By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

FertiPro N.V.
Industriepark Noord 32
8730 Beernem
Belgium

Facility ID Number: F005046

Holds Certificate No: **MDSAP 734316**

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
Brazil: RDC ANVISA n. 67/2009, RDC ANVISA n. 665/2022 - Good Manufacturing Practices, RDC ANVISA n. 551/2021
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

The design and development, manufacture, and distribution of medical devices and subassemblies in the field of Assisted Reproductive Technology (ART), including medical devices containing human albumin solution, animal-derived raw materials and/or antibiotics, and cell culture media and in-vitro diagnostic reagents and kits used in the diagnosis of fertility.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2018-10-08 Effective Date: 2024-10-02 Expiry Date: 2027-10-01

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

...making excellence a habit.™

Certificate No: **MDSAP 734316**

Location	Registered Activities
FertiPro N.V. Industriepark Noord 32 8730 Beernem Belgium Facility ID Number: F005046	The design and development, manufacture, distribution and sales of medical devices and subassemblies in the field of Assisted Reproductive Technology (ART), including medical devices containing human albumin solution, animal-derived raw materials and/or antibiotics, and cell culture media and in-vitro diagnostic reagents and kits used in the diagnosis of fertility.
FertiPro Support & Services bv Industriepark Oost 2 8730 Beernem Belgium Facility ID Number: F005046	The storage, packaging and shipping of non-active medical devices and subassemblies in the field of Assisted Reproductive Technology (ART), including medical devices containing human albumin solution, animal derived raw materials and/or antibiotics, and cell culture media and in vitro diagnostics used in the diagnosis of fertility.

Original Registration Date: 2018-10-08 Effective Date: 2024-10-02 Expiry Date: 2027-10-01