DNV BUSINESS ASSURANCE

EC CERTIFICATE - FULL QUALITY ASSURANCE SYSTEM

Certificate No. 11593-2007-CE-NOR Rev. 12.0
This Certificate consists of 4 pages

This is to certify that the Quality Management System of

VITROLIFE SWEDEN AB

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 Article 11.1.a and Annex II (Module H1) and Article 11.3.a and Annex II excluding section 4 (Module H) of Council Directive 93/42/EEC on Medical Devices, as amended, and found to comply

Further details are given overleaf

Place and date:
Høvik, 15 April 2016

For DNV GL BUSINESS ASSURANCE
NORWAY AS

Mariann Jeremiassen
Certification Manager

NORWEGIAN ACCREDITATION
PROD 002

Notified Body No.:
0434

This Certificate is valid until:
05 July 2021

Aud Løken Eiklid
Technical Reviewer

This Certificate has been digitally signed. See www.dnv.com/digitalsignatures for more info

Jurisdiction

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

Certificate history

Products covered by this Certificate

Revision	Description	Issue Date
	First certificate issued	2006-07-05
1.0	Original Certificate	2007-11-08
2.0	Adding of new components to the device	2008-03-13
3.0	Manufacturer address changed and new devices included	2009-03-19
4.0	Changes in product names - version numbers for G-1, G-2 are removed	2010-01-20
5.0	Adding of new component to the device	2010-12-17
6.0	Recertification of the IVF media	2011-07-05
7.0	Change in product name	2012-03-21
8.0	Adding of new components to the device	2012-10-23
9.0	Adding of new devices	2014-01-31
10	Including both visiting and postal address	2015-02-20
11	Recertification of the IVF media	2016-07-05
12	**Adding of new components to the device (in bold)**	**2016-04-15**

Product Description	Product	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 • FREEZE-KIT 1™ embryo freezing solutions • 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	Class III*

In Vitro Fertilisation System	• G-GAMETE™ gamete preparation medium • IVF™ fertilization and cleavage medium • SpermRinse™ sperm preparation medium • HYASE™-10X denudation of oocytes • CCM™ embryo culture medium • 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** IVF media containing recombinant human albumin: • EmbryoGlue® medium for embryo transfer • ICSI™ medium for use in ICSI 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 • G-FreezeKit Blast™ blastocyst freezing media • G-ThawKit Blast™ blastocyst thawing media	Class III*
In Vitro Fertilisation System	IVF media not containing human serum albumin/recombinant human albumin, and not to be supplemented prior to use: • ASP™ oocyte retrieval and rinsing	Class III*
In Vitro Fertilisation System	• SpermGrad™ medium for gradient sperm separation	Class IIb
In Vitro Fertilisation System	• OVOIL™ for covering of medium during IVF	Class IIa
In Vitro Fertilisation System	• G-RINSE™ medium for rinsing	Class Is

*Design assessment is covered by a separate design examination certificate no 11593-2007-CE-NOR-D

The complete list of devices is filed with the Notified Body.

Sites covered by this certificate

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

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 the local DNV Office of any intended updating of the quality system and DNV 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 DNV 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 DNV.

END OF CERTIFICATE