

EU Technical Documentation Assessment Certificate

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

MDR 729085 R000

Manufacturer: FertiPro N.V.

Address:

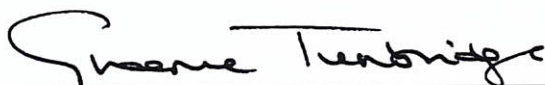
Industriepark Noord 32
8730 Beernem
Belgium

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: **2024-06-20**

Starting Validity Date: **2024-06-20**

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

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Page 1 of 3

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:

| Device Name | Model | Type (Codes as per (EU) 2017/2185) | Intended Purpose (as per the IFU) | Risk Classification | Basic UDI-DI |
|-----------------------------|--|---|--|------------------------|-----------------|
| SpermFreeze | SPF001 SPF05 SPF010 SPF SPF050 SPF100 | MDN1212 | SpermFreeze is a cell culture media for the cryopreservation of human spermatozoa and sperm from testicular biopsies (TESE). | Class III | 5411967SPFWT147 |
| SpermFreeze with phenol red | SPF001PR SPF005PR SPF010PR SPF012PR SPF020PR SPF050PR | | | | |
| SpermFreeze SSP | SSP001 SSP005 SSP010 SSP20 SSP020 SSP050 SSP125 | MDN1212 | SpermFreeze SSP, SpermCryo All-round or SpermTec Cryo are cell culture media for the cryopreservation of human spermatozoa. | Class III | 5411967SPF152 |
| SpermCryo All-round | SPCA-0005 SPCA-0010 | | | | 5411967GYNS6M |
| SpermTec Cryo | STC-5 STC-10 | | | | |

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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 | 3207157 | Issued. |
| 2024-02-12 | 3908401 | Amended – approval of sterilisation related changes. |
| 2024-05-24 | 30108626 | Amended – approval of change to transfer isolator. Administrative change to remove horizontal MDN codes from device schedule. |
| Current | 3892616 | Supplemented – addition of SpermCryo All-round and SpermTec Cryo. Intended purpose expansion for SpermFreeze (with phenol red). Amended – administrative change to the format of how the information on the certificate is presented (all in tabular form). |

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Page 3 of 3

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