EU Technical Documentation Assessment Certificate

Certificate no.:
C597141

Initial certification date:
22 September 2023

Valid Until:
21 September 2028

This is to certify that:
In Vitro Fertilisation system

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

Has been assessed and found to comply with respect to:
Technical Documentation Assessment as described in Annex IX (Chapter II) of Regulation 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

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:

Type of medical device and identification no., Basic UDI-DI		**Class**	**EMDN code**
Basic UDI-DI	735002591AAPE8	III	U08020502
Gx-IVF™			
Intended purpose of the Medical Device			
Medium for preparation and handling of gametes, for in vitro fertilisation and intrauterine insemination.			

Type of medical device and identification no., Basic UDI-DI		**Class**	**EMDN code**
Basic UDI-DI	735002591AAQEA	III	U08020503
Gx-TL™			
Intended purpose of the Medical Device			
Medium for culture of embryos from fertilisation to the blastocyst stage and for embryo transfer.			

Type of medical device and identification no., Basic UDI-DI		**Class**	**EMDN code**
Basic UDI-DI	735002591AAREC	III	U08020502
Gx-MOPS™ PLUS			
Intended purpose of the Medical Device			
Medium for handling and manipulating oocytes and embryos in ambient atmosphere.			

Type of medical device and identification no., Basic UDI-DI		Class	EMDN code
Basic UDI-DI	735002591AAHDQ	III	U08020502
G-MOPS™ PLUS			
Intended purpose of the Medical Device			
Medium for handling and manipulating oocytes and embryos in ambient atmosphere.			

Type of medical device and identification no., Basic UDI-DI		Class	EMDN code
Basic UDI-DI	735002591AACDE	III	U08020503
G-1™ PLUS			
Intended purpose of the Medical Device			
Medium for culture of embryos from the pronucleate stage to day 2 or day 3.			

Type of medical device and identification no., Basic UDI-DI		Class	EMDN code
Basic UDI-DI	735002591AADDG	III	U08020503
G-2™ PLUS			
Intended purpose of the Medical Device			
Medium for culture of embryos from day 3 to the blastocyst stage.			

Type of medical device and identification no., Basic UDI-DI		Class	EMDN code
Basic UDI-DI	735002591AAFDL	III	U08020502
G-IVF™ PLUS			
Intended purpose of the Medical Device			
Medium for preparation and handling of gametes and for in vitro fertilisation.			

Type of medical device and identification no., Basic UDI-DI		Class	EMDN code
Basic UDI-DI	735002591AALDY	III	U08020502
HSA-solution™			
Intended purpose of the Medical Device			
Human serum albumin solution (100 mg/mL) 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.			

Type of medical device and identification no., Basic UDI-DI		Class	EMDN code
Basic UDI-DI	735002591AAKDW	III	U08020503
G-TL™			
Intended purpose of the Medical Device			
Medium for culture of embryos from fertilisation to the blastocyst stage.			

Type of medical device and identification no., Basic UDI-DI		Class	EMDN code
Basic UDI-DI	735002591AAEDJ	III	U08020502
G-GAMETE™			
Intended purpose of the Medical Device			
Medium for handling and manipulating oocytes and embryos in ambient atmosphere.			

Type of medical device and identification no., Basic UDI-DI		Class	EMDN code
Basic UDI-DI	735002591AAME2	III	U08020502
HYASE™-10X			
Intended purpose of the Medical Device			
Medium for removal of cumulus cells.			

Type of medical device and identification no., Basic UDI-DI		Class	EMDN code
Basic UDI-DI	735002591ABEDM	III	U08020502
SpermRinse™			
Intended purpose of the Medical Device			
Medium for sperm preparation.			

Type of medical device and identification no., Basic UDI-DI		Class	EMDN code
Basic UDI-DI	735002591ABCDH	III	U08020501
SpermFreeze Solution™			
Intended purpose of the Medical Device			
Medium for cryopreservation of human sperm.			

Type of medical device and identification no., Basic UDI-DI		Class	EMDN code
Basic UDI-DI	735002591AASEE	III	U08020502
G-PGD™			
Intended purpose of the Medical Device			
Medium for embryo biopsy.			

Type of medical device and identification no., Basic UDI-DI		Class	EMDN code
Basic UDI-DI	735002591AAHDQ	III	U08020502
G-MOPS™			
Intended purpose of the Medical Device			
Medium for oocyte collection and for handling and manipulating oocytes and embryos in ambient atmosphere.			

Type of medical device and identification no., Basic UDI-DI		Class	EMDN code
Basic UDI-DI	735002591ABFDP	III	U08020501
FreezeKit™ Cleave			

Intended purpose of the Medical Device
Solutions for freezing of pronuclear oocytes and cleavage-stage embryos.

Type of medical device and identification no., Basic UDI-DI		Class	EMDN code
Basic UDI-DI	735002591ABHDT	III	U08020501
ThawKit™ Cleave			
Intended purpose of the Medical Device			
Solutions for thawing of frozen pronuclear oocytes and cleavage-stage embryos.			

Type of medical device and identification no., Basic UDI-DI		Class	EMDN code
Basic UDI-DI	735002591AAUEJ	III	U08020501
RapidVit™ Blast			
Intended purpose of the Medical Device			
Media for vitrification of human blastocyst stage embryos.			

Type of medical device and identification no., Basic UDI-DI		Class	EMDN code
Basic UDI-DI	735002591AAVEL	III	U08020501
RapidWarm™ Blast			
Intended purpose of the Medical Device			
Media for warming of vitrified human blastocyst stage embryos.			

Type of medical device and identification no., Basic UDI-DI		Class	EMDN code
Basic UDI-DI	735002591AAWEN	III	U08020501
RapidVit™ Cleave			
Intended purpose of the Medical Device			
Media for vitrification of cleavage stage embryos.			

Type of medical device and identification no., Basic UDI-DI	Class	EMDN code

Basic UDI-DI	735002591AAXEQ	III	U08020501
RapidWarm™ Cleave			
Intended purpose of the Medical Device			
Media for warming of vitrified cleavage stage embryos.			

Type of medical device and identification no., Basic UDI-DI		**Class**	**EMDN code**
Basic UDI-DI	735002591AAYES	III	U08020501
RapidVit™ Omni			
Intended purpose of the Medical Device			
Media for vitrification of oocytes through to blastocyst stage embryos.			

Type of medical device and identification no., Basic UDI-DI		**Class**	**EMDN code**
Basic UDI-DI	735002591AAZEU	III	U08020501
RapidWarm™ Omni			
Intended purpose of the Medical Device			
Media for warming of vitrified oocytes through to blastocyst stage embryos.			

Type of medical device and identification no., Basic UDI-DI		**Class**	**EMDN code**
Basic UDI-DI	735002591ABADD	III	U08020501
RapidVit™ Oocyte			
Intended purpose of the Medical Device			
Media for vitrification of human oocytes (MII).			

Type of medical device and identification no., Basic UDI-DI		**Class**	**EMDN code**
Basic UDI-DI	735002591ABBDF	III	U08020501
RapidWarm™ Oocyte			
Intended purpose of the Medical Device			
Media for warming of vitrified human oocytes (MII).			

Type of medical device and identification no., Basic UDI-DI		Class	EMDN code
Basic UDI-DI	735002591AABDC	III	U08020502
EmbryoGlue®			
Intended purpose of the Medical Device			
Medium for embryo transfer.			

Type of medical device and identification no., Basic UDI-DI		Class	EMDN code
Basic UDI-DI	735002591AANE4	III	U08020502
ICSI™			
Intended purpose of the Medical Device			
Medium for immobilization and isolation of sperm prior to intracytoplasmic sperm injection, ICSI.			

Type of medical device and identification no., Basic UDI-DI		Class	EMDN code
Basic UDI-DI	735002591AAADA	III	U08020502
ASP™			
Intended purpose of the Medical Device			
Medium for oocyte retrieval and rinsing (follicle flushing).			

Type of medical device and identification no., Basic UDI-DI		Class	EMDN code
Basic UDI-DI	735002591AAJDU	III	U08020502
G-RINSE™			
Intended purpose of the Medical Device			
Solution for rinsing of contact materials and for washing of the cervix.			

Type of medical device and identification no., Basic UDI-DI	Class	EMDN code

Basic UDI-DI	735002591ABDDK	III	U08020502
SpermGrad™			
Intended purpose of the Medical Device			
Medium for gradient sperm separation.			

Type of medical device and identification no., Basic UDI-DI		**Class**	**EMDN code**
Basic UDI-DI	735002591AAOE6	III	U08020502
OVOIL™			
Intended purpose of the Medical Device			
Oil for covering of medium during in vitro fertilisation and micro-manipulation procedures.			

Type of medical device and identification no., Basic UDI-DI		**Class**	**EMDN code**
Basic UDI-DI	735002591AAOE6	III	U08020502
OVOIL HEAVY™			
Intended purpose of the Medical Device			
Oil for covering of medium during in vitro fertilisation and micro-manipulation procedures.			

Conformity Assessment for devices listed is covered by separate EU Quality Management System Certificate No.: C597140

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 inform the Notified Body of any intended change of the products detailed above and the Notified Body will assess the changes and decide if the certificate remains valid.

The following may render this Certificate invalid:

- Changes in the design of the products to which this Certificate refers.
- Changes in requirements of the scheme to which this Certificate refers.

Conformity declaration and marking of product

Terms and conditions

This Certificate must be accompanied with a valid EU Quality Management System Certificate.

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.