

# 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
Ultrasound Transmission Gel	14214	The sterile gel can be used for all ultrasound procedure where a sterile transmission gel is needed.	735002591ABUEM
Vacuum Pump Tubing	17201, 17202, 17203	For connection between the needle set and the vacuum pump	735002591ABSEH
Micromanipulation pipettes	See Appendix	Micromanipulation pipettes are intended for micro-manipulation of embryos, cells and gametes during assisted reproductive technology (ART).	735002591ACADG
- Biopsy Pipette		For aspiration of cells for pre-implantation genetic testing.	
- Handling Pipette		For handling and manipulation of embryos, cells and gametes during ART procedures.	
- Hatching Pipette		To create a hole in the zona pellucida to enable assisted hatching or embryo biopsy.	
- Holding Pipette		To hold the oocyte or embryo when performing ICSI or other micromanipulation procedures.	
- ICSI Pipette		For aspiration and intracytoplasmic injection of a single sperm into the oocyte.	
- Partial Zona Dissection (PZD) Pipette		To create a small slit in the zona pellucida to enable assisted hatching or embryo biopsy.	
Pasteur Pipettes	16201, 16202	Handling and transferring of liquids, media and gametes during assisted reproductive technology procedures.	735002591ABZEX
Serological Pipettes	16203, 16204, 16205, 16206	Handling and transferring of liquids, media and gametes during assisted reproductive technology procedures.	735002591ABZEX

**Risk Class**

Medical Device in Risk Class Is

**Single Registration Number (SRN)**

SE-MF-000002389

**Conformity assessment procedure**

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

**Notified Body**

DNV Product Assurance AS, Notified Body number 2460

**EU Quality Management System Certificate**

Certificate no.: 10000500633-PA-NoMA-SVK

**Attestation**

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

This Declaration of Conformity is issued under the sole responsibility of Vitrolife Sweden AB and is valid until 05 September 2027.



Hans Lehmann  
Director Regulatory Affairs  
Västra Frölunda

## Appendix

Product name	REF number
Biopsy Pipette	15646
Biopsy Pipette	15152
Biopsy Pipette	15146
Biopsy Pipette	15143
Biopsy Pipette	15112
Biopsy Pipette	15602
Biopsy Pipette	15113
Biopsy Pipette	15114
Biopsy Pipette	15147
Biopsy Pipette	15115
Biopsy Pipette	15148
Biopsy Pipette	15116
Biopsy Pipette	15117
Biopsy Pipette	15149
Biopsy Pipette	15118
Biopsy Pipette	15119
Biopsy Pipette	15121
Biopsy Pipette	15122
Biopsy Pipette	15603
Biopsy Pipette	15123
Biopsy Pipette	15124
Biopsy Pipette	15125
Biopsy Pipette	15126
Biopsy Pipette	15127
Biopsy Pipette	15128
Biopsy Pipette	15150
Biopsy Pipette	15605
Biopsy Pipette	15144
Biopsy Pipette	15142
Biopsy Pipette	15151
Biopsy Pipette	15133
Biopsy Pipette	15138
Biopsy Pipette	15145
Biopsy Pipette	15120
Handling Pipette	15530
Handling Pipette	15531
Handling Pipette	15532
Handling Pipette	15533
Handling Pipette	15534
Handling Pipette	15535
Handling Pipette	15536

Handling Pipette	15537
Handling Pipette	15538
Hatching Pipette	15130
Hatching Pipette	15102
Hatching Pipette	15103
Hatching Pipette	15104
Hatching Pipette	15105
Hatching Pipette	15108
Hatching Pipette	15107
Hatching Pipette	15111
Hatching Pipette	15141
Holding Pipette	15318
Holding Pipette	15319
Holding Pipette	15324
Holding Pipette	15327
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Holding Pipette	15331
Holding Pipette	15284
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Holding Pipette	15301
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Holding Pipette	15306
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Holding Pipette	15309
Holding Pipette	15311
Holding Pipette	15316
Holding Pipette	15317
Holding Pipette	15322
Holding Pipette	15323
Holding Pipette	15333
Holding Pipette	15320
Holding Pipette	15334
Holding Pipette	15335
ICSI Pipette	15339
ICSI Pipette	15342
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ICSI Pipette	15425
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ICSI Pipette	15441
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ICSI Pipette	15611
ICSI Pipette	15401
ICSI Pipette	15402
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ICSI Pipette	15444
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ICSI Pipette	15653
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ICSI Pipette	15451
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ICSI Pipette	15540
ICSI Pipette	15541
ICSI Pipette	15542
ICSI Pipette	15543
ICSI Pipette	15420
ICSI Pipette	15613
ICSI Pipette	15358
PZD Pipette	15669
PZD Pipette	15525
PZD Pipette	15526
PZD Pipette	15527