

# EU Technical Documentation Assessment Certificate

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

## MDR 729093 R000

**Manufacturer:** FertiPro N.V.

**Address:**

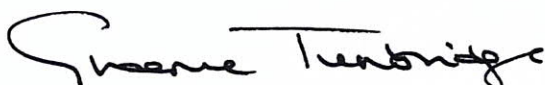
Industriepark Noord 32  
8730 Beernem  
Belgium

**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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### Device Schedule:

#### Intended Purpose as per the Instructions for Use:

The media are used *in vitro* for manipulation during ART (Assisted Reproductive Technology) procedures of patients with infertility problems. The media are used for washing of human ova, spermatozoa and embryos. FertiCult Flushing Medium can also be used for swim-up techniques of human spermatozoa, sperm injection in oocytes during intracytoplasmic sperm injection (ICSI), introduction of washed spermatozoa in the uterus (IUI) and for embryo transfer. The media can also be used for the preparation of density gradient media.

**Risk Classification:** Class III

**Basic UDI-DI for Flushing Medium, FertiCult Flushing Medium & Sil-Select Plus Sperm Washing / Insemination Medium:** 5411967FLUSH1WY

**Basic UDI-DI for SpermWash & SpermTec Wash:** 5411967GYNW6V

**Type:** MDN 1212

Device Name	Model
Flushing Medium without human albumin	FLUSH001N
	FLUSH_002_N
	FLUSH005N
	FLUSH010N
	FLUSH020_NHSA_NIS
	FLUSH050N
	FLUSH100N
	FLUSH250N
	FLUSH500N

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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 Name	Model
FertiCult Flushing Medium	FLUSH001 FLUSH_002 FLUSH005 FLUSH010 FLUSH012 FLUSH020 FLUSH22.8 FLUSH050 FLUSH100 FLUSH250 FLUSH500
FertiCult Flushing Medium with phenol red	FLUSH001PHR FLUSH_002_PHR FLUSH005PHR FLUSH010PHR FLUSH012PHR FLUSH020PHR FLUSH22.8PHR FLUSH050PHR FLUSH100PHR FLUSH250PHR FLUSH500PHR

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Device Name	Model
FertiCult Flushing Medium with gentamicin	FLUSH001G FLUSH_002_G FLUSH005G FLUSH010G FLUSH012G FLUSH020G FLUSH22.8G FLUSH050G FLUSH100G FLUSH250G FLUSH500G
FertiCult Flushing Medium with phenol red & gentamicin	FLUSH001PRG FLUSH_002_PRG FLUSH005PRG FLUSH010PRG FLUSH012PRG FLUSH020PRG FLUSH22.8PRG FLUSH050PRG FLUSH100PHR_G FLUSH250PRG FLUSH500PHR_G
Sil-Select Plus Sperm Washing / Insemination Medium without human albumin	WASH001N WASH002N WASH005N WASH010N WASH012N WASH020N WASH050N WASH100N WASH250N WASH500N

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Device Name	Model
Sil-Select Plus Sperm Washing / Insemination Medium	WASH001 WASH_002 WASH005 WASH010 WASH012 WASH020 WASH050 WASH100 WASH250 WASH500
Sil-Select Plus Sperm Washing / Insemination Medium with phenol red	WASH001PR WASH_002_PR WASH005PR WASH010PR WASH012PR WASH020PR WASH050PR WASH100PR WASH250PR WASH500PR
Sil-Select Plus Sperm Washing / Insemination Medium with gentamicin	WASH001G WASH_002_G WASH005G WASH010G WASH012G WASH020G WASH050G WASH100G WASH250G WASH500G

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Device Name	Model
Sil-Select Plus Sperm Washing / Insemination Medium with phenol red & gentamicin	WASH001PRG WASH_002_PRG WASH005PRG WASH010PRG WASH012PRG WASH020PRG WASH050PRG WASH100PRG WASH250PRG WASH500PRG
SpermWash	SW-0002 SW-0010 SW-0050 SW-0100 SW-0250 SW-0500
SpermTec Wash	STW-2RG STW-10RG STW-50RG STW-100RG STW-250RG STW-500RG

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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](mailto:Certificate.Verification@bsigroup.com))*

Date	Reference Number	Action
2022-03-16	3207205	Issued.
2023-09-07	3895155	Amended – addition of new location for MEA test.
2023-11-13	3892696	Supplemented – addition of SpermWash & SpermTec Wash.
2024-02-12	3908435	Amended – administrative change to remove subcontractor name from previous certificate history entry. Approval of sterilisation related changes.
Current	30108638	Amended – approval of change to transfer isolator. Administrative change to remove horizontal MDN codes from device schedule.

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