

# EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

**MDR 729049 R000**

**Manufacturer:** FertiPro N.V.

**Address:**

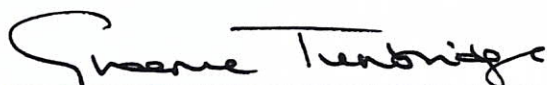
Industriepark Noord 32  
8730 Beernem  
Belgium

**Single Registration Number:** BE-MF-000000313

**Scope:** See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II 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: **2025-01-10**

Starting Validity Date: **2025-01-10**

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

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### Device Schedule: Class III and Class IIb devices

Class III	Intended purpose
IVF Basics HTF	See MDR 729082
FertiCult Aspiration Medium	See MDR 729083
Sil-Select Stock, Sil-Select Plus, Gradient, SpermFilter & SpermTec	See MDR 729084
SpermFreeze, SpermCryo All-round, SpermTec Cryo	See MDR 729085
VitriFreeze/VitriThaw	See MDR 729086
VitriFreeze ES/VitriThaw ES	
FertiVit Cooling Kit/FertiVit Warming Kit	See MDR 729087
10% PVP in FertiCult Flushing Medium	See MDR 729089
Hyaluronidase in FertiCult Flushing Medium	See MDR 729090
FertiCult IVF Media	See MDR 729091
GAIN Medium	See MDR 729092
FertiCult Flushing Media, SpermWash & SpermTec Wash	See MDR 729093

### Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
FertiCult Mineral Oil	Class IIa
FertiCult High Viscosity Oil	

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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	3206804	Issued.
2022-06-22	3679841	Supplemented – addition of VitriFreeze/VitriThaw, VitriFreeze ES/VitriThaw ES and FertiVit Cooling Kit/FertiVit Warming Kit.
2023-02-27	3730680	Supplemented – addition of OEM Washing Media/OEM Sperm Washing Media, OEM Culture Media and Hyaluronidase in FertiCult Flushing Medium
2023-07-12	3915047	Supplemented – addition of FertiCult Aspiration Medium
2023-11-10	30001937	Amended – Device name change (OEM HTF Media to IVF Basics HTF). Supplemented – Addition of SpermFilter, SpermTec, SpermWash & SpermTec Wash.
2024-06-20	30205088	Supplemented – addition of SpermCryo All-round and SpermTec Cryo.
Current	30337933	Restricted – removal of OEM Washing Media/OEM Sperm Washing Media and OEM Culture Media.

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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.

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Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.  
A Member of the BSI Group of Companies.