

EC CERTIFICATE

Number: 2111436CE02

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4)

(Devices in Class IIa, IIb or III)

Manufacturer:

FertiPro N.V.

Industriepark Noord 32

8730 Beernem

Belgium

For the product category(ies)

Media for the preparation, handling, washing, cryopreservation, in vitro culture and culture overlay of human embryos, ova and spermatozoa for use in In Vitro Fertilization (IVF) / IntraCytoplasmic Sperm Injection (ICSI), Assisted Reproductive Technologies (ART) and Embryo Transfer.

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

0344

Documents, that form the basis of this certificate:

Certification Notice 2111436CN, initially dated 11 December 2007

Addendum, initially dated 23 October 2009

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for design, manufacture and final inspection for the above mentioned product category in accordance to the provisions of Annex II of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. For placing on the market of Class III devices an additional EC design examination certificate according to Annex II (4) is mandatory. The necessary information related to the quality management system of the manufacturer, including facilities and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 1 October 2018
Issued for the first time: 23 October 2009
Reissued: 1 October 2015

DEKRA Certification B.V.



drs. G.J. Zoetbrood
Managing Director



ing. A.A.M. Laan
Certification Manager

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DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

ADDENDUM

Belonging to certificate: 2111436CE02

1/11

CE MARKING OF CONFORMITY MEDICAL DEVICES

Media for the preparation, handling, washing, cryopreservation, in vitro culture and culture overlay of human embryos, ova and spermatozoa for use in In Vitro Fertilization (IVF) / IntraCytoplasmic Sperm Injection (ICSI), Assisted Reproductive Technologies (ART) and Embryo Transfer.

Issued to:

FertiPro N.V.
Industriepark Noord 32
8730 Beernem
Belgium

This certificate covers the following product(s):

Class IIa: mineral oil for culture overlay

Product name	FertiCult Mineral Oil
Product code	MINOIL050
	MINOIL050_32
	MINOIL100
	MINOIL100_32
	MINOIL250
	MINOIL500

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drs. G.J. Zoetbrood
 Managing Director



ing. A.A.M. Laan
 Certification Manager

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Issued to:

FertiPro N.V.
Industriepark Noord 32
8730 Beernem
Belgium

Class IIb: media without ancillary medicinal substance

Product name	Sil-Select Stock	Sil-Select Stock with phenol red
Product code	SIS010	SIS010PR
	SIS012	SIS012PR
	SIS020	SIS020PR
	SIS050	SIS050PR
	SIS050_32	SIS050_32PR
	SIS100	SIS100_32PR
	SIS100_32	SIS250PR
	SIS250	SIS250PR
	SIS500	SIS500PR
	SIS5000	

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CE MARKING OF CONFORMITY MEDICAL DEVICES

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Issued to:

FertiPro N.V.
Industriepark Noord 32
8730 Beernem
Belgium

Class IIb: media without ancillary medicinal substance

Product name	Sil-Select Plus Upper Layer	Sil-Select Plus Upper layer with phenol red
Product code	SIP025UP	SIP025PR_UP
	SIP042UP	SIP042PR_UP
	SIP012UP	SIP010PR_UP
	SIP020UP	SIP012PR_UP
	SIP020UP_AF	SIP020PR_UP
	SIP050UP	SIP050PR_UP
	SIP050UP_AF	SIP100PR_UP
	SIP100UP	SIP250PR_UP
	SIP100UP_AF	SIP500PR_UP
	SIP250UP	
	SIP500UP	

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CE MARKING OF CONFORMITY MEDICAL DEVICES

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Issued to:

FertiPro N.V.
Industriepark Noord 32
8730 Beernem
Belgium

Class IIb: media without ancillary medicinal substance

Product name	Sil-Select Plus 80%	Sil-Select Plus 80% with phenol red
Product code	SIP80_010	SIP80_010PR
	SIP80_012	SIP80_012PR
	SIP80_020	SIP80_020PR
	SIP80_050	SIP80_050PR
	SIP80_100	SIP80_100PR
	SIP80_250	SIP80_250PR
	SIP80_500	SIP80_500PR

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CE MARKING OF CONFORMITY MEDICAL DEVICES

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Issued to:

FertiPro N.V.
Industriepark Noord 32
8730 Beernem
Belgium

Class IIb: media without ancillary medicinal substance

Product name	Sil-Select Plus Lower layer	Sil-Select Plus Lower layer with phenol red
Product code	SIP025LO	SIP025PR_LO
	SIP042LO	SIP042PR_LO
	SIP012LO	SIP010PR_LO
	SIP020LO	SIP012PR_LO
	SIP020LO_AF	SIP020PR_LO
	SIP050LO	SIP050PR_LO
	SIP050LO_AF	SIP100PR_LO
	SIP100LO	SIP250PR_LO
	SIP100LO_AF	SIP500PR_LO
	SIP250LO	
	SIP500LO	

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CE MARKING OF CONFORMITY MEDICAL DEVICES

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Issued to:

FertiPro N.V.
Industriepark Noord 32
8730 Beernem
Belgium

Class IIb: media without ancillary medicinal substance

Product name	FertiCult Flushing medium without human albumin	Washing/Insemination medium without human albumin	OEM Culture medium without human albumin
Product code	FLUSH001N	WASH001N	OEM_CULT001N
	FLUSH_002_N	WASH002N	OEM_CULT002N
	FLUSH005N	WASH005N	OEM_CULT005N
	FLUSH010N	WASH010N	OEM_CULT010N
	FLUSH020_NHSA_NIS	WASH012N	OEM_CULT020N
	FLUSH050N	WASH020N	OEM_CULT050N
	FLUSH100N	WASH050N	OEM_CULT100N
	FLUSH250N	WASH100N	OEM_CULT250N
	FLUSH500N	WASH250N	OEM_CULT500N
		WASH500N	

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CE MARKING OF CONFORMITY MEDICAL DEVICES

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Issued to:

FertiPro N.V.
Industriepark Noord 32
8730 Beernem
Belgium

Class III: Media with human albumin

Product name	Reference to DE certificate number
SpermFreeze	2111436DE04
EmbryoFreeze/Thaw	
EmbryoFreeze	
EmbryoThaw	
VitriFreeze	
VitriThaw	
VitriFreeze ES	
VitriThaw ES	
OEM Culture medium	2111436DE05
FertiCult Flushing medium	2111436DE03
FertiCult Flushing medium with phenol red	
Washing/ Insemination medium	
Washing/ Insemination medium with phenol red	
OEM washing medium	

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Issued to:

FertiPro N.V.
Industriepark Noord 32
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Class III: Media with gentamicin

Product name	Reference to DE certificate number
OEM Culture medium without human albumin with gentamicin	2111436DE05

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FertiPro N.V.
Industriepark Noord 32
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Silica particle based density gradient system for semen preparation (Class III)

Product name	Reference to DE certificate number
Sil-Select Stock with gentamicin	2111436DE06
Sil-Select Stock with phenol red and gentamicin	
Sil-Select Plus Upper layer with gentamicin	
Sil-Select Plus Upper layer with phenol red and gentamicin	
Sil-Select Plus 80% with gentamicin	
Sil-Select Plus 80% with phenol red and gentamicin	
Sil-Select Lower layer with gentamicin	
Sil-Select Lower layer with phenol red and gentamicin	

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CE MARKING OF CONFORMITY MEDICAL DEVICES

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Issued to:

FertiPro N.V.
Industriepark Noord 32
8730 Beernem
Belgium

Class III: Media with human albumin and gentamicin

Product name	Reference to DE certificate number
GAIN Medium Blastocyst	2111436DE05
OEM Culture medium with gentamicin	
OEM Culture medium with gentamicin and phenol red	
FertiCult Flushing medium with gentamicin	2111436DE03
FertiCult Flushing medium with phenol red and gentamicin	
Washing/ Insemination medium with gentamicin	
Washing/ Insemination medium with phenol red and gentamicin	
OEM Washing medium with phenol red and gentamicin	
OEM Sperm Washing medium	
OEM Sperm Washing medium Plus	
GAIN Medium Early Stage	2111436DE03 / 2111436DE05

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11/11

CE MARKING OF CONFORMITY MEDICAL DEVICES

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Issued to:

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Industriepark Noord 32
8730 Beernem
Belgium

Media with specific medium supplement (Class III)

Product name	Reference to DE certificate number
10% PVP in FertiCult Flushing medium	2111436DE07
FertiCult Aspiration medium	
OEM Aspiration medium	

Initial date: 23 October 2009

Revision date: 25 November 2015

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