EU Declaration of Conformity

Manufacturer

Vitrolife Sweden AB
Gustaf Werners gata 2
SE-421 32 Västra Frölunda
Sweden

Product	REF number	Indication for use	Basic UDI-DI
ASP™	10100	Medium for oocyte retrieval and rinsing (follicle flushing).	735002591AAADA
EmbryoGlue®	10085 10168	Medium for embryo transfer.	735002591AABDC
FreezeKit™ Cleave	10166	Solutions for freezing of pronuclear oocytes and cleavage-stage embryos.	735002591ABFDP
G-1™ PLUS	10128	Medium for culture of embryos from the pronucleate stage to day 2 or day 3.	735002591AACDE
G-2™ PLUS	10132	Medium for culture of embryos from day 3 to the blastocyst stage.	735002591AADDG
G-GAMETE™	10126	Medium for handling and manipulating oocytes and embryos in ambient atmosphere.	735002591AAEDJ
G-IVF™ PLUS	10134 10136	Medium for preparation and handling of gametes and for in vitro fertilisation.	735002591AAFDL
G-MOPS™	10129	Medium for oocyte collection and for handling and manipulating oocytes and embryos in ambient atmosphere.	735002591AAHDQ
G-MOPS™ PLUS	10130	Medium for handling and manipulating oocytes and embryos in ambient atmosphere.	735002591AAHDQ
G-PGD™	10074	Medium for embryo biopsy.	735002591AASEE
G-RINSE™	10069	Solution for rinsing of contact materials and for washing of the cervix. Not for culture.	735002591AAJDU
G-TL™	10145	Medium for culture of embryos from fertilisation to the blastocyst stage.	735002591AAKDW
Gx-TL™	10172	Medium for culture of embryos from fertilisation to the blastocyst stage and for embryo transfer.	735002591AAQEA
Gx-IVF™	10171	Medium for preparation and handling of gametes, for *in vitro* fertilisation and intrauterine insemination.	735002591AAPE8
Gx-MOPS™ PLUS	10173	Medium for handling and manipulating oocytes and embryos in ambient atmosphere.	735002591AAREC
HSA-solution™	10064	HSA-solution contains Human serum albumin solution (100 mg/mL) and 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.	735002591AALDY
HYASE™-10X	10176	Medium for removal of cumulus cells.	735002591AAME2

Product	REF number	Indication for use	Basic UDI-DI
ICSI™	10111	Medium for immobilization and isolation of sperm prior to intracytoplasmic sperm injection, ICSI.	735002591AANE4
OVOIL™	10029	Oil for covering of medium during in vitro fertilisation and micro-manipulation procedures.	735002591AAOE6
OVOIL HEAVY™	10174	Oil for covering of medium during in vitro fertilisation and micro-manipulation procedures.	735002591AAOE6
RapidVit™ Blast	10119	Media for vitrification of human blastocyst stage embryos.	735002591AAUEJ
RapidVit™ Cleave	10117	Media for vitrification of cleavage stage embryos.	735002591AAWEN
RapidVit™ Omni	10123	Media for vitrification of oocytes through to blastocyst stage embryos.	735002591AAYES
RapidVit™ Oocyte	10121	Media for vitrification of human oocytes (MII).	735002591ABADD
RapidWarm™ Blast	10120	Media for warming of vitrified human blastocyst stage embryos.	735002591AAVEL
RapidWarm™ Cleave	10118	Media for warming of vitrified cleavage stage embryos.	735002591AAXEQ
RapidWarm™ Omni	10124	Media for warming of vitrified oocytes through to blastocyst stage embryos.	735002591AAZEU
RapidWarm™ Oocyte	10122	Media for warming of vitrified human oocytes (MII).	735002591ABBDF
SpermFreeze Solution™	10137	Medium for cryopreservation of human sperm.	735002591ABCDH
SpermGrad™	10099 10102 10138 10139 10238 10239 10338 10339	Medium for gradient sperm separation.	735002591ABDDK
SpermRinse™	10101 10146	For sperm preparation.	735002591ABEDM
ThawKit™ Cleave	10167	Solutions for thawing of frozen pronuclear oocytes and cleavage-stage embryos.	735002591ABHDT

Risk Class

Medical Device in Risk Class III

Single Registration Number (SRN)

SE-MF-000002389

Conformity assessment procedure

The procedure specified in Annex IX of Regulation (EU) 2017/745 on Medical Devices.

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Notified Body

DNV Product Assurance AS, Notified Body number 2460

EU Certificate

EU Quality Management System Certificate no.: C597140
EU Technical Documentation Assessment Certificate no.: C597141

Attestation

We hereby declare that the listed products are in conformity with Regulation (EU) 2017/745 on Medical Devices as well as with:

- Article 1 point 2 and Annex I of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (acetylcysteine, gentamicin, heparin, human serum albumin, recombinant human albumin)

- Directive 2000/70/EC of the European Parliament and of the Council of 16 November 2000 amending Council Directive 93/42/EEC as regards medical devices incorporating stable derivates of human blood or human plasma (human serum albumin)

- Commission Regulation (EU) No 722/2012 of 8 August 2012 concerning particular requirements as regards the requirements laid down in Council Directives 90/385/EEC and 93/42/EEC with respect to active implantable medical devices and medical devices manufactured utilising tissues of animal origin (hyaluronidase)

This Declaration of Conformity is issued under the sole responsibility of Vitrolife Sweden AB.

Electronically signed by: Hans Lehmann
Reason: Approver
Date: Jul 26, 2024 15:02 GMT+2

Hans Lehmann
Director Regulatory Affairs
Västra Frölunda

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