

EC CERTIFICATE

Full Quality Assurance System

Certificate No.:
241683-2017-CE-NOR-NA-PS Rev. 4.0

Project No.:
PRJC-470047-2013-MSL-NOR

Valid Until:
24 January 2023

This is to certify that the quality system of:

Vitrolife Sweden AB

Gustaf Werners gata 2, SE-421 32 Västra Frölunda, Sweden

For design, production and final product inspection/testing of:
Disposable devices for IVF

Has been assessed with respect to:

**THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN
ANNEX II EXCLUDING 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, 13 January 2021

For:
DNV GL PRESAFE AS
Notified Body No.: 2460

Mariann Jeremiassen

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



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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 22720-2008-CE-NOR Rev. 4.0 (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	2018-01-24
3.0	Scope extension; new device	2019-01-02
4.0	Editorial change	2021-01-13

Products covered by this Certificate:

Product Description	Product Name	Class
Disposable Devices for IVF	Pipettes <ul style="list-style-type: none"> • Blastomere Biopsy Pipette • Denudation Pipette • Hatching Pipette • Holding Pipette • ICSI Pipette • Partial Zona Dissection (PZD) Pipette • Transfer Pipette 	Is
	Accessories for IVF <ul style="list-style-type: none"> • Ultrasound Transmission Gel • Transducer cover • Vacuum Pump Tubing 	Is

Sites covered by this certificate

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

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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 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 Presafe of any intended updating of the quality system and Presafe 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. Presafe 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 Presafe.

End of Certificate