EU Quality Management System Certificate

Certificate no.:
10000500631-PA-NoMA-SVK

Initial certification date:
06 September 2022

Valid Until:
05 September 2027

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:

Disposable Devices for IVF

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, 03 May 2023

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

Mariann Jeremiassen
Management Representative

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	2603927	06 September 2022
1.0	Editorial changes	2603927	24 March 2023
2.0	Addition of devices	2603941	27 April 2023
3.0	**Correction of error (in bold)**	**2603941**	**03 May 2023**

Products covered by this Certificate:		
Product Description	**Product Name**	**Class**
Disposable Devices for IVF	Follicle Aspiration Set ▪ Follicle Aspiration Set, Single Lumen ▪ Follicle Aspiration Set, Double Lumen ▪ Follicle Aspiration Set, Single Lumen, Luer ▪ Follicle Aspiration Set, Single Lumen, Luer with Tubing ▪ Follicle Aspiration Set, Reduced Single Lumen ▪ Follicle Aspiration Set, Reduced Single Lumen, Luer ▪ Follicle Aspiration Set, Reduced Double Lumen	IIa
	Gynaecological Needles ▪ Amniocentesis Needle ▪ Chorion Biopsy Needle ▪ Cyst Puncture Needle with Stylet ▪ Cyst Puncture Needle without Stylet	
	Anaesthetic Needle ▪ Local Anaesthesia Needle	
	Disposable Vitrification Device ▪ Rapid-i™Kit	
Labware	Sperm Collection Container	
	Square Dishes ▪ Culture Dish 40 m**m** ▪ Micro-droplet Culture Dish ▪ 5 Well Culture Dish ▪ Center Well Dish ▪ ICSI Dish	
	Round Dishes ▪ Culture Dish 60 mm ▪ Collection Dish 90 mm	

Labware	Collection Tubes ▪ Oocyte Collection Tube 14 mL ▪ Sample Tube 5 mL	IIa
	Centrifuge Tubes ▪ Centrifuge Tube 15 mL ▪ Centrifuge Tube 50 mL	

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)

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.

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.