

# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

FertiPro N.V.  
Industriepark Noord 32  
8730 Beernum  
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.

This certificate is traceable to this company's original registration certificate number 2219501 dated October 8, 2018 and issued by DEKRA.

For and on behalf of BSI:

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Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2018-10-08

Effective Date: 2020-12-17

Expiry Date: 2021-10-01



BSI Group America Inc. is an MDSAP authorized auditing organization

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Certificate No: **MDSAP 734316**

Location	Registered Activities
FertiPro N.V. Industriepark Noord 32 8730 Beernum 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 B.V.B.A Industriepark Oost 2 8730 Beernum 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: 2020-12-17

Expiry Date: 2021-10-01

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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](http://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.