Declaration of Conformity

Manufacturer

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

Product, REF number and Intended use

Media	REF	Indication for use
EmbryoGlue®	10085 10168	Medium for embryo transfer
ASP™	10100	Medium for oocyte retrieval and rinsing (follicle flushing)
ICSI™	10111	Medium for immobilization and isolation of sperm prior to intracytoplasmic sperm injection, ICSI
G-RINSE™	10069	Solution for rinsing of contact materials and for washing of the cervix. Not for culture.
OVOIL™	10029	Oil for covering of medium during in vitro fertilisation and micro-manipulation procedures.
OVOIL HEAVY™	10174	Oil for covering of medium during in vitro fertilisation and micro-manipulation procedures.
FreezeKit™ Cleave	10166	Solutions for freezing of pronuclear oocytes and cleavage-stage embryos
Thawkit™ Cleave	10167	Solutions for thawing of frozen pronuclear oocytes and cleavage-stage embryos
G-1™ PLUS	10128	Medium for culture of embryos from the pronucleate stage to day 2 or day 3
G-2™ PLUS	10132	Medium for culture of embryos from day 3 to the blastocyst stage
G-GAMETE™	10126	Medium for handling and manipulating oocytes and embryos in ambient atmosphere
G-IVF™ PLUS	10134 10136	Medium for preparation and handling of gametes and for in vitro fertilisation
G-MOPS™	10129	Medium for oocyte collection and for handling and manipulating oocytes and embryos in ambient atmosphere

Media	REF	Indication for use
G-MOPS™ PLUS	10130	Medium for handling and manipulating oocytes and embryos in ambient atmosphere
G-PGD™	10074	Medium for embryo biopsy
G-TL™	10145	Medium for culture of embryos from fertilisation to the blastocyst stage
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.
HYASE™-10X	10176	Medium for removal of cumulus cells
RapidVit™ Blast	10119	Media for vitrification of human blastocyst stage embryos
RapidWarm™ Blast	10120	Media for warming of vitrified human blastocyst stage embryos
RapidVit™ Cleave	10117	Media for vitrification of cleavage stage embryos
RapidWarm™ Cleave	10118	Media for warming of vitrified cleavage stage embryos
RapidVit™ Omni	10123	Media for vitrification of oocytes through to blastocyst stage embryos
RapidWarm™ Omni	10124	Media for warming of vitrified oocytes through to blastocyst stage embryos
RapidVit™ Oocyte	10121	Media for vitrification of human oocytes (MII)
RapidWarm™ Oocyte	10122	Media for warming of vitrified human oocytes (MII)
SpermFreeze™ Solution	10137	Medium for cryopreservation of human sperm
SpermRinse™	10101 10146	For sperm preparation
SpermGrad™	10099 10102 10138 10139 10238 10239 10338 10339	Medium for gradient sperm separation

Vitrolife Sweden AB
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Product category
Medical Device in Risk Class IIa (OVOIL™, OVOIL™ HEAVY)
Medical Device in Risk Class IIb (SpermGrad™)
Medical Device in Risk Class III (remaining IVF media listed above)

Notified Body
DNV GL Presafe AS, Notified Body number 2460

Attestation
We hereby declare that the products mentioned above fulfil the Essential Requirements as stated in Annex I to the Council Directive 93/42/EEC on Medical Devices, as amended by 2007/47/EC. This Declaration of Conformity is issued under the sole responsibility of Vitrolife Sweden AB.

Place and Date
Göteborg on 17 May 2023

Signature
On behalf of Vitrolife Sweden AB

Electronically signed by: Hans Lehmann
Reason: Approver
Date: May 17, 2023 16:07 GMT+2

Vitrolife
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Hans Lehmann
Director Regulatory Affairs