



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 Product Containing Gentamicin Sulphate, Human Tissue/Plasma and Tissue of Animal Origin

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:	252.896
Original Approval:	23 December 2013
Last Amended on:	10 December 2019
Remains valid until:	22 December 2021

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

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 Product Containing Gentamicin Sulphate,
Human Tissue/Plasma and Tissue of Animal Origin**

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: 252.896

Original Approval: 23 December 2013

Last Amended on: 10 December 2019

Remains valid until: 22 December 2021

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.



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 Product Containing Gentamicin Sulphate,
Human Tissue/Plasma and Tissue of Animal Origin**

GMDN Code: 44046

CONCLUSION OF EXAMINATION:

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

Registration Number: 252.896

Original Registration: 23 December 2013

Last Amended on: 10 December 2019

Remains valid until: 22 December 2021

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

722/2012

*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. 554 of 2003)*

HAS EXAMINED THE DESIGN DOSSIER

Submitted by

FUJIFILM Irvine Scientific, Inc

2511 Daimler Street

Santa Ana

CA 92705

USA

For Product Family

**Reproductive Laboratory Product Containing Gentamicin Sulphate,
Human Tissue/Plasma and Tissue of Animal Origin**

GMDN Code: 44046

CONCLUSION of EXAMINATION:

Complies with the Annex requirements of Regulation 722/2012

Registration Number: 252.896

Original Registration: 23 December 2013

Last Amended on: 10 December 2019

Remains valid until: 22 December 2021

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 93/42/EEC and/or Regulation 722/2012,
or with the conditions prescribed for use of the product must receive further approval from NSAI.

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



Attachment to Certificate 252.896 dated 23 December 2013

This Certificate covers 1 model

Model Reference

Detail

90101

Hyaluronidase Solution