

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 748614 R000

Manufacturer: Gynemed GmbH & Co. KG

Address:

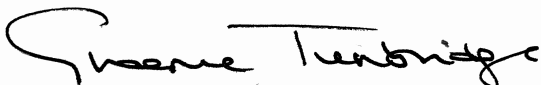
Wagrienring 24b
23730 Sierksdorf
Germany

Single Registration Number: DE-MF-000005264

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):



Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2024-03-15**

Current Issue Date: **2024-06-06**

Starting Validity Date: **2024-06-06**

Expiry Date: **2029-03-14**

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Device Schedule: Class III and Class IIb devices

Class IIb	Intended purpose
GM501 Gradient 100%	GM501 Gradient 100% is a stock solution for semen preparation. GM501 Gradient 45% & 90% are discontinuous gradient systems which effectively separate spermatozoa from seminal plasma, and select a subpopulation of spermatozoa with good motility, viability and chromatin integrity.
GM501 Gradient 90%	
GM501 Gradient 45%	

Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
GM501 Mineral Oil	Class IIa

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2024-03-15	3424957	Issued.
Current	30188093	Amended – administrative change to correct manufacturer’s SRN. Supplemented – addition of GM501 Mineral Oil.



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Validity of this certificate is conditional on the Manufacturer’s quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.