

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

FertiPro nv
Industriepark Noord 32
8730 Beernem
Belgium

Facility ID Number: F005046

Holds Certificate No:

MDSAP 734316

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure; Brasil - RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009; 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, 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 diagnostics used in the diagnosis of fertility.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2018-10-08

Effective Date: 2021-10-02

Expiry Date: 2022-10-01



BSI Group America Inc. is an MDSAP authorized auditing organization

Certificate No: **MDSAP 734316**

Location	Registered Activities
FertiPro nv 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 diagnostics 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.



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This certificate remains the property of BSI and shall be returned immediately upon request.
An electronic certificate can be authenticated [online](#). Printed copies can be validated at www.bsigroup.com/ClientDirectory
To be read in conjunction with the scope above or the attached appendix.

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A Member of the BSI Group of Companies.