

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.

CE 1275

**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.	Diode Laser 800-2100nm for phlebology, dermatology, surgical (urology, otorhinolaryngology, gynecology, pneumology, proctology, lipolysis)		
	<ul style="list-style-type: none"> Type Ceralas E Article: Article list Laser Ceralas E 	17-447	IIb
	<ul style="list-style-type: none"> Type Ceralas HPD Article: Article list Laser Ceralas HPD 	17-447	IIb
	<ul style="list-style-type: none"> Type Leonardo Article: Article list Laser Leonardo 	17-447	IIb
2.	Diode Laser 630-800nm for Phototherapy		
	<ul style="list-style-type: none"> Type Ceralas PDT Article: Article list Laser Ceralas PDT 	17-447	IIb
	<ul style="list-style-type: none"> Type Ceralas E Article: Article list Laser Ceralas E 	17-447	IIb
3.	Diode Laser 532 / 630-808nm for Ophthalmology		
	<ul style="list-style-type: none"> Type Ceralas I / 630-808nm Article: Article list Laser Ceralas I 	17-447	IIb
4.	Probes for Diode Laser phlebology, urology, surgical (otorhinolaryngology, pneumology, proctology, lipolysis) ophthalmology, phototherapy		
	<ul style="list-style-type: none"> Type Bare Fiber, single-use, sterile Article: Article list probes 	17-807	IIa
	<ul style="list-style-type: none"> Type Bare Fiber, reusable Article: Article list probes 	17-807	IIa
	<ul style="list-style-type: none"> Type Endoprobe, single-use, sterile Article: Article list probes 	17-807	IIa
	<ul style="list-style-type: none"> Type Gas Liquid Cooled, single-use, sterile Article: Article list probes 	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"> Type Side Fiber, single-use, sterile Article: Article list probes 	17-807	Ila
	<ul style="list-style-type: none"> Type PLDD Bare Fiber, single-use, sterile Article: Article list probes 	17-807	Ila
	<ul style="list-style-type: none"> Type Cylindrical diffuser, single-use, sterile Article: Article list probes 	17-807	Ila
	<ul style="list-style-type: none"> Type ELVeS Fiber, single-use, sterile Article: Article list probes 	17-807	Ila
	<ul style="list-style-type: none"> Type Twister, single-use, sterile Article: Article list probes 	17-807	Ila
	<ul style="list-style-type: none"> Type ELVeS Radial, single-use, sterile Article: Article list probes 	17-807	Ila
5.	Probes for Ho:YAG-Laser		
	<ul style="list-style-type: none"> Type StarMedTec bare fiber for Ho:YAG Laser, single-use, sterile Article: Article list probes 	17-807	Ila
	<ul style="list-style-type: none"> Type StarMedTec bare fiber for Ho:YAG Laser, reusable Article: Article list probes 	17-807	Ila
6.	Introducer for Probes phlebology and surgical		
	<ul style="list-style-type: none"> Type ELVeS Plus Catheter, sterile Article: Article list Introducer 	17-807	Ila
	<ul style="list-style-type: none"> Type Laparoscopic Sheath Article: Article list Introducer 	18-097	Ila

Modification No. 1 and 3 – pos. removed of March 12, 2012(Procedure-No.: 1911693; Reg. No.: 1901874-006-000-001)
 Supplement No. 6 of May 25, 2012 (Procedure-No.: 1920840; Reg. No.: 1901874-006-000-002)
 Supplement No. 1 of May 8, 2013 (Procedure-No.: 1930822; Reg. No.: 1901874-006-000-003)
 Supplement No. 6 of May 24, 2013 (Procedure-No.: 1930823; Reg. No.: 1901874-006-000-004)

Nuremberg, May 24, 2013

Claus-Uwe Hinrichs
 Certification Office
 Medical Devices

