECM®, Complete Multiblast®, Blastocyst Thaw, Embryo Thaw, Vit Kit® Freeze/Thaw, Continuous Single Culture™ Medium Complete, Continuous Single Culture™ -NX Complete, Multipurpose Handling Medium™ Complete, Embryo Biopsy Medium)

GMDN Code: 44046

CONCLUSION OF EXAMINATION:

complies with the requirements of Annex II, Section 4.3 of Directive 2000/70/EC

Registration Number:	**252.794**
Original Registration:	**15 December 2009**
Last Amended on:	**11 October 2019**
Remains valid until:	**14 December 2023**

Signed:

Approved by:
Geraldine Larkin
Chief Executive Officer, NSAI

Approved by:
Elaine Darcy
European Medical Device Operations Manager

CONDITIONS OF VALIDITY:

This certificate remains valid on condition that the Approved Quality System is maintained in an adequate and efficacious manner

Note: Changes which could affect conformity with the essential requirements of Directive 2000/70/EC or with the conditions prescribed for use of the product must receive further approval from NSAI.

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

EC Design Examination 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)*

HAS EXAMINED THE DESIGN DOSSIER
Submitted by

FUJIFILM Irvine Scientific, Inc

2511 Daimler Street
Santa Ana
CA 92705
USA

For Product Family

Reproductive Laboratory Products containing Gentamicin Sulphate and Human tissues/plasma (Complete ECM®, Complete Multiblast®, Blastocyst Thaw, Embryo Thaw, Vit Kit® Freeze/Thaw, Continuous Single Culture™ Medium Complete, Continuous Single Culture™ -NX Complete, Multipurpose Handling Medium™ Complete, Embryo Biopsy Medium)

GMDN Code: 44046

CONCLUSION of EXAMINATION:

NSAI have performed an examination of the design dossier relating to the above named product family and conclude that the design complies with the requirements of Directive 93/42/EEC on Medical Devices, Annex II (4)

Registration Number:	**252.794**
Original Approval:	**15 December 2009**
Last Amended on:	**11 October 2019**
Remains valid until:	**14 December 2023**

Signed:

Approved by:
Geraldine Larkin
Chief Executive Officer, NSAI

Approved by:
Elaine Darcy
European Medical Device Operations Manager

CONDITIONS OF VALIDITY:

This certificate remains valid on condition that the Approved Quality System is maintained in an adequate and efficacious manner. Approved model numbers are included in the associated attachment

Note: Not valid without a valid Annex II Section 3 Certificate.

Changes which could affect conformity with the essential requirements of Directive 93/42/EEC or with the conditions prescribed for use of the product must receive further approval from NSAI.

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

Attachment to Certificate 252.794 dated 15 December 2009

This Certificate covers 12 model(s)

Model Reference	Detail
90110	Blastocyst Thaw Media - contains: • 3x10mL, Blastocyst Thaw – T1, Catalog #90104 • 3x10mL, Blastocyst Thaw – T2, Catalog #90106
90124	Embryo Thaw Media – contains: • 2x10mL, Embryo Thaw – T1, Catalog #90118 • 2x10mL, Embryo Thaw – T2, Catalog #90120 • 2x10mL, Embryo Thaw – T3, Catalog #90122
90142	• 2x20mL, Complete Early Cleavage Medium® (ECM®) with Dextran Serum Supplement (DSS)
90143	• 2x20mL, Complete MultiBlast Medium® with Dextran Serum Supplement (DSS)
90133	Vit Kit® - Freeze – Vitrification Freeze, #90133-SO–contains: • 2x1mL, Equilibration Solution, ES, Catalog #90131 • 2x1mL, Vitrification Solution, VS, Catalog #90132 Vit Kit® - Freeze – Vitrification Freeze, #90133-DSOC–contains: • 9x1mL Equlibration Solution, ES, Catalog #90131 • 9x1mL Vitrification Solution, VS, Catalog #90132
90137	Vit Kit® - Thaw – Vitrification Thaw, #90133-SO–contains: • 4x2mL, Thawing Solution, TS, Catalog #90134 • 1x2mL, Dilution Solution, DS, Catalog #90135 • 1x2mL, Washing Solution, WS, Catalog #90136 Vit Kit® - Thaw – Vitrification Thaw, #90133-DSOC–contains: • 8x2mL, Thawing Solution, TS, Catalog #90134 • 5x2mL, Dilution Solution, DS, Catalog #90135 • 5x2mL, Washing Solution, WS, Catalog #90136
90165	• 2x20mL Continuous Single Culture™ Complete
90166	• 100mL, Multipurpose Handling Medium Complete • 500mL, Multipurpose Handling Medium Complete

Attachment to Certificate 252.794 dated 15 December 2009

This Certificate covers 12 model(s)

Model Reference	Detail
	• 12x12mL, Multipurpose Handling Medium Complete
90103	• 2x20mL, Embryo Biopsy Medium
90168	• 2x20mL, Continuous Single Culture – NX Complete, CSCM-NXC
90183	Vit Kit – Warm NX – contains: • 6x2mL Thawing NX – TS • 2x1mL Dilution NX – DS • 4x1mL Washing NX – WS Vit Kit – Warm NX Single Solution Packages – contains: • 20mL Thawing NX – TX • 20mL Dilution NX – DS • 20mL Washing NX – WS
90188	Vit Kit – Freeze NX – contains: • 3x1mL Washing NX – WS • 3x1mL Equilibration NX - ES • 1x1mL Vitrification NX – VS