

**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**

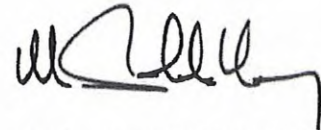
Siemensstrasse 44, 53121 Bonn, Germany  
**Facility:** Brühler Strasse 30 53119 Bonn, Germany

**Products:** Diode Lasers, Probes for Lasers, Handpieces, Introducer for Probes, Athletic LED

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. Please contact Kiwa for details.

Design Examination according to Medical Devices Directive 93/42/EEC Annex-II Section 4 certificate is also mandatory for class III device covered by this certificate.

**Report Number:** M.4508.06  
**Date of first issue:** 14 March 2016  
**Date of last issue:** 25 May 2021  
**Revision Number:** 06  
**Expiry Date:** 12 March 2024



Muhteşem Gökhan Yücel  
Head of Notified Body

25 May 2021, Istanbul, Turkey



CERTIFICATE



**EC Certificate**  
**Design Examination According to**  
**Medical Devices Directive 93/42/EEC Annex-II Section 4**

**Certificate Number: 1984-MDD-21-745**

We hereby declare that a design examination has been carried out on the devices listed hereafter following the requirements of the national legislation to which the undersigned is subjected, transposing Annex II Section 4 of the Directive 93/42/EEC on medical devices. We certify that the design of the device(s) listed thereafter conforms with the relevant provisions of Annex II Section 4 of the Directive 93/42/EEC on medical devices as transposed into national legislation.

**Organization**

**CeramOptec GmbH**

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

**Product:** CALA, Single Use, Sterile

**Type:** Cala Fiber

The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

Full quality assurance system according to Medical Devices Directive 93/42/EEC Annex-II Section 3 certificate is also mandatory for class III devices covered by this certificate.

**Report Number:** M.4508.06

**Expiry Date:** 12 March 2024

Kiwa Belgelendirme Hizmetleri A.Ş. is Notified Body under Council Directive 93/42/EEC concerning medical devices with identification number: 1984

**Muhteşem Gökhan Yücel**  
Head of Notified Body

15 March 2021, Istanbul, Turkey





# CERTIFICATE



Page 1/2

**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: 06**

Concerned medical devices;

**Product:** Diode Lasers

- Types:**
- Type Ceralas E
  - Type Ceralas HPD
  - Type Leonardo
  - Type Leonardo HPD
  - Type Leonardo Mini
  - Type Leonardo Bonsai
  - Type Leonardo FPS

**Product:** Probes for Lasers

- Types:**
- Type Bare Fiber, single-use, sterile
  - Type Bare Fiber, reusable, sterile
  - 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, sterile
  - X-Ray, single-use, sterile
  - CALA, single-use, sterile

Muhteşem Gökhan Yücel  
Head of Notified Body

25 May 2021, Istanbul, Turkey



# CERTIFICATE



Page 2/2

**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: 06**

Concerned medical devices;

**Product:** Handpieces

**Type:** Type Derma Handpiece; reusable, Loma Handpiece

**Product:** Introducer for Probes

**Type:** Type ELVeS Plus Catheter, sterile

**Product:** Athletic LED

Kiwa Belgelendirme Hizmetleri A.Ş. is Notified Body under Council Directive 93/42/EEC concerning medical devices with identification number: 1984

Muhteşem Gökhan Yücel  
Head of Notified Body

25 May 2021, Istanbul, Turkey





CERTIFICATE



**CeramOptec**  
**CeramOptec GmbH**

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

with a scope of

**Design, production, distribution and service of optical preforms,  
optical fibers and fiber optic delivery systems**

Has established a quality management system in accordance  
with international standard.

*" Following elements of the standard are excluded "*

*" None "*

**ISO 9001:2015**

Certificate No : M 10351  
Initial Certification Date : 14 March 2016  
Certification Date : 28 February 2019  
Expiration Date : 27 February 2022



Quality Management System  
TS EN ISO/IEC 17021-1

AB-0006-YS



TÜRKAK BDS NO  
YS-CFC6-6520

General Manager

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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: 28 February 2019 - R 02

## CeramOptec CeramOptec GmbH

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

with a scope of

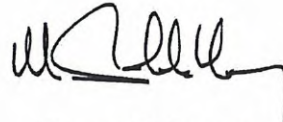
**Design and development, manufacture, installation,  
distribution and service of fiber optic delivery  
systems and laser systems with accessories**

Medical devices - Quality management systems - Requirements for  
regulatory purposes

*"Following elements of the standard are excluded"*  
*"7.5.9.2.2"*

## EN ISO 13485:2016

Certificate No : M 10352  
Initial Certification Date : 14 March 2016  
Certification Date : 28 February 2019  
Expiration Date : 27 February 2022



General Manager

Kiwa Certification Services Inc.  
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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.*