Digitally signed by Grecu Mihnea Ioan
Date: 2024.02.14 13:59:28 EET
Reason: MoldSign Signature
Location: Moldova

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

ORIGIO A/S
Knardrupvej 2
2760 Måløv
Denmark

Facility ID Number: F005203

Holds Certificate No: **MDSAP 738514**

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure
Canada: Medical Devices Regulations - Part 1 - SOR 98/282
USA: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

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

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2020-01-30 Effective Date: 2023-01-30 Expiry Date: 2026-01-29

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM
BSI Group America Inc. is an MDSAP recognised auditing organization

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