EC DESIGN-EXAMINATION CERTIFICATE

Number: 2154875DE01

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

Manufacturer:
Gynemed GmbH & Co. KG
Lubecker Straße 9
23738 Lensahn
Germany

For the product

GM501 CRYO - 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 2154875CN, initially dated 27 November 2012
CE Marking of Conformity 2154875CE01
Addendum, initially dated 2 March 2016

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: 2 March 2016
Reissued: 12 November 2018

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

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: 2154875DE01

EC DESIGN-EXAMINATION
MEDICAL DEVICES

GM501 CRYO - Cell culture media for the cryopreservation of spermatozoa, oocytes and embryos for use in IVF, ICSI or similar procedures of ART

Issued to:

Gynemed GmbH & Co. KG
Lubecker Straße 9
23738 Lensahn
Germany

This certificate covers the following product(s):

Devices:
GM501 EmbryoStore (kit)
GM501 EmbryoStore Freezing Medium
GM501 EmbryoStore Thawing Medium 1
GM501 EmbryoStore Thawing Medium 2
GM501 EmbryoStore Thawing Medium 3
GM501 SpermStore
GM501 SpermStore 9er
GM501 VitriStore (kit)
GM501 VitriStore Freeze (kit)
GM501 VitriStore Freeze Pre-vitrification Medium
GM501 VitriStore Freeze Medium 1
GM501 VitriStore Freeze Medium 2
GM501 VitriStore Thaw (kit)
GM501 VitriStore Thaw Medium 1
GM501 VitriStore Thaw Medium 2
GM501 VitriStore Thaw Medium 3
GM501 VitriStore Thaw Medium 4
GM501 GentleVit Freeze (kit)
GentleVit – GM501 Pre-vitrification medium
GentleVit – GM501 GentleVit Freeze Medium 1

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MEDICAL DEVICES

GM501 CRYO - Cell culture media for the cryopreservation of spermatozoa, oocytes and embryos for use in IVF, ICSI or similar procedures of ART

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GentleVit – GM501 GentleVit Freeze Medium 2
GentleVit – GM501 GentleVit Freeze Medium 3
GentleVit – GM501 GentleVit Freeze Medium 4
GentleVit – GM501 GentleVit Freeze Medium 5
GM501 GentleVit Thaw (kit)
GentleVit – GM501 GentleVit Thaw Medium 1
GentleVit – GM501 GentleVit Thaw Medium 2
GentleVit – GM501 GentleVit Thaw Medium 3
GentleVit – GM501 GentleVit Thaw Medium 4
GentleVit – GM501 GentleVit Thaw Medium 5
GentleVit – GM501 GentleVit Thaw Medium 6

Initial date: 2 March 2016
Revision date: 19 September 2018

DEKRA Certification B.V.

B.T.M. Holtus
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