CERTIFICATE OF REGISTRATION

This is to certify that

Origio A/S

Knardrupvej 2, Malov 2760 Denmark
D-U-N-S: 305025269

operates a

Quality Management System

which complies with the requirements of

ISO 13485:2016 and the requirements of the following regulatory authorities

Australia:
- Therapeutic Goods (Medical Devices) Regulations 2002: Schedule 3, Part 1 - Full Quality Assurance System

Canada:
- Medical Device Regulations SOR/98-282, Part 1

United States:
- 21 CFR Part 803 - Medical Device Reporting
- 21 CFR Part 806 - Reports of Corrections and Removals
- 21 CFR Part 807 (Subparts A to D) - Establishment Registration and Device Listing
- 21 CFR Part 820 - Quality System Regulation

for the following scope of certification

Design, development, manufacture, final testing and distribution of storage devices, cell culture products, needles and catheters for use in Assisted Reproductive Technology (ART) procedures.

Certificate No.:	CERT-0127163	Original Certification Date:	2020-01-30
File No.:	1034927	Certification Effective Date:	2020-01-30
Issue Date:	2020-03-19	Certificate Expiry Date:	2023-01-29

Heather Mahon
Global Head of Technical Services SAI Global Assurance

Certified System
ISO 13485:2016

SAI Global is an MDSAP authorized auditing organization.
MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM

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