

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 diagnostics used in the diagnosis of fertility.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2018-10-08

Effective Date: 2023-10-03

Expiry Date: 2024-10-01



BSI Group America Inc. is an MDSAP recognised auditing organization

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Certificate No: **MDSAP 734316**

Location

FertiPro N.V.
Industriepark Noord 32
8730 Beernem
Belgium
Facility ID Number: F005046

FertiPro Support & Services bv
Industriepark Oost 2
8730 Beernem
Belgium
Facility ID Number: F005046

Registered Activities

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.

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

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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](https://www.bsigroup.com/ClientDirectory). 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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