

EU Technical Documentation Assessment Certificate

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

MDR 729084 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: **2024-06-12**

Starting Validity Date: **2024-06-12**

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:

Sil-Select Stock, SpermTec G-100 & SpermFilter Stock are stock solutions for preparing a density gradient system for semen preparation.

Sil-Select Plus, and Gradient, SpermFilter Ready-to-use gradient & SpermTec are discontinuous gradient systems which effectively separate spermatozoa from seminal plasma, and select a subpopulation of spermatozoa with good motility, viability and chromatin integrity.

Sil-Select Stock, Sil-Select Plus, Gradient, SpermFilter & SpermTec can be used in sperm preparation methods for further use in intra uterine insemination (IUI), in vitro fertilization (IVF) intra-cytoplasmic sperm injection (ICSI) and related assisted reproductive technologies (ART).

Risk Classification: Class III

Basic UDI-DI for Sil-Select Stock, Sil-Select Plus & Gradient: 5411967DENSG1S5

Basic UDI-DI for SpermFilter & SpermTec: 5411967GYND5P

Type: MDN 1212

Device Name	Model
Sil-Select Stock	SIS010
	SIS012
	SIS020
	SIS050
	SIS050_32
	SIS100
	SIS100_32
	SIS250
	SIS500
	SIS030_P
	SIS050_P
	SIS100_P
	SIS500_P

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Device Name	Model
Sil-Select Stock with phenol red and gentamicin	SIS010PRG SIS012PRG SIS020PRG SIS050PRG SIS050_32PRG SIS100PRG SIS100_32PRG SIS250PRG SIS500PRG
Sil-Select Plus UPPER LAYER	SIP012UP SIP025UP SIP042UP SIP010UP SIP020UP SIP020UP_AF SIP050UP SIP050UP_AF SIP050UP_32 SIP100UP SIP100UP_AF SIP250UP SIP500UP

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Device Name	Model
SpermFilter Stock Solution 100%	SPF100-0010 SPF100-0050 SPF100-0100 SPF100-0250 SPF100-0500
SpermTec G-100	ST-100-10 ST-100-50 ST-100-100 ST-100-250 ST-100-500
Sil-Select Stock with phenol red	SIS010PR SIS012PR SIS020PR SIS050PR SIS050_32PR SIS100PR SIS100_32PR SIS250PR SIS500PR
Sil-Select Stock with gentamicin	SIS010G SIS012G SIS020G SIS050G SIS050_32G SIS100G SIS100_32G SIS250G SIS500G

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Device Name	Model
Sil-Select Plus UPPER LAYER with phenol red	SIP025PR_UP
	SIP042PR_UP
	SIP010PR_UP
	SIP012PR_UP
	SIP020PR_UP
	SIP050PR_UP_20
	SIP050PR_UP
	SIP100PR_UP_20
	SIP100PR_UP
	SIP250PR_UP
	SIP500PR_UP
Sil-Select Plus UPPER LAYER with gentamicin	SIP025G_UP
	SIP042G_UP
	SIP010G_UP
	SIP012G_UP
	SIP020G_UP
	SIP050G_UP
	SIP050G_UP_32
	SIP100G_UP
	SIP100G_UP_32
	SIP250G_UP
	SIP500G_UP

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Device Name	Model
Sil-Select Plus UPPER LAYER with phenol red and gentamicin	SIP025PRG_UP SIP042PRG_UP SIP010PRG_UP SIP012PRG_UP SIP020PRG_UP SIP050PRG_UP SIP050PRG_UP_32 SIP100PRG_UP SIP100PRG_UP_32 SIP250PRG_UP SIP500PRG_UP
SpermFilter Ready-to-use gradient 45%	SPF45-0010 SPF45-0050 SPF45-0100 SPF45-0250
SpermTec G-45	ST-45-10RG ST-45-50RG ST-45-100RG ST-45-250RG
Sil-Select Plus 80%	SIP80_025 SIP80_010 SIP80_012 SIP80_020 SIP80_050 SIP80_050_32 SIP80_100 SIP80_100_20 SIP80_250 SIP80_500

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Device Name	Model
Sil-Select Plus 80% with phenol red	SIP80_025PR SIP80_010PR SIP80_012PR SIP80_020PR SIP80_050PR SIP80_050PR_32 SIP80_100PR SIP80_100PR_32 SIP80_250PR SIP80_500PR
Sil-Select Plus 80% with gentamicin	SIP80_025G SIP80_010G SIP80_012G SIP80_020G SIP80_050G_20 SIP80_050G SIP80_100G_20 SIP80_100G SIP80_250G SIP80_500G
Sil-Select Plus 80% with phenol red and gentamicin	SIP80_025PRG SIP80_010PRG SIP80_012PRG SIP80_020PRG SIP80_050PRG SIP80_050PRG_32 SIP80_100PRG SIP80_100PRG_32 SIP80_250PRG SIP80_500PRG

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Device Name	Model
SpermFilter Ready-to-use gradient 80%	SPF80-0010 SPF80-0050 SPF80-0100 SPF80-0250
SpermTec G-80	ST-80-10RG ST-80-50RG ST-80-100RG ST-80-250RG
Sil-Select Plus LOWER LAYER	SIP025LO SIP042LO SIP010LO SIP012LO SIP020LO SIP020LO_AF SIP050LO SIP050LO_AF SIP050LO_32 SIP100LO SIP100LO_AF SIP250LO SIP500LO
Sil-Select Plus LOWER LAYER with phenol red	SIP025PR_LO SIP042PR_LO SIP010PR_LO SIP012PR_LO SIP020PR_LO SIP050PR_LO_20 SIP050PR_LO SIP100PR_LO_20 SIP100PR_LO SIP250PR_LO SIP500PR_LO

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Device Name	Model
Sil-Select Plus LOWER LAYER with gentamicin	SIP025G_LO
	SIP042G_LO
	SIP010G_LO
	SIP012G_LO
	SIP020G_LO
	SIP050G_LO
	SIP050G_LO_32
	SIP100G_LO
	SIP100G_LO_32
	SIP250G_LO
	SIP500G_LO
Sil-Select Plus LOWER LAYER with phenol red and gentamicin	SIP025PRG_LO
	SIP042PRG_LO
	SIP010PRG_LO
	SIP012PRG_LO
	SIP020PRG_LO
	SIP050PRG_LO
	SIP100PRG_LO_32
	SIP100PRG_LO
	SIP050PRG_LO_32
	SIP250PRG_LO
	SIP500PRG_LO

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Device Name	Model
Gradient 45	GR-45-025
	GR-45-042
	GR-45-010
	GR-45-012
	GR-45-020
	GR-45-020_AF
	GR-45-050
	GR-45-050_AF
	GR-45-050_32
	GR-45-100
	GR-45-100_AF
	GR-45-250
	GR-45-500
Gradient 45 with phenol red	GR-45-025PR
	GR-45-042PR
	GR-45-010PR
	GR-45-012PR
	GR-45-020PR
	GR-45-050PR_20
	GR-45-050PR
	GR-45-100PR
	GR-45-100PR_20
	GR-45-250PR
	GR-45-500PR

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Gradient 45 with gentamicin	GR-45-025G
	GR-45-042G
	GR-45-010G
	GR-45-012G
	GR-45-020G
	GR-45-050G
	GR-45-050G_32
	GR-45-100G
	GR-45-100G_32
	GR-45-250G
	GR-45-500G
Gradient 45 with phenol red and gentamicin	GR-45-025PRG
	GR-45-042PRG
	GR-45-010PRG
	GR-45-012PRG
	GR-45-020PRG
	GR-45-050PRG
	GR-45-050PRG_32
	GR-45-100PRG
	GR-45-100PRG_32
	GR-45-250PRG
	GR-45-500PRG
	GR-45-030PRG_P
	GR-45-050PRG_P
	GR-45-100PRG_P
	GR-45-500PRG_P

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Device Name	Model
Gradient 80	GR-80-025 GR-80-010 GR-80-012 GR-80-020 GR-80-050 GR-80-050_32 GR-80-100 GR-80-100_20 GR-80-250 GR-80-500
Gradient 80 with phenol red	GR-80-025PR GR-80-010PR GR-80-012PR GR-80-020PR GR-80-050PR GR-80-050PR_32 GR-80-100PR GR-80-100PR_32 GR-80-250PR GR-80-500PR
Gradient 80 with gentamicin	GR-80-025G GR-80-010G GR-80-012G GR-80-020G GR-80-050G_20 GR-80-050G GR-80-100G_20 GR-80-100G GR-80-250G GR-80-500G

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Device Name	Model
Gradient 80 with phenol red and gentamicin	GR-80-025PRG GR-80-010PRG GR-80-012PRG GR-80-020PRG GR-80-050PRG GR-80-050PRG_32 GR-80-100PRG GR-80-100PRG_32 GR-80-250PRG GR-80-500PRG GR-80-030PRG_P GR-80-050PRG_P GR-80-100PRG_P GR-80-500PRG_P
Gradient 90	GR-90-025 GR-90-042 GR-90-010 GR-90-012 GR-90-020 GR-90-020_AF GR-90-050 GR-90-050_AF GR-90-050_32 GR-90-100 GR-90-100_AF GR-90-250 GR-90-500

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Device Name	Model
Gradient 90 with phenol red	GR-90-025PR GR-90-042PR GR-90-010PR GR-90-012PR GR-90-020PR GR-90-050PR_20 GR-90-050PR GR-90-100PR_20 GR-90-100PR GR-90-250PR GR-90-500PR
Gradient 90 with gentamicin	GR-90-025G GR-90-042G GR-90-010G GR-90-012G GR-90-020G GR-90-050G GR-90-050G_32 GR-90-100G GR-90-100G_32 GR-90-250G GR-90-500G

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Device Name	Model
Gradient 90 with phenol red and gentamicin	GR-90-025PRG
	GR-90-042PRG
	GR-90-010PRG
	GR-90-012PRG
	GR-90-020PRG
	GR-90-050PRG
	GR-90-050PRG_32
	GR-90-100PRG
	GR-90-100PRG_32
	GR-90-250PRG
	GR-90-500PRG

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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	3268167	Issued.
2023-11-08	3846478	Supplemented – addition of SpermFilter & SpermTec.
2024-02-12	3898624	Amended – approval of sterilisation related changes.
2024-05-24	30108375	Amended – approval of change to transfer isolator. Administrative change to remove horizontal MDN codes from device schedule.
Current	3846436	Amended – Approval of change to aseptic fill line.

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