

EU Quality Management System Certificate

Certificate no.
1340GB448241217

Final Assessment Report no.
1340AU28F

Effective date
2024-12-17

Expiry date
2028-07-02

This is to certify that the quality system of

Dr. Arabin GmbH & Co. KG

Alfred-Herrhausen-Str. 44, 58455 Witten, Germany

SRN: DE-MF-000005474

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, 2024-12-17

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

Marcus Harder
Certification Body

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



DNV

Certificate no.: [1340GB448241217](#)
Place and date: [Hamburg, 2024-12-17](#)

Sites covered by this certificate

Dr. Arabin GmbH & Co. KG, Alfred-Herrhausen-Str. 44, 58455 Witten, Germany

Dr. Arabin GmbH & Co. KG, Koenigsallee 36, 14193 Berlin, Germany





DNV

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Products covered by this certificate

Class IIa medical devices

Category	EMDN code	Medical devices/groups of medical devices
MDN 1214	U089005	PESSARIANS

Class IIb medical devices

Category	EMDN code	Medical devices/groups of medical devices
MDN 1214	U1007	UTERINE CERCLAGE DEVICES

Intended purpose

The Cerclage Pessar Perforated is used for secondary prevention of preterm birth.

