

EC CERTIFICATE

Number: 2217576CE02

Full Quality Assurance System

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

Manufacturer:

VITROMED GmbH

Hans-Knöll-Straße 6
07745 Jena
Germany

For the product category(ies)

Media for the preparation, handling and culture overlay of human embryos, ova and spermatozoa for use in In Vitro Fertilization (IVF) and Assisted Reproductive Technologies (ART)

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

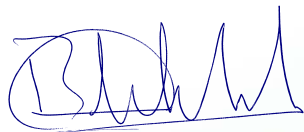
Documents, that form the basis of this certificate:

Certification Notice 2217576CN, initially dated 28 July 2017
Addendum, initially dated 22 December 2017

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 2023
Issued for the first time: 22 December 2017
Revised: 25 April 2019
Reissued: 29 January 2019

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.A. van Vugt
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed

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: 2217576CE02

1/1

CE MARKING OF CONFORMITY MEDICAL DEVICES

Media for the preparation, handling and culture overlay of human embryos, ova and spermatozoa for use in In Vitro Fertilization (IVF) and Assisted Reproductive Technologies (ART)

Issued to:

VITROMED GmbH
Hans-Knöll-Straße 6
07745 Jena
Germany

This certificate covers the following product(s):

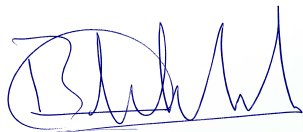
Class IIa: mineral oil for culture overlay

Product name VITROMED V-OIL
V-OIL-P100 (PETG)
V-OIL-P500 (PETG)
V-OIL-G100 (Glass bottles)
V-OIL-G500 (Glass bottles)

Initial date: 22 December 2017

Revision date: 25 April 2019

DEKRA Certification B.V.

A blue ink signature of B.T.M. Holtus, the Managing Director, is written over a faint, repeating pattern of the DEKRA logo.

B.T.M. Holtus
Managing Director

A blue ink signature of J.A. van Vugt, the Certification Manager, is written over a faint, repeating pattern of the DEKRA logo.

J.A. van Vugt
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed

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