



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

File No.: 1034927

Issue Date: 2020-03-19

Original Certification Date: 2020-01-30

Certification Effective Date: 2020-01-30

Certificate Expiry Date: 2023-01-29

Heather Mahon

Global Head of Technical Services SAI Global Assurance



ISO 13485:2016

SAI Global is an MDSAP
authorized auditing organization.



Registered by:

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