Declaration of Conformity

Manufacturer

Vitrolife Sweden AB
Box 9080 (Gustaf Werners gata 2)
SE-400 92 Göteborg
Sweden

Product

Denudation Pipette
Transfer Pipette
ICSI Pipette
Holding Pipette
Blastomere Biopsy Pipette
Hatching Pipette
Partial Zona Dissection (PZD) Pipette

Intended Use

Denudation Pipette is intended for removal of cumulus cell layers.
Transfer Pipette is intended for manipulation and transfer of oocytes, embryos and blastocysts or to check fertilisation.
ICSI Pipette is intended for aspiration and intracytoplasmic injection of a single sperm into the oocyte.
Holding Pipette is intended to be used to hold the oocyte or embryo when performing ICSI or other micromanipulation procedures.
Blastomere Biopsy Pipette is intended for aspiration of blastomeres for pre-implantation genetic diagnosis.
Hatching Pipette is intended to be used to create a hole in the zona pellucida to enable assisted hatching or embryo biopsy.
Partial Zona Dissection (PZD) Pipette is intended to be used to create a small slit in the zona pellucida to enable assisted hatching or embryo biopsy

Product Category

Medical Device in Risk Class Is

Attestation

I hereby declare that the products Denudation Pipette, Transfer Pipette, ICSI Pipette, Holding Pipette, Blastomere Biopsy Pipette, Hatching Pipette, Partial Zona Dissection (PZD) Pipette fulfill the Essential Requirements as stated in Annex I to the Council Directive 93/42/EEC as amended by 2007/47/EC.

Vitrolife Sweden AB
Reg.No 556546-6298

Postal address:
Box 9080
SE-400 92 Göteborg
Sweden

Visiting address:
Gustaf Werners gata 2
SE-421 32 V Frölunda
Sweden

Tel +46-31-721 80 00
Fax +46-31 721 80 99
www.vitrolife.com

Place and Date
Göteborg on 10 June 2013

Signature

Hans Lehmann
Director QA/QC

Vitrolife Sweden AB
Reg No 556546-6298

Postal address:
Box 9080
SE-400 92 Göteborg
Sweden

Visiting address:
Gustaf Werners gata 2
SE-421 32 V Frölunda
Sweden

Tel +46-31-721 80 00
Fax +46-31 721 80 99
www.vitrolife.com