

EU Quality Management System Certificate

Certificate no.
7303GB448240424

Final Assessment Report no.
7303AU09F

Effective date
2024-04-24

Expiry date
2027-08-19

This is to certify that the quality system of

Gomina AG

Raiftstrasse 4, 3989 Niederwald, Switzerland

SRN: CH-MF-000031798

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, 2024-04-24

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


Lorenz Runge
Director Certification Body



Certificate no.: [7303GB448240424](#)
Place and date: [Hamburg, 2024-04-24](#)

Sites covered by this certificate

Gomina AG, Raiftstrasse 4, 3989 Niederwald, Switzerland

Authorised representative

GOMINA Deutschland GmbH, Ludwig-Vierling-Strasse 7, 89233 Neu-Ulm

SRN: DE-AR-000027738





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Products covered by this certificate

Class I medical devices

For class I medical devices that are reusable surgical instruments (class Ir), the audit of the quality management system was limited to the aspects relating to the reuse of the device, in particular cleaning, disinfection, sterilisation, maintenance and functional testing, and the related instructions for use.

Category	Class	Medical devices/groups of medical devices
MDN 1208	Ir	Non-active non-implantable instruments

Class IIa medical devices

Category	EMDN code	Medical devices/groups of medical devices
MDN 1208	L0107	Surgical saws and blades, reusable
	V0103	Blades, single-use - not included in other classes
	V0199	Cutting devices, single-use - other

