GYNEMED

EC Declaration of Conformity
GM508 CultActive

Group: General/Other IVDs all IVDs other than those covered by Annex II and IVDs for self-testing

according to Annex III of the IVD Directive 98/79/EC

We hereby declare under our own responsibility that the below listed in-vitro diagnostic medical devices are in conformity with the essential requirements referred to in Annex I Directive 98/79/EC, as last amended by Directive 2007/47/EC of 05th September 2007.

Undersigned declares to fulfill the obligations imposed by Annex III section 2 to 5:

- Availability of the technical documentation set in Annex III (section 3), allowing the assessment of the conformity of the product with the requirements of the Directive.
- The manufacturer shall take necessary measures to ensure that the manufacturing process follows the principles of quality assurance as appropriate for the products manufactured (Annex III section 4).
- The manufacturer shall institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective actions (Annex III section 5).

This statement is based on the certification of the quality management system on the basis of the harmonized standard ISO 13485, Process No.: QS - 6587, reissued on 2022-08-26 by MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin, Hamburg. In the fields of design and development, manufacture, final inspection and distribution of products for reproductive medicine.

This Declaration of Conformity is signed below, certifying that the requirements of Annex I and Annex III have been met and documented.

GYNEMED GmbH & Co. KG
Wagrienring 24b
23730 Sierksdorf
Germany

Sierksdorf, 2023-09-15

J. Heinzmann

Dr. Julia Heinzmann
(Managing Director)

Appendix for EC Declaration of Conformity (product list)

GYNEMED GmbH & Co. KG
Wagrienring 24b
23730 Sierksdorf
Germany

This product list is part of the EC Declaration of Conformity "Declaration_of_Conformity_GM508_CultActive". It specifies the CE-marked products in accordance with the provisions of Council Directive 98/79/EC, as last amended by Directive 2007/47/EC of the 05th September 2007 will be manufactured and sold.

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

All products produced from 2023-09-15 have been produced under this declaration.

Product list

GM508 CultActive

Product description		Article number
GM508 CultActive	1ml	4 GM 508CULT-active1

Sierksdorf, 2023-09-15

Dr. Julia Heinzmann
(Managing Director)