EU Quality Management System Certificate

Certificate no.:
10000473271-PA-NoMA-DNK

Initial certification date:
27 June 2022

Valid Until:
27 June 2027

This is to certify that the quality system of

Vitrolife A/S

Jens Juuls Vej 20, 8260 Viby J, Denmark
SRN: DK-MF-000001892

For design, production and final product inspection/testing of:
IVF incubators and culture dishes

Has been assessed and found to comply with respect to:
The conformity assessment procedure described in Annex IX, (Chapter I) of Regulation (EU) 2017/745 on Medical Devices

Place and date:
Høvik, 27 June 2022

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

Alessandra Rinna
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 V0.4

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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	2554285	27 June 2022

Products covered by this Certificate:

Product Description	Product Name	Class
The intended use of the EmbryoScope+ incubator is to provide an environment with controlled temperature and gas concentrations (CO2 and optionally O2) for the culture of gametes and/or embryos and to acquire images of these during incubation.	EmbryoScope EmbryoScope+ EmbryoScope Flex EmbryoScope 8	IIa
IVF incubators (The intended use of incubator is to provide an environment with controlled temperature and gas concentrations (CO2 and optionally O2) for the culture of gametes and/or embryos.)	CulturePro	IIa
Culture dishes	CulturePro Dish EmbryoSlide EmbryoSlide+ EmbryoSlide+ ic8 dish EmbyoSlide Flex	IIa

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
Vitrolife A/S	Jens Juuls Vej 20, 8260 Viby J, Denmark

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.