EU QUALITY MANAGEMENT SYSTEM CERTIFICATE

Certificate no.	Final Assessment Report no.	Effective date	Expiry date
1324GB448250829	1324AU29F	2025-08-29	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 & development, manufacturing and final product inspection/testing of

Medical devices/groups of medical devices at locations as 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, 2025-08-29

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

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

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

820111 EN Rev. 6 2025.07.16

Certificate no.: 1324GB448250829
Place and date: Hamburg, 2025-08-29

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

Preceding certificate

Certificate no.	Issue date	Identification of changes
1324GB448250618	2025-06-18	Addition of MDN 1212, EMDN A090101

Certificate no.: 1324GB448250829
Place and date: Hamburg, 2025-08-29

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 condition.

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

Class IIa medical devices

Category	EMDN code	Medical devices/groups of medical devices
MDN 1212	A090101	ORGAN COLLECTION BAGS