EC DESIGN
Examination Certificate

Certificate No.:	Project No.:	Valid Until:
241688-2017-CE-NOR-NA-PS Rev. 2.0	PRJC-470047-2013-MSL-NOR	27 May 2024

This is to certify that:

In Vitro Fertilisation System

Manufactured by:

Vitrolife Sweden AB

Gustav Werners gata 2, 421 32 Västra Frölunda, Sweden

Has been assessed with respect to:

EXAMINATION OF THE DESIGN OF THE PRODUCT AS DESCRIBED IN ANNEX II SECTION 4 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

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

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.
NOTIFIED BODY: DNV GL PRESAFE AS, Veritasveien 3, N-1363 Høvik, Norway - Registered Enterprise No: NO 997 067 401 MVA .

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-D (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:

Type of medical device and identification no.:	Medical Device Class:	GMDN code:
In Vitro Fertilization System	III	
Short description of the Medical Device:		

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
- 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
- HSA-solution™ supplementation medium
- SpermRinse™ sperm preparation medium
- HYASE™-10X denudation of oocytes
- SpermFreeze Solution™ medium for sperm cryopreservation
- RapidVit™ Oocyte media for vitrification of oocytes
- RapidWarm™ Oocyte media for warming of vitrified oocytes
- G-TL™ medium for culture of embryos from fertilization to the blastocyst stage
- RapidVit™ Omni media for vitrification
- RapidWarm™ Omni media for warming

IVF media containing recombinant human albumin:

- EmbryoGlue® medium for embryo transfer

- ICSI™ medium for use in ICSI
- G-MM™ supplementation medium

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

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

The In vitro fertilization culture media is for the different procedures and for the individual stages of embryo development. The composition for each medium is given in the product specification.

Some of the media contains Human Serum Albumin (HSA) or recombinant human albumin (rHA) or must be supplemented with HSA or recombinant human albumin prior to use. The HSA/rHA has several functions in the IVF media, it acts in the colloid osmotic regulation, as a pH buffer, membrane stabilizer, carrier of growth promoting substances, surfactant, scavenger and as a nutrient. The function of HSA/rHA is not differentiated between the different medical devices used for the IVF procedures. The justification and safety for HSA/rHA respectively have been evaluated by EMA and a positive scientific opinion has been received.

Some media contain gentamicin or penicillin G to secure sterility in the solution during the IVF procedure.

The ASP™ oocyte retrieval and rinsing medium contains heparin as an anticoagulation factor. The justification and safety have been evaluated by the Swedish competent authority and a positive scientific opinion has been received.

The FreezeKit™ Cleave embryo freezing solutions and ThawKit™ Cleave embryo thawing solutions have a new buffer system, changed concentrations of cryoprotectants, and includes several new components compared to the THAW-KIT 1™ embryo thawing solutions. The system is optimized by reduced number of solutions used for freezing and thawing. The changes have generated a more physiological and cryoprotective environment similar to the composition of the G-Series media from Vitrolife.

The kits RapidVit™ Oocyte and RapidWarm™ Oocyte is for vitrification and warming of vitrified human oocytes, respectively.

RapidVit™ Omni and RapidWarm™ Omni are combined media for vitrification and warming of oocytes, cleavage stage and blastocyst stage embryos.

The G-TL™ is a medium for culture of embryos from fertilization to the blastocyst stage.

The IVF medium HYASE™-10X contains derivative from ovine and bovine species. Procedure according to the Commission Regulation (EU) No 722/2012 has been followed. The material is covered by an EDQM certificate.

The components are manufactured by aseptic filtering.

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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 inform Presafe of any intended change of the products detailed above and Presafe will assess the changes and decide if the certificate remains valid.

The following may render this Certificate invalid:

- Changes in the design of the products to which this Certificate refers.
- Changes in requirements of the scheme to which this Certificate refers.

Conformity declaration and marking of product

This Certificate must be accompanied with a valid EC Certificate Full Quality Assurance System.

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