

EC DESIGN-EXAMINATION CERTIFICATE

Number: 2239487DE02

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

Manufacturer:

VITROMED GmbH
Hans-Knöll-Straße 6
07745 Jena
Germany

For the product

Cell culture media for the cryopreservation of spermatozoa, oocytes and embryos for use in IVF, ICSI or similar procedures of ART

Documents, that form the basis of this certificate:

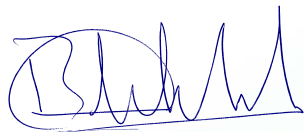
Certification Notice 2217576CN, initially dated 28 July 2017
CE Marking of Conformity 2239487CE02
Addendum, initially dated 4 February 2020

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 2023
Issued for the first time: 4 February 2020
Revised: 20 February 2020

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.A. van Vugt
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
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ADDENDUM

Belonging to certificate: 2239487DE02

1/1

EC DESIGN-EXAMINATION MEDICAL DEVICES

Cell culture media for the cryopreservation of spermatozoa, oocytes and embryos for use in IVF, ICSI or similar procedures of ART

Issued to:

VITROMED GmbH
Hans-Knöll-Straße 6
07745 Jena
Germany

This certificate covers the following product(s):

Media with human albumin and phenol red:

Reference bottle;

V-SFM-01_05G (5 ml Glass bottle)

V-SFM-01_20G (20 ml Glass bottle)

References kit;

V-SFM-K2_01G (4 X 1 ml Glass bottle)

V-SFM-K2_05G (4 X 5 ml Glass bottle)

V-SFM-K2_10G (4 x 10 ml Glass bottle)

V-SFM-K2_12G (4 X 12 ml Glass bottle)

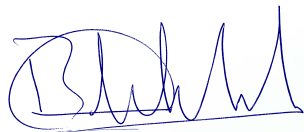
V-SFM-K2_20G (4 X 20 ml Glass bottle)

V-SFM-K2_50G (4 X 50 ml Glass bottle)

Initial date: 4 February 2020

Revised: 20 February 2020

DEKRA Certification B.V.

A blue ink signature of B.T.M. Holtus, consisting of stylized, overlapping loops and lines.

B.T.M. Holtus
Managing Director

A blue ink signature of J.A. van Vugt, featuring a large, flowing 'J' and 'V'.

J.A. van Vugt
Certification Manager

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