

MANAGEMENT SYSTEM CERTIFICATE

Certificate no.
1324GB452250618

Final assessment report no.
1324AU29F

Effective date
2025-06-18

Expiry date
2028-04-08

This is to certify that

Raguse Gesellschaft für medizinische Produkte mbH

Südfeld 6, 59387 Ascheberg-Herbern, Germany

Has introduced, applies, and maintains a management system at the sites listed on the following pages.

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, 2025-06-18

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



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


Marcus Harder
Certification Body Operations



DNV

Certificate no.: [1324GB452250618](#)
Place and date: [Hamburg, 2025-06-18](#)

Activities and products/services covered by this certificate

Design and development, manufacturing, and distribution of

- Collection systems for organs and tissue
- Surgical gowns
- Drapes

Manufacturing and distribution of

- Procedure packs in the field of
 - General surgery
 - Anaesthesiology
 - Angiology
 - Dentology
 - Dermatology
 - Endocrinology
 - Gastroenterology
 - Vessel surgery
 - Gynaecology
 - Haematology
 - Internal medicine
 - Cardiology
 - Oral and maxillofacial surgery
 - Oncology
 - Ophthalmology
 - Orthopaedics
 - Phlebology
 - Plastic, reconstructive and aesthetic surgery
 - Radiology
 - Thorax surgery
 - Trauma surgery
 - Urology





DNV

Certificate no.: [1324GB452250618](#)
Place and date: [Hamburg, 2025-06-18](#)

Sites covered by this certificate and associated (partial) scopes

Raguse Gesellschaft für medizinische Produkte mbH, Südfeld 6, 59387 Ascheberg, Germany
Design and development, manufacturing, and distribution of

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 - Plastic, reconstructive and aesthetic surgery
 - Radiology
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 - Urology





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Raguse Medizinische Produkte Romania SRL, Str. Malinului Nr. 12, 555300 Cismadie (Heltau), Romania
Manufacturing of

- Collection systems for organs and tissue
- Surgical gowns
- Drapes
- Procedure packs in the field of
 - General surgery
 - Anaesthesiology
 - Angiology
 - Dentology
 - Dermatology
 - Endocrinology
 - Gastroenterology
 - Vessel surgery
 - Gynaecology
 - Haematology
 - Internal medicine
 - Cardiology
 - Oral and maxillofacial surgery
 - Oncology
 - Ophthalmology
 - Orthopaedics
 - Phlebology
 - Plastic, reconstructive and aesthetic surgery
 - Radiology
 - Thorax surgery
 - Trauma surgery
 - Urology

Raguse Medizinische Produkte Maroc SARL, Douar Takad / Sidi Bibi, MA-87100 Chtouka ait Baha, Morocco
Manufacturing of

- Surgical gowns
- Drapes