EC CERTIFICATE

Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
246961-2017-CE-NOR-NA-PS Rev.2.0	PRJC-470047-2013-MSL-NOR	27 May 2024

This is to certify that the quality system of:

Vitrolife Sweden AB

Gustaf Werners gata 2, 421 32 Västra Frölunda, Sweden

For design, production and final product inspection/testing of:
In Vitro Fertilisation System

Has been assessed with respect to:
THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN ANNEX II OF COUNCIL DIRECTIVE 93/42/EEC ON MEDICAL DEVICES, AS AMENDED

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 20 October 2020

For:
DNV GL PRESAFE AS

Notified Body No.: 2460

Cathrine Wisbech

The certificate is digitally verified by blockchain technology. For more info, see www.dnvgl.com/assurance/certificates-in-the-blockchain.html

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Replaces certificate 11593-2007-CE-NOR Rev. 13.0 (NB 0434) following transfer of Notified Body functions to DNV GL Nemko Presafe AS (NB 2460)	2017-11-14
1.0	Editorial changes	2017-12-04
2.0	Recertification	2020-10-20

Products covered by this Certificate:

Product Description	Product Name	Class
In Vitro Fertilisation System	IVF media containing human serum albumin • G-MOPS™ PLUS handling medium • G-1™ PLUS cleavage medium • G-2™ PLUS culture medium for blastocysts • G-IVF™ PLUS fertilization medium • HSA-solution™ supplementation medium • FreezeKit™ Cleave embryo freezing solutions • THAW-KIT 1™ embryo thawing solutions • ThawKit™ Cleave embryo thawing solutions • RapidVit™ Blast embryo vitrification solutions • RapidWarm™ Blast embryo warming solutions • RapidVit™ Cleave embryo vitrification solutions • RapidWarm™ Cleave embryo warming solutions • G-GAMETE™ gamete preparation medium • SpermRinse™ sperm preparation medium • HYASE™-10X denudation of oocytes • SpermFreeze Solution™ medium for sperm cryopreservation • G-TL™ medium for culture of embryos from fertilization to the blastocyst stage • RapidVit™ Oocyte media for vitrification of oocytes • RapidWarm™ Oocyte media for warming of vitrified oocytes • RapidVit™ Omni media for vitrification • RapidWarm™ Omni media for warming	III*
	IVF media containing recombinant human albumin: • EmbryoGlue® medium for embryo transfer • ICSI™ medium for use in ICSI • G-MM™ supplementation medium	III*

In Vitro Fertilisation System	IVF media which must be supplemented with HSA-solution™ or G-MM™ prior to use: • G-1™ cleavage medium • G-2™ culture medium for blastocysts • G-IVF™ fertilization medium • G-MOPS™ handling medium • G-PGD™ embryo biopsy medium	III*
	IVF media not containing human serum albumin/recombinant human albumin, and not to be supplemented prior to use: • ASP™ oocyte retrieval and rinsing • G-RINSE™ for rinsing of contact materials and for washing of the cervix	III*
	IVF media not containing human serum albumin/recombinant human albumin, and not to be supplemented prior to use: • SpermGrad™ medium for gradient sperm separation	IIb
	IVF media not containing human serum albumin/recombinant human albumin, and not to be supplemented prior to use: • OVOIL™ for covering of medium during IVF • OVOIL HEAVY™ for covering of medium during IVF and micro-manipulation procedures	IIa

* Design assessment is covered by a separate EC-Design Examination Certificate No.: 241688-2017-CE-NOR-NA-PS Rev. 2.0

Sites covered by this certificate

Site Name	Address
Vitrolife Sweden AB (visiting address)	Gustaf Werners gata 2, SE-421 32 Västra Frölunda, Sweden
Vitrolife Sweden AB (postal address)	Box 9080, SE-400 92 Göteborg, Sweden

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate