

# EU Quality Management System Certificate

Certificate no.  
7303GB448230622

Final Assessment Report no.  
7303AU09F

Effective date  
2023-06-22

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 Chapter I 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, 2023-06-22

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 [info@medcert.de](mailto:info@medcert.de)

**Markus Bianchi**  
Director Certification Body



Certificate no.: [7303GB448230622](#)  
Place and date: [Hamburg, 2023-06-22](#)

### 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

### Products covered by this certificate

#### Class IIa medical devices

Category	EMDN code	Medical devices/groups of medical devices
MDN 1208	L0107	SURGICAL SAWS AND BLADES, REUSABLE
	L0399	GENERAL SURGERY INSTRUMENTS, REUSABLE – OTHER
	L0922	ORTHOPAEDIC SURGERY GUIDES, REUSABLE
	V0103	BLADES, SINGLE-USE – NOT INCLUDED IN OTHER CLASSES
	V0199	CUTTING DEVICES, SINGLE-USE - OTHER

