CERTIFICATE

Number: 2219501

The management system of the organization(s) and locations mentioned on the addendum belonging to:

FertiPro N.V.

Industriepark Noord 32
8730 Beernem
Belgium

Manufacturer DUNS 373904101

Conforms with the following standard and regulatory requirements:

ISO 13485:2016

Australia:	Therapeutic Goods (Medical Devices) Regulations, 2002 and Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure
Brazil:	RDC ANVISA N. 16/2013, 23/2012 and 67/2009
Canada:	Medical Devices Regulations - Part 1- SOR 98/282
United States:	21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D and 21 CFR 820

Scope:
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.

Certificate expiry date:	2021-10-01
Certificate effective date:	2018-10-08
Certified since:	2018-10-08

This certificate is valid for the organization(s) and/or locations mentioned on the addendum.

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

J.A. van Vugt
Certification Manager

The validation of the validity of this certificate can be checked through DEKRA's website using the following link:
https://www.dekra-product-safety.com/en/certified-organizations

DEKRA Certification B.V. is recognized under the Medical Devices Single Audit Program.

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

ADDENDUM

To certificate: 2219501

The management system of the organization(s) and/or location(s) of:

FertiPro N.V.

Industriepark Noord 32
8730 Beernem
Belgium

Certified organization(s) and/or locations:	Different scope
FertiPro Support & Services B.V.B.A Industriepark Oost 2 8730 Beernem Belgium	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.

Addendum expiry date: 2021-10-01
Addendum effective date: 2018-10-08