# EC Declaration of Conformity

# EmbryoScope 8

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| **Manufacturer** | Vitrolife A/S |
| **Manufacturer address** | Jens Juuls Vej 20<br>8260 Viby J<br>Denmark |
| **Single Registration Number** | DK-MF-000001892 |
| **Basic UDI-DI** | 5712714INC-01KD |
| **Product** | EmbryoScope 8 |
| **Product code** | 16409 |
| **Product category** | IVF incubators and culture dishes |
| **Classification** | Class IIa according to Annex VIII, rule(s) 2 |
| **Intended purpose** | The intended use of the EmbryoScope 8 incubator is to provide an environment with controlled temperature and gas concentrations ($CO_2$ and optionally $O_2$) for the culture of gametes and/or embryos and to acquire images of these during incubation. |
| **Notified Body** | DNV Product Assurance AS<br>Veritasveien 1<br>1363 Høvik<br>Norway |
| **Notified Body identification No.** | 2460 |
| **Conformity assessment procedure** | Annex IX of the Medical Device Regulation (EU) 2017/745 |
| **Certificate(s)** | 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.

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| **Place and date of issue** | VIBY J, JUNE 30, 2022 |
| **Name and authority** | Henrik Wahlgren, QA Manager |
| **Signature** |  |