

EC Declaration of Conformity GM501 Mineral Oil

We, Gynemed GmbH & Co. KG, hereby declare under our sole responsibility, that the distributed CE marked products, specified in the annexed product list, conform to the product(s) covered by the "MDR Certificate", reference number: 748614, issued for the first time on 2024-03-15, in the current revision dated on 2024-06-06, delivered by BSI Group The Netherlands B.V., Amsterdam, The Netherlands, Notified Body Identification Number 2797, in accordance with Annex IX of the "MDR", the Regulation (EU) 2017/745 of the European Parliament and of the Council.

In addition, we ensure and declare that the distributed CE marked products, as mentioned and falling within Class IIa (rule 2), meet the provisions of the MDR, the Regulation (EU) 2017/745 of the European Parliament and of the Council which apply to them.

This declaration is based on the application of the Quality System approved for the design, development, manufacture and final inspection of the products concerned and on assessment of technical documentation of Regulation (EU) 2017/745, in accordance with Annex IX of the Regulation.

This declaration is supported by the Quality System certification based on the harmonized standard ISO13485:2016, Quality System Certificate with reference number: 6587GB445240521 with certificate effective date 2024-05-21 and delivered by MedCert Zertifizierungs- und Prüfungsgesellschaft für die Medizin, Hamburg.

GYNEMED GmbH & Co. KG
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23730 Sierksdorf
Germany
SRN: DE-MF-000005264

Sierksdorf, 2024-10-24



Dr. Julia Heinzmann
(Managing Director)

The validity of this declaration is attached to the corresponding certificates of the notified bodies.

Appendix for EC Declaration of Conformity (product list)

GYNEMED GmbH & Co. KG
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Germany

This product list is part of the EC Declaration of Conformity "Declaration_of_Conformity_GM501_Mineral_Oil_MDR_EN" It specifies the CE-marked products in accordance with the provisions of the Regulation (EU) 2017/745 of the European Parliament and of the Council.

The following list contains the names of the products and the product numbers.

All products produced from 2024-10-03 have been produced under this declaration.

Product list

GM501 Mineral Oil

GM501 Mineral Oil is a ready-to-use oil for covering the medium during IVF/ICSI treatment. GM501 Mineral Oil protects the medium from evaporation and thereby stabilizes pH and temperature.

Product description	Volume	Article number	BASIC UDI-DI
GM501 Mineral Oil	100 ml	4 MO 0100	426017319MOIL93
	250 ml	4 MO 0250	
	500 ml	4 MO 0500	

Product documentation: STED_GM501_Mineral_Oil_GY

Sierksdorf, 2024-10-24



Dr. Julia Heinzmann
(Managing Director)