



**EC Declaration of Conformity
According to 93/42/EEC, Annex II**

Manufacturer: **Biolase, Inc.**
4 Cromwell
Irvine, CA 92618 / USA

EU Representative: **MT Promedt Consulting GmbH**
Altenhofstrasse 80
D-66386 St. Ingbert / Germany

Product: **Waterlase iPlus Dental Laser System**

Part Number: **per part list**

Declaration: By the virtue of this declaration, Biolase, Inc. declares, under its sole responsibility, that the Waterlase iPlus Dental Laser System is a class IIb medical device and it is manufactured in conformity with the Essential Requirements of Annex I and applicable provisions of the Council Directive 93/42/EEC, as demonstrated by the EC Certificate of Conformity No. 4652GB410200427.

UMDNS Code: 17-768

Notified Body: **MEDCERT GmbH**
CE 0482
Pilatuspool 2
20355 Hamburg / Germany

Alicia Mszyca
Director, Regulatory Affairs
Biolase, Inc.

2020-05-05

This Declaration of Conformity is limited to the devices built under the Technical File, rev.5.

Part List

REF	Description
7200854-01	Waterlase iPlus Dental Laser System, Pearl White
7200854-02	Waterlase iPlus Dental Laser System, Racing Red
7200854-03	Waterlase iPlus Dental Laser System, Gloss Black
7200854-04	Waterlase iPlus Dental Laser System, Midnight Blue
7200854-05	Waterlase iPlus Dental Laser System, Bright Lime
7200854-07	Waterlase iPlus Dental Laser System, Burnt Orange
7200854-08	Waterlase iPlus Dental Laser System, Pink
7200854-09	Waterlase iPlus Dental Laser System, Platinum
7200854-11	Waterlase iPlus Dental Laser System, Purple
7200854-12	Waterlase iPlus Dental Laser System, Yellow
7200854-13	Waterlase iPlus Dental Laser System, Aquarium
7200854-14	Waterlase iPlus Dental Laser System, Jungle
7200854-15	Waterlase iPlus Dental Laser System, Fish
7200854-16	Waterlase iPlus Dental Laser System, Zebra

REF	Description
7200854-01P	Waterlase iPlus Dental Laser System, Pearl White, <i>Refurbished</i>
7200854-02P	Waterlase iPlus Dental Laser System, Racing Red, <i>Refurbished</i>
7200854-03P	Waterlase iPlus Dental Laser System, Gloss Black, <i>Refurbished</i>
7200854-04P	Waterlase iPlus Dental Laser System, Midnight Blue, <i>Refurbished</i>
7200854-05P	Waterlase iPlus Dental Laser System, Bright Lime, <i>Refurbished</i>
7200854-07P	Waterlase iPlus Dental Laser System, Burnt Orange, <i>Refurbished</i>
7200854-08P	Waterlase iPlus Dental Laser System, Pink, <i>Refurbished</i>
7200854-09P	Waterlase iPlus Dental Laser System, Platinum, <i>Refurbished</i>
7200854-11P	Waterlase iPlus Dental Laser System, Purple, <i>Refurbished</i>
7200854-12P	Waterlase iPlus Dental Laser System, Yellow, <i>Refurbished</i>
7200854-13P	Waterlase iPlus Dental Laser System, Aquarium, <i>Refurbished</i>
7200854-14P	Waterlase iPlus Dental Laser System, Jungle, <i>Refurbished</i>
7200854-15P	Waterlase iPlus Dental Laser System, Fish, <i>Refurbished</i>
7200854-16P	Waterlase iPlus Dental Laser System, Zebra, <i>Refurbished</i>

Attachment to declaration of conformity Waterlase Laser System originally issued May 5th, 2020:

EC Declaration of Conformity
According to 93/42/EEC, Annex II

Manufacturer Name:	BIOLASE MG LLC
Manufacturer Address:	27042 Towne Centre Drive, Suite 270 Foothill Ranch, CA 92610 / USA
Authorized Representative:	MT Promedt Consulting GmbH
Authorized Representative Address:	Ernst-Heckel-Straße 7, St. Ingbert, Germany, 66386
Name of the Device(s):	Waterlase Laser System
Part Number:	See attachment below
UMDNS Code: Classification:	17768 IIb
Declaration:	By the virtue of this declaration, Biolase MG LLC declares, under its sole responsibility, that the Waterlase Laser Systems are Class IIb devices manufactured in conformity with the Essential Requirements of Annex I and applicable provisions of the Directive 93/42/EEC as demonstrated by the EC Certificate of Conformity Number 4652GB410210517A and Notified Body MDR Offer Confirmation Letter. Further explanation can be provided in the Biolase Letter on CE upon request.
Notified Body:	DNV MEDCERT GmbH
Notified Body Number:	CE 0482
Notified Body Address:	Pilatuspool 2, Hamburg, Germany, 20355

This declaration of conformity is issued under the sole responsibility of Biolase MG LLC.

All supporting documentation is retained at the premises of the manufacturer.

Alina Sivriver

Alina Sivriver
Sr. Manager, Clinical Research and R&D; PRRC
2025-03-25

SOP-026 Rev. D, Attachment I - EU DOC Template - ECO-001467



Part List

Reference Number	Description	Basic UDI-DI / EUDAMED DI	UDI-DI
7210001	Waterlase Express	00647529 0301 NS / B-00647529003534	00647529002339
7200854-01	Waterlase iPlus, Pearl White	00647529 0302 NU / B-00647529003831	00647529003831
7200854-02	Waterlase iPlus, Racing Red	00647529 0302 NU / B-00647529003848	00647529003848
7200854-03	Waterlase iPlus, Gloss Black	00647529 0302 NU / B-00647529003855	00647529003855
7200854-04	Waterlase iPlus, Midnight Blue	00647529 0302 NU / B-00647529003862	00647529003862
7200854-05	Waterlase iPlus, Bright Lime	00647529 0302 NU / B-00647529003879	00647529003879
7200854-07	Waterlase iPlus, Burnt Orange	00647529 0302 NU / B-00647529003886	00647529003886
7200854-09	Waterlase iPlus, Platinum	00647529 0302 NU / B-00647529003893	00647529003893
7200854-11	Waterlase iPlus, Purple	00647529 0302 NU / B-00647529003909	00647529003909
7200854-12	Waterlase iPlus, Yellow	00647529 0302 NU / B-00647529003916	00647529003916
7200854-13	Waterlase iPlus, Aquarium	00647529 0302 NU / B-00647529003923	00647529003923
7200854-14	Waterlase iPlus, Jungle	00647529 0302 NU / B-00647529003930	00647529003930
7200854-15	Waterlase iPlus, Fish	00647529 0302 NU / B-00647529003947	00647529003947
7200854-16	Waterlase iPlus, Zebra	00647529 0302 NU / B-00647529003954	00647529003954

SOP-026 Rev. D, Attachment I - EU DOC Template - ECO-001467

Reference Number	Description	Basic UDI-DI / EUDAMED DI	UDI-DI
7200854-17	Waterlase iPlus, Rose Gold	00647529 0302 NU / B-00647529004340	00647529004340
7200401	Waterlase MD Turbo	00647529 0304 64 / B-00647529001554	00647529001554
7200861	Waterlase MDX 300	00647529 0303 NW / B-00647529000304	00647529000298
7200860	Waterlase MDX 450	00647529 0303 NW / B-00647529000298	00647529000304
7210002	EdgePro	00647529 0303 NW	00647529004135
7200854-01P	Waterlase iPlus CPO, Pearl White	00647529 0302 NU	00647529003831
7200854-02P	Waterlase iPlus CPO, Racing Red	00647529 0302 NU	00647529003848
7200854-03P	Waterlase iPlus CPO, Gloss Black	00647529 0302 NU	00647529003855
7200854-04P	Waterlase iPlus CPO, Midnight Blue	00647529 0302 NU	00647529003862
7200854-05P	Waterlase iPlus CPO, Bright Lime	00647529 0302 NU	00647529003879
7200854-07P	Waterlase iPlus CPO, Burnt Orange	00647529 0302 NU	00647529003886
7200854-09P	Waterlase iPlus CPO, Platinum	00647529 0302 NU	00647529003893
7200854-11P	Waterlase iPlus CPO, Purple	00647529 0302 NU	00647529003909
7200854-12P	Waterlase iPlus CPO, Yellow	00647529 0302 NU	00647529003916
7200854-13P	Waterlase iPlus CPO, Aquarium	00647529 0302 NU	00647529003923
7200854-14P	Waterlase iPlus CPO, Jungle	00647529 0302 NU	00647529003930
7200860-06P	Waterlase MDX 450 CPO	00647529 0302 NU	00647529002506
7200861-06P	Waterlase MDX 300 CPO	00647529 0302 NU	00647529002513