

EC DESIGN-EXAMINATION CERTIFICATE

Number: 2111436DE07

Directive 93/42/EEC on Medical devices, Annex II (4)
(Devices in Class III)

Manufacturer:

FertiPro N.V.
Industriepark Noord 32
8730 Beernem
Belgium

For the product

Cell culture media with specific supplement for use in IVF, ICSI or similar procedures of ART.

Documents, that form the basis of this certificate:

Certification Notice 2111436CN, initially dated 11 July 2007
Addendum, initially dated 25 July 2014

DEKRA hereby declares that the design of the product(s) falling within the product category mentioned above, 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, based on an examination in accordance with Annex II (4) of this Directive. The manufacturer has implemented a quality assurance system for the above mentioned product category in accordance to the provisions of Annex II (4) of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance.

The necessary information and the reference to the relevant documentation, of the products concerned and the examinations and 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: 25 July 2014
Reissued: 1 October 2015

DEKRA Certification B.V.

A blue ink signature of G.J. Zoetbrood, consisting of a stylized first name and a more formal last name.

drs. G.J. Zoetbrood
Managing Director

A blue ink signature of A.A.M. Laan, appearing as a cursive, somewhat abstract scribble.

ing. A.A.M. Laan
Certification Manager

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DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
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ADDENDUM

Belonging to certificate: 2111436DE07

1/2

EC DESIGN-EXAMINATION MEDICAL DEVICES

Cell culture media with specific supplement for use in IVF, ICSI or similar procedures of ART.

Issued to:

FertiPro N.V.
Industriepark Noord 32
8730 Beernem
Belgium

This certificate covers the following product(s):

Product name	10% PVP in FertiCult Flushing medium
Product code	PVP0.2
	PVP0.2S
	PVP1

DEKRA Certification B.V.



drs. G.J. Zoetbrood
 Managing Director



ing. A.A.M. Laan
 Certification Manager

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ADDENDUM

Belonging to certificate: 2111436DE07

EC DESIGN-EXAMINATION MEDICAL DEVICES

Cell culture media with specific supplement for use in IVF, ICSI or similar procedures of ART.

Issued to:

FertiPro N.V.
Industriepark Noord 32
8730 Beernem
Belgium

Product name	FertiCult Aspiration medium	OEM Aspiration medium
Product code	ASPI020	OEM_ASPI020
	ASPI050	OEM_ASPI050
	ASPI100	OEM_ASPI100
	ASPI250	OEM_ASPI250
	ASPI500	OEM_ASPI500

Initial date: 25 July 2014
Revision date: 1 October 2015

DEKRA Certification B.V.



drs. G.J. Zoetbrood
Managing Director



ing. A.A.M. Laan
Certification Manager

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