Certificate

EC Certificate

Full Quality Assurance System according to Medical Devices Directive 93/42/EEC Annex-II Section 3

Certificate Number: 1984-MDD-16-372

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subjected, transposing annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive.

Organization:

CeramOptec GmbH

Siemensstrasse 44, 53121 Bonn, Germany
Facility: Brühler Strasse 30 53119 Bonn, Germany

Products: The products defined at the enclosure which is the part of this certificate and contains two pages.

The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits.

Report Number:	M.4508.02
Date of first issue:	14 March 2016
Date of last issue:	16 January 2017
Revision Number:	01
Expiry Date:	13 March 2019

16 January 2017, Istanbul, Turkey

Head of Notified Body

Kiwa Meyer Certification Services Inc.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, Istanbul, Turkey
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Certificate

kiwa
Partner for progress

Enclosure of the Certificate:

Full Quality Assurance System according to
Medical Devices Directive 93/42/EEC Annex II Section 3
Certificate Number: 1984-MDD-16-372, Revision Number: 01

Concerned medical devices;

Product: Diode Lasers
Types:

- Type Ceralas E
- Type Ceralas HPD
- Type Leonardo

Product: Probes for Lasers
Types:

- Type Bare Fiber, single-use, sterile
- Type Bare Fiber, reusable
- Type Endoprobe, single-use, sterile
- Type Gas Liquid Cooled, single-use, sterile
- Type Side Fiber, single-use, sterile
- Type PLDD Bare Fiber, single-use, sterile
- Type Cylindrical diffuser, single-use, sterile
- Type ELVeS Fiber, single-use, sterile
- Type Twister, single-use, sterile
- Type ELVeS Radial, single-use, sterile
- Type Bare fiber for Ho:YAG Laser, single-use, sterile
- Type Bare fiber for Ho:YAG Laser, reusable

Kiwa Meyer Certification Services Inc. is Notified Body under Council Directive 93/42/EEC concerning medical devices with identification number : 1984

16 January 2017, Istanbul, Turkey

Head of Notified Body

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Certificate

Enclosure of the Certificate:

Full Quality Assurance System according to
Medical Devices Directive 93/42/EEC Annex II Section 3
Certificate Number: 1984-MDD-16-372, Revision Number: 01

Concerned medical devices;

Product: Handpieces
Type:

- Type Laser Focus Handpiece, reusable
- Type Derma Handpiece; reusable

Product: Introducer for Probes
Type:

- Type ELVeS Plus Catheter, sterile

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16 January 2017, Istanbul, Turkey

Head of Notified Body

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Certificate

kiwa
Partner for progress

CeramOptec GmbH

Siemensstrasse 44 53121 Bonn Germany
Facility: Brühler Strasse 30 53119 Bonn Germany

with a scope of

Design and development, manufacture, installation, distribution and service of fiber optic delivery systems and laser systems with accessories

Medical devices - Quality management systems - Requirements for regulatory purposes

" Following elements of the standard are excluded "
"7.5.3.2.2" "8.2.4.2"

EN ISO 13485:2012

Certificate No	: M 10352
Initial Certification Date	: 14 March 2016
Certification Date	: 14 March 2016
Expiration Date	: 13 March 2019

General Manager

TÜRKAK
Medical Device Q.M.S.
TS EN ISO/IEC 17021
AB-0006-YS

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Certificate is valid till expiration date, subject to successful completion of periodical surveillance audits.
Please contact above numbers for detailed information.

Last Modified: 14 March 2016- R 00