



MANAGEMENT SYSTEM CERTIFICATE

Certificate no.
4652GB451230106

Final assessment report no.
4652AU19F

Effective date
2023-01-06

Expiry date
2024-06-08

This is to certify that the management system of

Biolase, Inc.

27042 Towne Centre Drive, Foothill Ranch, CA 92610, United States of America

Facility ID: F006005

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)
Brazil:	RDC ANVISA n. 665/2022; RDC ANVISA n. 551/2021; RDC ANVISA n. 67/2009
Canada:	Medical Devices Regulations (SOR/98-282) – Part 1 (applicable requirements)
Japan:	MHLW Ministerial Ordinance 169, Article 4 to Article 68; PMD Act (as applicable)
United States:	21 CFR 803; 21 CFR 806; 21 CFR 807; 21 CFR 820

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

Place and date
Hamburg, 2023-01-06

DNV MEDCERT is an MDSAP
authorised auditing organisation

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

Markus Bianchi
Director Certification

The certificate is only valid when provided entirely with all of
its pages. To verify the validity of this certificate, contact
info@medcert.de

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

AUTHORISED UNIT: DNV MEDCERT GmbH (previously: MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH)
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Certificate no.: [4652GB451230106](#)
Place and date: [Hamburg, 2023-01-06](#)

Activities and products/services covered by this certificate

Design and development, manufacture, final inspection, distribution and servicing of

- Medical and dental laser systems
- Laser tips

Manufacture, final inspection, and distribution of

- Dental bleaching gels
- Dental desensitizers

Sites covered by this certificate

Biolase, Inc., 27042 Towne Centre Drive, Foothill Ranch, CA 92610, United States of America
Facility ID: F006005

Site-specific scope

Design and development, manufacture, final inspection, distribution, and servicing of

- Medical and dental laser systems
- Laser tips

Manufacture, final inspection, and distribution of

- Dental bleaching gels
- Dental desensitizers

Biolase, Inc., 4225 Prado Road, Corona, CA 92880, United States of America
Facility ID: F006007

Site-specific scope

Design and development, manufacture, final inspection, distribution, and servicing of

- Medical and dental laser systems
- Laser tips

Manufacture, final inspection, and distribution of

- Dental bleaching gels
- Dental desensitizers