

EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 729092 R000

Manufacturer: FertiPro N.V.

Address:

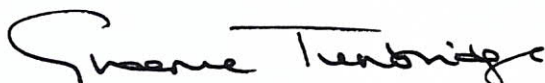
Industriepark Noord 32
8730 Beernem
Belgium

Single Registration Number: BE-MF-000000313

Scope: See attached **Device Schedule**

On the basis of our assessment of the technical documentation in accordance with Regulation (EU) 2017/745, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):



Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2022-03-16**

Current Issue Date: **2024-05-24**

Starting Validity Date: **2024-05-24**

Expiry Date: **2027-03-15**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
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Device Schedule:

Intended Purpose as per the Instructions for Use:

GAIN™ medium is a single-step cell culture medium for use with human embryos and gametes. It can be used in the following procedures:

- For semen washing and Intra Uterine Insemination (IUI).
- For oocytes handling/incubation in preparation of, or during fertilization by In Vitro Fertilization (IVF)/ Intra Cytoplasmic Sperm Injection (ICSI).
- For embryo culture from day 1 to expanded blastocyst stage.
- For embryo transfer (ET)

Risk Classification: Class III

Basic UDI-DI: 5411967GAIN1SL

Type: MDN 1212

Device Name	Model
GAIN Medium	GAIN005
	GAIN010
	GAIN020
	GAIN050
	GAIN100
	GAIN250

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2022-03-16	3207201	Issued.
2023-09-07	3895154	Amended – addition of new location for MEA test.
2024-02-12	3908425	Amended – administrative change to remove subcontractor name from previous certificate history entry. Approval of sterilisation related changes.
Current	30108622	Amended – approval of change to transfer isolator. Administrative change to remove horizontal MDN codes from device schedule.

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