



# CERTIFICATE



This is to certify that the company

## CeramOptec GmbH

Siemensstr. 44  
53121 Bonn  
Germany

with the organizational units/sites as listed in the annex

has implemented and maintains a **Quality Management System**.

Scope of certification:

Design, development and manufacturing of sterile optical fiber, fiber optic delivery systems and laser systems with accessories and service of laser systems with accessories.

**-AUS (a), CAN, JPN, USA (a,b,c,d)**

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

## ISO 13485 : 2016

including applicable country-specific regulatory requirements, as indicated below the scope (full references of abbreviations are listed in the annex)

Certificate registration no.	31625288 MDSAP16
Certificate unique ID	1000199001
Effective date	2025-01-09
Expiry date	2028-01-08
Frankfurt am Main	2025-01-09



## DQS Medizinprodukte GmbH

Heinrich von Mettenheim  
Managing Director



August-Schanz-Straße 21, 60433 Frankfurt am Main,  
Tel. +49 (0) 69 95427-300, [info-med@dqs.de](mailto:info-med@dqs.de)

**DQS Medizinprodukte GmbH is recognized under the Medical Devices Single Audit Program.**

Visit <https://www.dqs.de/en/customer-database/> to validate this certificate.

The validity of the certification can only be verified by the QR-code.



**Annex to certificate**  
**Certificate registration No.: 31625288 MDSAP16**  
**Certificate unique ID: 1000199001**  
**Effective date: 2025-01-09**

## **CeramOptec GmbH**

Siemensstr. 44  
53121 Bonn  
Germany

### **Audited site**

**31626958**  
**CeramOptec GmbH**  
Siemensstr. 44  
53121 Bonn  
Germany

**31626959**  
**CeramOptec GmbH**  
Brühler Str. 30  
53119 Bonn  
Germany

### **REPs FEI No.: site scope and country-specific requirements**

Design, development and manufacturing of  
sterile optical fiber, fiber optic delivery systems  
and laser systems with accessories and service  
of laser systems with accessories.

**-AUS (a), CAN, JPN, USA (a,b,c,d)**

**REPs FEI No.: F007849**

Design, development and manufacturing of  
sterile optical fiber, fiber optic delivery systems  
and laser systems with accessories and service  
of laser systems with accessories.

**-AUS (a), CAN, JPN, USA (a,b,c,d)**

**REPs FEI No.: F007849**



**Annex to certificate**  
**Certificate registration No.: 31625288 MDSAP16**  
**Certificate unique ID: 1000199001**  
**Effective date: 2025-01-09**

## **CeramOptec GmbH**

Siemensstr. 44  
53121 Bonn  
Germany

### **Full references of country-specific requirements of MDSAP participating Regulatory Authorities**

<b>Abbreviation</b>	<b>Jurisdiction</b>	<b>Reference</b>
AUS	Australia	(a) Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 – Full Quality Assurance Procedure (b) Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 4 – Production Quality Assurance Procedure
BRA	Brazil	RDC ANVISA n. 665/2022 RDC ANVISA n. 551/2021 RDC ANVISA n. 67/2009
CND	Canada	Medical Devices Regulations – Part 1- SOR 98/282 Medical Devices Regulations – Part 1.1 – SOR 98/282 (as applicable)
JPN	Japan	MHLW Ministerial Ordinance 169, Article 4 to Article 68 Japan PMD Act (as applicable)
USA	United States	(a) 21 CFR Part 803 (b) 21 CFR Part 806 (c) 21 CFR Part 807 (d) 21 CFR Part 820 (e) 21 CFR Part 821