

EC Declaration of Conformity

iDAScore

Manufacturer	Vitrolife A/S
Manufacturer address	Jens Juuls Vej 20 8260 Viby J Denmark
Single Registration Number	DK-MF-000001892
Basic UDI-DI	5712714SWT-01W9
Product	iDAScore
Product code	16536
Product category	Software – Decision Support Tools
Classification	Class I according to Annex VIII, rule(s) 11
Intended purpose	The device evaluates early embryo development through acquired embryo time-lapse videos to assist embryo selection. The device assigns a score to each embryo that identifies embryos with the highest chance of implantation. The device is an adjunct to clinical decision-making, and the final assessment and decision must be made by a medical professional.

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

Roskilde May 25, 2021

Name and authority

Henrik Wahlgren, QA Manager

Signature

