MED CERT®

Certification. Medical Only.

EC Certificate of Conformity

The Notified Body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany

herewith certifies that the company:

Biolase, Inc.
27042 Towne Centre Drive
Foothill Ranch, CA 92610
United State of America

with locations listed in the appendix

has introduced, applies and maintains a quality assurance system for the products / product categories listed in the appendix.

The compliance of this quality assurance system with the below mentioned requirements of the **Council Directive 93/42/EEC** was verified by an audit:

Annex II without section 4

This certification is subject to surveillance by MEDCERT.

Effective date: **2021-05-17**
Expiry date: **2023-06-08**

Report No.: 4652PS16F
Process No.: QS – 4652
Certificate No.: 4652GB410210517A

Hamburg, 2021-05-17

MEDCERT Certification Body
(Dr. Andreas Schich)

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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-237.10.15

MEDCERT Identification Number: 0482

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Appendix of EC Certificate of Conformity

Process No.: QS – 4652
Certificate No.: 4652GB410210517A

List of locations included in the scope of certificate

4225 Prado Road
Corona, CA 92880
United State of America

– End of list –

This appendix is integral part of the above-referenced certificate.
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Appendix of EC Certificate of Conformity

Process No.: QS – 4652
Certificate No.: 4652GB410210517A

List of products / product categories included in the scope of certificate

- **Medical and dental laser systems**
- **Laser tips**

– End of list –

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ZLG-BS-237.10.15

To whom it may concern

DNV MEDCERT GmbH
Pilatuspool 2
20355 Hamburg
Germany

Tel: +49 40 2263325-0
E-mail: Medcert-Info@dnv.com

Date: 2023-06-29

Our reference: QS-4652

Notified Body Confirmation Letter
Certification No: N/A

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

To whom it may concern,

This letter confirms that DNV Medcert GmbH, a Notified Body (NB), designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0482 on Nando[1], has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer.

Biolase, Inc.
27042 Towne Centre Drive
CA 92610 Foothill Ranch
United States of America
SRN[2]: US-MF-000028587

The devices covered by the formal application and the written agreement mentioned above are identified in the tables (in the appendix of this letter). Table 1 identifies the devices for which an MDR application has been received, a written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by 20 March 2023 for the relevant devices.

[1] Nando (New Approach Notified and Designated Organisations) Information System, https://ec.europa.eu/growth/tools-databases/nando/.
[2] Single registration number (SRN) according to Article 31 (2) of MDR.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by EU 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding well established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips, and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa devices, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

For DNV MEDCERT GmbH

Lorenz Runge
Chief Certification

Appendix (see following pages):

- Table 1 and Table 2
- Revision history

Appendix

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
General and multidisciplinary surgery instruments	Class IIa	N/A	Certificate 4652GB410210517A NB 0482
Laser surgery instruments	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate 4652GB410210517A NB 0482

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
None	None	None	None

Confirmation Letter Revision History:

Date	NB internal reference traceable to each version of the letter	Action
2023-06-29	N/A	Initial issue

MANAGEMENT SYSTEM CERTIFICATE

Certificate no.	Final assessment report no.	Effective date	Expiry date
4652GB451240923	4652AU21F	2024-09-23	2027-06-08

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
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, 2024-09-23

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

DNV MEDCERT is an MDSAP authorised auditing organisation

Marcus Harder
Director 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

Certificate no.: 4652GB451240923
Place and date: Hamburg, 2023-09-23

Activities and products/services covered by this certificate

Design and development, manufacturing, distribution, and servicing of

- Medical and dental laser systems
- Laser tips
- Laser fibers

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 and distribution of

- Medical and dental laser systems
- Laser tips
- Laser fibers

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

Site-specific scope
Manufacturing and servicing of

- Medical and dental laser systems
- Laser tips
- Laser fibers