



MANAGEMENT SYSTEM CERTIFICATE

Certificate no.
7086GB451250310

Final assessment report no.
7086AU16F

Effective date
2025-03-10

Expiry date
2027-10-17

This is to certify that the management system of
Optima Medical Swiss AG
Bundesstrasse 7, 6300 Zug, Switzerland
Facility ID: F006030

With the sites as mentioned on the following pages

Has been found to conform to the quality management system standard
ISO 13485:2016 and the following country-specific requirements

Australia: Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 (without 1.6)
Canada: Medical Devices Regulations (SOR/98-282) – Part 1 (applicable requirements)

This certificate is valid for the scope of activities and products/services indicated on the following pages.

Place and date
Hamburg, 2025-03-10

For the issuing office
DNV MEDCERT GmbH
Pilatuspool 2, 20355 Hamburg, Germany

DNV MEDCERT is an MDSAP
authorised auditing organisation

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

Lack of fulfillment of conditions as set out in the Certification Agreement may render this Certificate invalid.

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AUTHORISED UNIT: DNV MEDCERT GmbH (previously: MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH)
Pilatuspool 2, 20355 Hamburg, Germany, Tel +49 40 2263325-0, www.med-cert.com, www.dnv.com

Activities and products/services covered by this certificate

Design and development, manufacturing, and distribution of

- Ophthalmic products (eye drops and eye lid solutions)
- Hyaluronate based lubricant eye drops
- Eye and skin rinsing solutions
- Liposomal inhalation solutions
- Ear care sprays
- Nasal sprays
- Moisturising sprays for oral cavities

Sites covered by this certificate

Optima Medical Swiss AG, Bundesstrasse 7, 6300 Zug, Switzerland

Facility ID: F006030

Site-specific scope

Oversight of matters related to the management process

