EU Quality Management System Certificate

Certificate no.:	Initial certification date:	Valid Until:
C597140	22 September 2023	21 September 2028

This is to certify that the quality system of

Vitrolife Sweden AB

Gustaf Werners gata 2, SE-421 32 Västra Frölunda, Sweden
SRN: SE-MF-000002389

For design, production, and final product inspection/testing of:

In Vitro Fertilisation System

Has been assessed and found to comply with respect to:

The conformity assessment procedure described in Annex IX, (Chapter I & III) of Regulation (EU) 2017/745 on Medical Devices

Place and date:
Høvik, 21 June 2024

For the issuing office:
DNV Product Assurance AS – Notified Body 2460
Veritasveien 1, 1363 Høvik, Norway

Alessandra Rinna
Management Representative

Certificate no.: C597140
Place and date: Høvik, 21 June 2024

Jurisdiction

Application of Regulation 2017/745 on medical devices, adopted as “Forskrift om Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Report No.	Issue Date
0.0	Original Certificate	2889459	22 September 2023
1.0	**Addition of devices (in bold)**	**2603872**	21 June 2024

Products covered by this Certificate:

Product Description	Product Name	Class*
Medium containing human serum albumin, acetylcysteine, and gentamicin. Medium for preparation and handling of gametes, for in vitro fertilisation and intrauterine insemination.	Gx-IVF™	III
Medium containing human serum albumin, hyaluronan, acetylcysteine, and gentamicin. Medium for culture of embryos from fertilisation to the blastocyst stage and for embryo transfer.	Gx-TL™	III
Medium containing human serum albumin, acetylcysteine, and gentamicin. Medium for handling and manipulating oocytes and embryos in ambient atmosphere.	Gx-MOPS™ PLUS	III
Medium containing human serum albumin, and gentamicin. **Medium for handling and manipulating oocytes and embryos in ambient atmosphere.**	**G-MOPS™ PLUS**	III
Medium containing human serum albumin, hyaluronan, and gentamicin. **Medium for culture of embryos from the pronucleate stage to day 2 or day 3.**	**G-1™ PLUS**	III
Medium containing human serum albumin, hyaluronan, and gentamicin. **Medium for culture of embryos from day 3 to the blastocyst stage.**	**G-2™ PLUS**	III
Medium containing human serum albumin, and gentamicin. **Medium for preparation and handling of gametes and for in vitro fertilisation.**	**G-IVF™ PLUS**	III
HSA-solution™ contains Human serum albumin solution (100 mg/mL) and is intended for use in assisted reproductive procedures which include gamete and embryo manipulation. These procedures include the use of HSA-solution™ as a supplement for culture medium.	**HSA-solution™**	III
Medium containing human serum albumin, hyaluronan, and gentamicin. **Medium for culture of embryos from fertilisation to the blastocyst stage.**	**G-TL™**	III
Medium containing human serum albumin, and gentamicin.	**G-GAMETE™**	III

Medium for handling and manipulating oocytes and embryos in ambient atmosphere		
Medium containing human serum albumin, hyaluronidase, and gentamicin. **Medium for removal of cumulus cells.**	**HYASE™-10X**	III
Medium containing human serum albumin, and gentamicin. **Medium for sperm preparation.**	**SpermRinse™**	III
Medium containing human serum albumin, and gentamicin. **Medium for cryopreservation of human sperm.**	**SpermFreeze Solution™**	III
Medium containing gentamicin. **Medium for embryo biopsy.**	**G-PGD™**	III
Medium containing gentamicin. **Medium for oocyte collection and for handling and manipulating oocytes and embryos in ambient atmosphere.**	**G-MOPS™**	III
Solutions containing human serum albumin, hyaluronan, and gentamicin. **Solutions for freezing of pronuclear oocytes and cleavage-stage embryos.**	**FreezeKit™ Cleave**	III
Solutions containing human serum albumin, hyaluronan, and gentamicin. **Solutions for thawing of frozen pronuclear oocytes and cleavage-stage embryos.**	**ThawKit™ Cleave**	III
Media containing human serum albumin, hyaluronan, and gentamicin. **Media for vitrification of human blastocyst stage embryos.**	**RapidVit™ Blast**	III
Media containing human serum albumin, hyaluronan, and gentamicin. **Media for warming of vitrified human blastocyst stage embryos.**	**RapidWarm™ Blast**	III
Media containing human serum albumin, hyaluronan, and gentamicin. **Media for vitrification of cleavage stage embryos.**	**RapidVit™ Cleave**	III
Media containing human serum albumin, hyaluronan, and gentamicin. **Media for warming of vitrified cleavage stage embryos.**	**RapidWarm™ Cleave**	III
Media containing human serum albumin, hyaluronan, and gentamicin. **Media for vitrification of human oocytes (MII).**	**RapidVit™ Oocyte**	III
Media containing human serum albumin, hyaluronan, and gentamicin. **Media for warming of vitrified human oocytes (MII).**	**RapidWarm™ Oocyte**	III
Media containing human serum albumin, hyaluronan, and gentamicin. **Media for vitrification of oocytes through to blastocyst stage embryos.**	**RapidVit™ Omni**	III
Media containing human serum albumin, hyaluronan, and gentamicin. **Media for warming of vitrified oocytes through to blastocyst**	**RapidWarm™ Omni**	III

stage embryos.		
Medium containing recombinant human albumin, hyaluronan, and gentamicin. **Medium for embryo transfer.**	**EmbryoGlue®**	III
Medium containing recombinant human albumin. **Medium for immobilization and isolation of sperm prior to intracytoplasmic sperm injection, ICSI.**	**ICSI™**	III
Medium containing heparin, and gentamicin. **Medium for oocyte retrieval and rinsing (follicle flushing).**	**ASP™**	III
Solution containing gentamicin. **Solution for rinsing of contact materials and for washing of the cervix.**	**G-RINSE™**	III
Medium for gradient sperm separation.	**SpermGrad™**	III
Oil for covering of medium during in vitro fertilisation and micro-manipulation procedures.	**OVOIL™**	III
Oil for covering of medium during in vitro fertilisation and micro-manipulation procedures.	**OVOIL HEAVY™**	III

* Class III and class IIb devices referred to in the second subparagraph of Article 52(4): Technical documentation assessment is covered by a separate EU Technical Documentation Assessment Certificate No.: C597141.

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
Vitrolife Sweden AB	Gustaf Werners gata 2, SE-421 32 Västra Frölunda, Sweden (visiting address) Box 9080, SE-400 92 Göteborg, Sweden (postal address)
Vitrolife Inc.	3601 South Inca Street, Englewood, Colorado 80110, USA

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 Notified Body of any intended updating of the quality system and the Notified Body 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. Notified Body reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.
- For the class III devices covered this certificate is dependent on the continued validity of the EU Technical Documentation Assessment Certificate, covering the devices.

The following may render this Certificate invalid:

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

Specific conditions - Class I devices, Systems and Procedure Packs:

- For class I device being placed on the market in a sterile condition, Class I devices with a measurement function and class I devices being reusable surgical instruments covered by this certificate the audit by the notified body of the quality management system was limited to the aspects required under article 52(7) of the regulation.
- For system and procedure packs being placed on the market in a sterile condition, covered by this certificate the audit by the notified body of the quality management system was limited to the aspects required under article 22(3) of the regulation.
- For Custom Made Class III implantable device the certification only relates to the Quality management system. Technical documentation assessment and issuance of EU Technical Documentation Assessment Certificate does not apply.

Conformity declaration and marking of product

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