

EC Certificate of Conformity

The Notified Body

**MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany**

herewith certifies that the company:

**Gynemed GmbH & Co. KG
Lübecker Str. 9
23738 Lensahn
Germany**

has introduced and maintains a quality assurance system for the products / product categories listed in the appendix.

The compliance of this quality assurance system with the below mentioned requirements of the **Council Directive 93/42/EEC** was verified by an audit:

Annex II without section 4

This certification is subject to surveillance by MEDCERT.

This certificate is valid from 28 July 2019 until 27 May 2024

Report No.: 6587FS11F
Process No.: QS – 6587
Certificate No.: 6587GB410190717

Hamburg, 17 July 2019



MEDCERT Certification Body
(Dr. Andreas Schich)

The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

MEDCERT Identification Number: 0482

Form F10010005e EN / Rev. 10 / 2019.05.22



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-237.10.15

Appendix of EC Certificate of Conformity

Process No.: QS – 6587

Certificate No.: 6587GB410190717

List of products / product categories included in the scope of certificate

- **Culture Media for the in vitro culture of human embryos, oocytes and spermatozoa for use in Assisted Reproductive Technology**
- **Density gradient for separation of cells including processing of sperm cells**
- **Mineral oil for assisted medical reproductive technologies**
- **Micropipettes for use in human reproductive technologies**
- **Medium for the liquefaction of ejaculates**

– End of list –

This appendix is integral part of the above-referenced certificate.
The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

MEDCERT Identification Number: 0482

Form F10010005e EN / Rev. 10 / 2019.05.22



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-237.10.15