Declaration of Conformity

Manufacturer

Vitrolife Sweden AB
Gustaf Werners gata 2
SE-421 32 Göteborg
Sweden

Product and Intended use

G-MOPS™ PLUS handling medium
G-1™ PLUS cleavage medium
G-2™ PLUS culture medium for blastocysts
G-IVF™ PLUS fertilization medium
FREEZE-KIT 1™ embryo freezing solutions
THAW-KIT 1™ embryo thawing solutions
FreezeKit™ Cleave embryo freezing solutions
ThawKit™ Cleave embryo thawing solutions
RapidVit™ Blast embryo vitrification solutions
RapidWarm™ Blast embryo warming solutions
RapidVit™ Cleave embryo vitrification solutions
RapidWarm™ Cleave embryo warming solutions
G- GAMETE™ gamete preparation medium
IVF™ fertilization and cleavage medium
SpermRinse™ sperm preparation medium
HYASE™-10X denudation of oocytes
SpermFreeze Solution™ medium for sperm cryopreservation
G-TL™ medium for culture of embryos from fertilization to the blastocyst stage
RapidVit™ Oocyte media for vitrification of oocytes
RapidWarm™ Oocyte media for warming of vitrified oocytes
RapidVit™ Omni media for vitrification
RapidWarm™ Omni media for warming
EmbryoGlue® medium for embryo transfer
ICSI™ medium for use in ICSI
G-1™ cleavage medium
G-2™ culture medium for blastocysts
G-IVF™ fertilization medium
G-MOPS™ handling medium
G-PGD™ embryo biopsy medium
G-FreezeKit Blast™ blastocyst freezing media
G-ThawKit Blast™ blastocyst thawing media
ASP™ oocyte retrieval and rinsing
G-RINSE™ medium for rinsing
SpermGrad™ medium for gradient sperm separation
OVOIL™ for covering of medium during IVF
HSA-solution™ for supplementation of IVF media
G-MM™ for supplementation of IVF media

Vitrolife Sweden AB
Reg.No 556546-6298

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Vitrolife

Product category

Medical Device in Risk Class Is (G-RINSE™)
Medical Device in Risk Class IIa (OVOIL™)
Medical Device in Risk Class IIb (SpermGrad™)
Medical Device in Risk Class III (remaining IVF media listed above)

Attestation

We hereby declare that the products mentioned above fulfil the Essential Requirements as stated in Annex 1 to the Council Medical Devices Directive 93/42/EEC as amended by 2007/47/EC.

Place and Date

Göteborg on 16 August 2016

Signature

On behalf of Vitrolife Sweden AB

Hans Lehmann
Director QA/RA

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