

## EC Declaration of Conformity

### EmbryoSlide+ culture dish

<b>Manufacturer</b>	Vitrolife A/S
<b>Manufacturer address</b>	Jens Juuls Vej 20 8260 Viby J Denmark
<b>Single Registration Number</b>	DK-MF-000001892
<b>Basic UDI-DI</b>	5712714DISH-01M2
<b>Product</b>	EmbryoSlide+ culture dish
<b>Product code</b>	16450
<b>Product category</b>	IVF incubators and culture dishes
<b>Classification</b>	Class IIa according to Annex VIII, rule(s) 2
<b>Intended purpose</b>	The EmbryoSlide+ culture dish is an accessory for embryo storage related to the EmbryoScope+ and EmbryoScope 8 incubators, which provide an environment with controlled temperature and gas concentrations (CO <sub>2</sub> and optionally O <sub>2</sub> ) for the development of gametes and/or embryos at or near body temperature.
<b>Notified Body</b>	DNV Product Assurance AS Veritasveien 1 1363 Høvik Norway
<b>Notified Body identification No.</b>	2460
<b>Conformity assessment procedure</b>	Annex IX of the Medical Device Regulation (EU) 2017/745
<b>Certificate(s)</b>	10000473271-PA-NoMA-DNK

We, the manufacturer, hereby declare that this EC Declaration of Conformity is issued under the sole responsibility of the manufacturer.

We, the manufacturer, hereby declare that the above-mentioned device is in conformity with the European Medical Device Regulation (EU) 2017/745.

**Place and date of issue** VIBY J, JUNE 30, 2022

**Name and authority** Henrik Wahlgren, QA Manager

**Signature**

