

MANAGEMENT SYSTEM CERTIFICATE

Certificate no. 6587GB452250707 Final assessment report no. 6587AU17F

Effective date 2025-07-07

Expiry date 2028-05-13

This is to certify that

Gynemed GmbH & Co. KG

Wagrienring 24b, 23730 Sierksdorf, Germany

has introduced, applies, and maintains a management system at the site listed on the following page.

This management system has been audited and found to conform to the quality management systems standard

EN ISO 13485:2016 + AC:2018 + A11:2021

This certificate is valid for the scope of activities and products/services indicated on the following pages.

Place and date Hamburg, 2025-07-07



For the issuing office DNV MEDCERT GmbH Pilatuspool 2, 20355 Hamburg, Germany

Markus Bianchi Certification Body Operations

The certificate is only valid when provided entirely with all of its pages. To verify the validity of this certificate, contact Medcert-Info@dnv.com



Certificate no.: 6587GB452250707 Place and date: Hamburg, 2025-07-07

Site, activities and products/services covered by this certificate

Gynemed GmbH & Co. KG, Wagrienring 24b, 23730 Sierksdorf, Germany

Design and development, manufacturing, and distribution of

• Products for reproductive medicine

Distribution of

Products for surgical and conservative gynaecology

Distribution, installation and servicing of

Medical devices

