

## 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
Rapid-i™ Kit	14406, 14419, 14420, 14421, 14422	Cryopreservation device intended to be used to contain, vitrify and maintain human embryos and/or oocytes(MII).	735002591AATEG
Follicle Aspiration Set		Follicle Aspiration Sets are intended for flushing and/or aspiration of oocytes from ovarian follicles.	735002591ABNE7
- Follicle Aspiration Set, Single Lumen	17103, 17107, 17112, 17125, 17156, 17130, 17119, 17126, 17116, 17120, 17157, 17104, 17185, 17186, 17189		
- Follicle Aspiration Set, Single Lumen, Luer	17154, 17152, 17140, 17137		
- Follicle Aspiration Set, Single Lumen, Luer with Tubing	17123		
- Follicle Aspiration Set, Double Lumen	17151, 17102, 17150, 17105, 17108, 17131, 17111, 17161, 17109, 17148, 17168		
- Follicle Aspiration Set, Reduced Single Lumen	17175, 17176, 17177, 17178, 17188		
- Follicle Aspiration Set, Reduced Single Lumen, Luer	17179, 17180		

- Follicle Aspiration Set, Reduced Double Lumen	17187		
Amniocentesis Needle	17801	Amniocentesis Needle is intended for ultrasound-guided amniocentesis.	735002591ABPEB
Chorion Biopsy Needle	17802	Chorion Biopsy Needle is intended for ultrasound-guided chorion biopsy.	735002591ABQED
Cyst Puncture Needle with Stylet	17809, 17803, 17806, 17805, 17811, 17812	Cyst Puncture Needle with/without Stylet is intended for ultrasound-guided puncture and aspiration of intra-abdominal cysts.	735002591ABREF
Cyst Puncture Needle without Stylet	17810, 17804, 17807		
Local Anaesthesia Needle	17701	Local Anaesthesia Needle is intended for application of ultrasound-guided local anaesthesia prior to transvaginal follicle aspiration.	735002591ABOE9
Square Dishes - Culture Dish 40 mm - Micro-droplet Culture Dish - 5 Well Culture Dish - Center Well Dish - ICSI Dish	16001 16003 16004 16005 16006	Handling and culture of gametes or embryos during assisted reproductive technology procedures.	735002591ABWER
Round Dishes - Culture Dish 60 mm - Collection Dish 90 mm	16002 16007		
Sperm Collection Container	16102	Sperm Collection Container is intended for sampling and handling of semen for ART procedures.	735002591ABXET
Collection Tubes - Oocyte Collection Tube 14 mL - Sample Tube 5 mL	16101 16103	Sampling, handling and purification of gametes during assisted reproductive technology procedures.	735002591ABYEV
Centrifuge Tubes - Centrifuge Tube 15 mL - Centrifuge Tube 50 mL	16105 16106		

**Risk Class**

Medical Device in Risk Class IIa

**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.: 10000500631-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