

# Certificate

LGA InterCert Zertifizierungsgesellschaft mbH, an accredited and recognized certification body for quality management systems, herewith certifies that the company

**CeramOptec**

**CeramOptec GmbH**  
**Siemensstraße 44**  
**53121 Bonn**  
**Germany**

has introduced a

## Quality Management System

in accordance with

### DIN EN ISO 9001:2008

Quality management systems - Requirements

for the scopes: Design, Production, Distribution and Service of Optical Preforms,  
Optical Fibers and Fiber Optic Delivery Systems

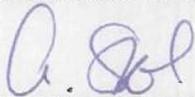
which is being applied.

In a certification audit carried out by LGA InterCert Zertifizierungsgesellschaft mbH, evidence was furnished proving that the quality system of the company fulfills the requirement of the above-mentioned standard.

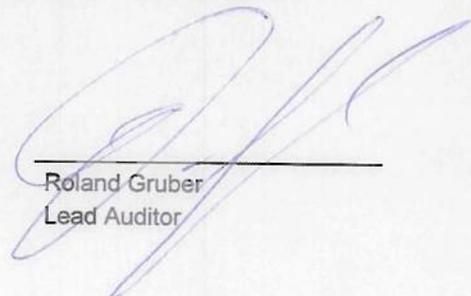
This certificate is valid until March 12, 2014

Registration no.: **QM-1901874**

Nuremberg, March 13, 2011



Andrea Sterl  
Authorized Signatory



Roland Gruber  
Lead Auditor

# Certificate

The LGA InterCert Zertifizierungsgesellschaft mbH, an accredited registrar for quality management systems, herewith confirms that the following company

**CeramOptec**

**CeramOptec GmbH**  
**Siemensstraße 44**  
**53121 Bonn**  
Germany

has introduced and applies a

## Quality Management System

for medical devices according to

**EN ISO 13485:2003 + AC:2009**

Requirements for regulatory purposes

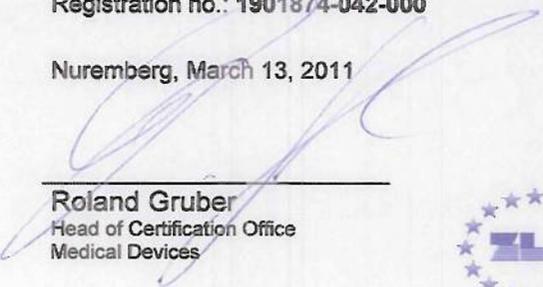
for the scopes: Design, Production, Distribution and Service of Fiber Optic Delivery Systems and Laser Systems with accessories

Proof of fulfillment of the above-mentioned standard has been provided by the certification through LGA InterCert.

This certificate is valid until March 12, 2016  
Registration no.: **1901874-042-000**

Audit report no.: 1901874  
of: January 20, 2011

Nuremberg, March 13, 2011

  
**Roland Gruber**  
Head of Certification Office  
Medical Devices



Akkreditiert durch  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln  
und Medizinprodukten  
ZLG-ZQ-980.02.14-46

# EC Certificate

The LGA InterCert GmbH – **Notified Body 1275** according to the EC Directive concerning medical devices – herewith confirms that the following company

**CeramOptec**

**CeramOptec GmbH**  
**Siemensstraße 44**  
**53121 Bonn**  
Germany

applies a

## Full Quality Assurance System

for the design, manufacture and final inspection of the medical devices as specified in the enclosure within the scopes: Fiber Optic Delivery Systems and Laser Systems with accessories

according to

## Directive 93/42/EEC, Annex II excluding (4).

In a certification audit carried out by LGA InterCert GmbH, evidence was furnished proving that the quality system of the company fulfills the requirement of the above-mentioned directive.  
The surveillance through the LGA InterCert GmbH is effected according to Annex II (5).

This certificate is valid until March 12, 2016  
Registration no.: 1901874-006-000

Audit report no.: 1901874  
of: January 20, 2011

Nuremberg, March 13, 2011

Roland Gruber  
Head of Certification Office  
Medical Devices



It is allowed for the company to sign the products specified in the enclosure with the adjoining sign.



**Enclosure of the Certificate Registration no. 1901874-006-000 of the company  
CeramOptec GmbH, Siemensstraße 44, 53121 Bonn, Germany**

Period of Validity March 13, 2011 until March 12, 2016

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The above-mentioned certificate refers to the following medical devices:

No.	Product	UMDNS-No.	Class
1.	<b>Diode Laser 800-2100nm for phlebology, dermatology, surgical (urology, otorhinolaryngology, gynecology, pneumology, proctology, lipolysis)</b>		
	<ul style="list-style-type: none"> <li>Type Ceralas D Article: Article list Laser Ceralas D</li> </ul>	17-447	IIb
	<ul style="list-style-type: none"> <li>Type Ceralas E Article: Article list Laser Ceralas E</li> </ul>	17-447	IIb
	<ul style="list-style-type: none"> <li>Type Ceralas HPD Article: Article list Laser Ceralas HPD</li> </ul>	17-447	IIb
2.	<b>Diode Laser 630-800nm for Phototherapy</b>		
	<ul style="list-style-type: none"> <li>Type Ceralas PDT Article: Article list Laser Ceralas PDT</li> </ul>	17-447	IIb
	<ul style="list-style-type: none"> <li>Type Ceralas E Article: Article list Laser Ceralas E</li> </ul>	17-447	IIb
3.	<b>Diode Laser 532 / 630-808nm for Ophthalmology</b>		
	<ul style="list-style-type: none"> <li>Type Ceralas G / 532nm Article: Article list Laser Ceralas G</li> </ul>	17-447	IIb
	<ul style="list-style-type: none"> <li>Type Ceralas I / 630-808nm Article: Article list Laser Ceralas I</li> </ul>	17-447	IIb
4.	<b>Probes for Diode Laser phlebology, urology, surgical (otorhinolaryngology, pneumology, proctology, lipolysis) ophthalmology, phototherapy</b>		
	<ul style="list-style-type: none"> <li>Type Bare Fiber, single-use, sterile Article: Article list probes</li> </ul>	17-807	IIa
	<ul style="list-style-type: none"> <li>Type Bare Fiber, reusable Article: Article list probes</li> </ul>	17-807	IIa
	<ul style="list-style-type: none"> <li>Type Endoprobe, single-use, sterile Article: Article list probes</li> </ul>	17-807	IIa
	<ul style="list-style-type: none"> <li>Type Gas Liquid Cooled, single-use, sterile Article: Article list probes</li> </ul>	17-807	IIa

**Enclosure of the Certificate Registration no. 1901874-006-000 of the company  
 CeramOptec GmbH, Siemensstraße 44, 53121 Bonn, Germany**

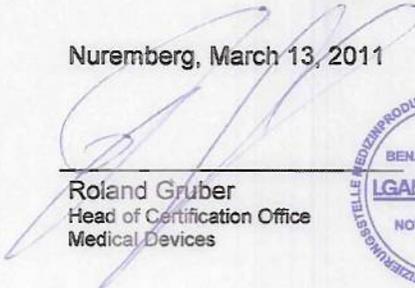
Period of Validity March 13, 2011 until March 12, 2016

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The above-mentioned certificate refers to the following medical devices:

No.	Product	UMDNS-No.	Class
	<ul style="list-style-type: none"> <li>Type Side Fiber, single-use, sterile Article: Article list probes</li> </ul>	17-807	Ila
	<ul style="list-style-type: none"> <li>Type PLDD Bare Fiber, single-use, sterile Article: Article list probes</li> </ul>	17-807	Ila
	<ul style="list-style-type: none"> <li>Type Cylindrical diffuser, single-use, sterile Article: Article list probes</li> </ul>	17-807	Ila
	<ul style="list-style-type: none"> <li>Type ELVeS Fiber, single-use, sterile Article: Article list probes</li> </ul>	17-807	Ila
	<ul style="list-style-type: none"> <li>Type Twister, single-use, sterile Article: Article list probes</li> </ul>	17-807	Ila
	<ul style="list-style-type: none"> <li>Type Radial, single-use, sterile Article: Article list probes</li> </ul>	17-807	Ila
<b>5.</b>	<b>Probes for Ho:YAG-Laser</b>		
	<ul style="list-style-type: none"> <li>Type StarMedTec bare fiber for Ho:YAG Laser, single-use, sterile Article: Article list probes</li> </ul>	17-807	Ila
	<ul style="list-style-type: none"> <li>Type StarMedTec bare fiber for Ho:YAG Laser, reusable Article: Article list probes</li> </ul>	17-807	Ila

Nuremberg, March 13, 2011

  
 Roland Gruber  
 Head of Certification Office  
 Medical Devices

