

EU Quality Management System Certificate

Certificate no.
3032GB448241218A

Final Assessment Report no.
3032AU26F

Effective date
2024-12-18

Expiry date
2027-09-24

This is to certify that the quality system of

Rhein Device GmbH

Rhein Device GmbH, Kamerunstraße 20, 50733 Köln, Germany

SRN: DE-MF-000005342

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, 2024-12-18



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

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

Markus Bianchi
Certification Body



DNV

Certificate no.: [3032GB448241218A](#)
Place and date: [Hamburg, 2024-12-18](#)

Sites covered by this certificate

Rhein Device GmbH, Kamerunstraße 20, 50733 Köln, Germany
Rhein Device GmbH c/o Orthogen, Ernst-Schneider-Platz 1, 40212 Düsseldorf, Germany
Rhein Device GmbH c/o Orthogen, Bahnstraße 66, 40210, Düsseldorf, Germany





DNV

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Products covered by this certificate

Class IIb medical devices, excluding implantable non-WET*

Category	EMDN code	Medical devices/groups of medical devices
MDN 1202	A020199	Syringes, single-use - other

Intended purpose

Medical devices for aseptic sampling, transport, storage for extended coagulation and separation of small volumes of blood for obtaining autologous conditioned serum (ACS, also named as Blood Cell Secretome, BCS)

