EU Quality Management System Certificate

Certificate no.:
10000500633-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:
Sterile medical devices for IVF procedures

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, 24 March 2023

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

Mariann Jeremiassen
Management Representative

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.
NOTIFIED BODY 2460: DNV Product Assurance AS, Veritasveien 1, 1363 Høvik, Norway, Tel +47 67 57 88 00, www.dnv.com
MCR-CO-078-A V0.5

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**	**2603936**	**6 September 2022**
1.0	**Editorial change**	**2603936**	**24 March 2023**

Products covered by this Certificate:

Product Description (and intended purpose for class IIb)	**Product Name**	**Class**
Sterile medical devices for IVF procedures	Vacuum Pump Tubing	**Is**
	Ultrasound Transmission Gel	
	Pipettes: Biopsy Pipette Handling Pipette Hatching Pipette Holding Pipette ICSI Pipette Partial Zona Dissection (PZD) Pipette	
Labware	Pasteur Pipette Serological Pipette	**Is**

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.