FUJIFILM
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IrvineScientific

FUJIFILM Irvine Scientific, Inc.
1830 East Warner Ave
Santa Ana, CA 92705

Self-Declaration of Compliance towards Provisions under Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 (Fulfillment of Extension Conditions)

This Self-Declaration is to declare under the sole responsibility of FUJIFILM Irvine Scientific, Inc. that the devices listed in Certificate No. 252.760 (IVF Medium containing Human Tissues/Plasma - See below for details) are in compliance with the Regulation (EU) 2023/607 amending Regulation (EU) 2017/745.

The devices included in the Certificate No. 252.760, IVF Medium containing Human Tissues/Plasma, were approved under MDD 93/42/EEC by the National Standards Authority of Ireland (NSAI) and had a valid certificate until September 05, 2022 The devices continue to comply with MDD 93/42/EEC. There have been no significant changes in the design and intended use.

FUJIFILM Irvine Scientific assures that these devices do not pose an unacceptable risk to the health, safety, or public health of patients, users, or others.

FUJIFILM Irvine Scientific implemented Quality Management System in accordance with MDR Article 10 (9).

An official application for conformity assessment in accordance with EU 2017/745 (MDR) Section 4.3, first subparagraph of Annex VII related to the devices as identified in the Table 1 below has been submitted on February 1, 2021 to the Notified Body, National Standards Authority of Ireland (NSAI) located in 1 Swift Square, Northwood, Santry, Dublin 9, Ireland.

Table 1. Devices covered by this declaration and covered in the official application:

Description	MDR Device Classification	Catalog Number	Packaging Size	Basic UDI-DI
Sperm Washing Medium	III	9983	100 mL	00893727002071
		9983	12x12mL	00893727002088
7% Polyvinylpyrrolidone with Human Serum Albumin	III	90121	5x0.5mL	00893727002163
10% Polyvinylpyrrolidone with Human Serum Albumin	III	90123	5x0.5mL	00893727002170
Arctic Sperm Cryopreservation Medium	III	90170	12x5mL	00857515006252

FUJIFILM Irvine Scientific has a signed written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following Notified Body on June 6, 2022:

National Standards Authority of Ireland (NSAI)
Notified Body identification number 0050
1 Swift Square,
Northwood, Santry,
Dublin 9, Ireland
Telephone: +353 (0)1 807 3800
Fax: +353 (0)1 807 3844
Email: medical.devices@nsai.ie

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Devices covered by this declaration meet all extension conditions and conditions specified in Regulation (EU) 2023/607. Therefore, the transition timeline of 31 December 2027 for Class III device apply to the devices covered by this declaration.

Signature and Date of Signature:

11/07/2023
Date

Chief Compliance & Quality Officer, CQO

Notified Body Contact Information:
National Standards Authority of Ireland (NSAI)
1 Swift Square,
Northwood, Santry,
Dublin 9, Ireland
Telephone: +353 (0)1 807 3800
Fax: +353 (0)1 807 3844
For confirmation of content of this declaration, please email: medical.devices@nsai.ie

Authorized Representative Information:
Emergo Europe
Westervoortsedijk 60
6827 AT Arnhem
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Tel: (31) (0) 70 345-8570
Email: EmergoVigilance@ul.com