

EU Quality Management System Certificate

Certificate no.
7334GB448250410

Final Assessment Report no.
7334AU10F

Effective date
2025-04-10

Expiry date
2026-11-09

This is to certify that the quality system of

Plasmaconcept AG

Breite Straße 2-4, 50667 Köln, Germany

SRN: DE-MF-000005281

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, 2025-04-10

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



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

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
Director Certification Body



Certificate no.: 7334GB448250410
Place and date: Hamburg, 2025-04-10

Preceding certificate

Certificate no.	Issue date	Identification of changes
7334GB448220504	2022-05-04	WO-011355; add new product group MDN 1202, A0201

Sites covered by this certificate

Plasmaconcept AG, Breite Straße 2-4, 50667 Köln, Germany





DNV

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Products covered by this certificate

Class IIa medical devices

Category	EMDN code	Medical devices/groups of medical devices
MDA 0306	B0499	AUTOTRANSFUSION DEVICES - OTHER
MDN 1202	A0201	SINGLE-USE SYRINGES

