Vitrolife

EC Declaration of Conformity

EmbryoScope+

Manufacturer	Vitrolife A/S
Manufacturer address	Jens Juuls Vej 20 8260 Viby J Denmark
Single Registration Number	DK-MF-000001892
Basic UDI-DI	5712714INC-01KD
Product	EmbryoScope+
Product code	16402
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+ incubator is to provide an environment with controlled temperature and gas concentrations (CO2 and optionally O2) for the culture of gametes and/or embryos and to acquire images of these during incubation.
Notified Body	DNV Product Assurance AS Veritasveien 1 1363 Høvik 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.

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