



Benannt durch/Designated by  
 Zentralstelle der Länder  
 für Gesundheitsschutz  
 bei Arzneimitteln und  
 Medizinprodukten  
 www.zgl.de  
 BS-MDR-099



Product Service

## EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III  
 (Class IIa and Class IIb Devices)

**No. G10 043306 0270 Rev. 01**

**Manufacturer: Ivoclar Vivadent AG**

Bendererstrasse 2  
 9494 Schaan  
 LIECHTENSTEIN

SRN Manufacturer - LI-MF-000000522

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).

The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.

The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.

The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.

For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:G10 043306 0270 Rev. 01](http://www.tuvsud.com/ps-cert?q=cert:G10 043306 0270 Rev. 01)

**Report No.:** 713262116 + 713266642

**Preceding Certificate No.:** G10 043306 0270 Rev. 00

**Valid from:** 2023-10-20

**Valid until:** 2026-05-04

**Date of Initial Issuance:** 2021-08-27

**Issue date:** 2023-10-20

Christoph Dicks  
 Head of Certification/Notified Body

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFICAT



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**Classification:** Class IIa  
**Device Group:** L159006 - DENTAL MATERIAL PROCESSING TOOLS,  
REUSABLE  
**Intended Purpose:** ./.

**Classification:** Class IIa  
**Device Group:** Q010101 - DENTAL RESTORATION DEVICES  
**Intended Purpose:** ./.

**Classification:** Class IIa  
**Device Group:** Q010104 - DENTAL PROCEDURE DEVICES - VARIOUS  
**Intended Purpose:** ./.

**Classification:** Class IIa  
**Device Group:** Q010199 - CONSERVATIVE DENTISTRY AND ENDODONTICS  
DEVICES - OTHER  
**Intended Purpose:** ./.

**Classification:** Class IIa  
**Device Group:** Q010699 - MATERIALS FOR THE PREPARATION OF CUSTOM-  
MADE DENTAL DEVICES - OTHER  
**Intended Purpose:** ./.

**Classification:** Class IIa  
**Device Group:** Q019006 - DENTAL MATERIAL APPLICATION TIPS AND  
BRUSHES, SINGLE-USE  
**Intended Purpose:** ./.

**Classification:** Class IIb  
**Device Group:** P010201 - DENTAL IMPLANTS AND ACCESSORIES  
**Intended Purpose:** Implant-supported hybrid restorations for the replacement of single  
teeth

**Classification:** Class IIb  
**Device Group:** P010201 - DENTAL IMPLANTS AND ACCESSORIES  
**Intended Purpose:** Single-tooth restorations in anterior and posterior teeth, 3-unit  
bridges up to the second premolar as the terminal abutment,  
implant-supported hybrid restorations for the replacement of single  
teeth.



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The validity of this certificate */.*  
 depends on conditions and/or  
 is limited to the following:

### Revision History:

Rev.	Dated	Report	Description
00	2021-08-27	713183138	-
01	2023-10-20	713262116 + 713266642	Supplemented: Device(s)/group of device(s) added