EU Quality Management System Certificate

Certificate no.	Final Assessment Report no.	Effective date	Expiry date
1324GB448250618	1324AU29F	2025-06-18	2030-04-08

This is to certify that the quality system of

Raguse Gesellschaft für medizinische Produkte mbH

Südfeld 6, 59387 Ascheberg-Herbern, Germany

SRN: DE-MF-000010699

For design, production, and final product inspection/testing of

Medical devices/groups of medical devices listed on the following pages

Has been assessed and found to comply with respect to

The conformity assessment procedure described in Annex IX, Chapters I and III of Regulation (EU) 2017/745 on Medical Devices

Any applicable limitations for certain medical devices are included in the following list or recorded in the final assessment report. This certification is subject to surveillance by DNV MEDCERT.

Place and date
Hamburg, 2025-06-18

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-096

For the issuing office
DNV MEDCERT GmbH – Notified Body 0482
Pilatuspool 2, 20355 Hamburg, Germany

Marcus Harder
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.: 1324GB448250618
Place and date: Hamburg, 2025-06-18

Sites covered by this certificate

Raguse Gesellschaft für medizinische Produkte mbH, Südfeld 6, 59387 Ascheberg, Germany

Raguse Medizinische Produkte Romania SRL, Str. Malinului Nr. 12, 555300 Cisnadie (Heltau), Romania

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

Certificate no.: 1324GB448250618
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Products covered by this certificate

Procedure packs according to Article 22, section 3

For procedure packs placed on the market in sterile condition, the audit of the quality management system was limited to the aspects relating to establishing, securing, and maintaining sterile conditions.

Category	Medical devices/groups of medical devices
MDS 1011	Devices in systems or procedure packs

Class I medical devices

For class I medical devices placed on the market in sterile condition (class Is), the audit of the quality management system was limited to the aspects relating to establishing, securing, and maintaining sterile conditions.

Category	Class	Medical devices/groups of medical devices
MDN 1214	Is	General non-active non-implantable devices used in health care and other non-active non-implantable devices