

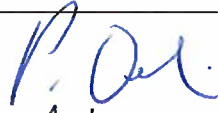
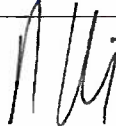
EU Declaration of Conformity according to Medical Device Regulation MDR 2017/745 Annex IV

We hereby declare that this EU Declaration of Conformity is issued under the sole responsibility of the manufacturer and the below mentioned products meet the provisions of the EU Regulation above. All supporting documentation is retained on the premises of the manufacturer and the Notified Body.

Product(s)	IPS e.max ZirCAD MO IPS e.max ZirCAD LT IPS e.max ZirCAD Prime IPS e.max ZirCAD LT Colouring Liquids (incl. Diluter & Indicator)
Basic-UDI-DI	76152082ACERA006F2
Document-ID	OTCS5999398
Document Version	3.0

Legal manufacturer		
	Ivoclar Vivadent AG Bendererstrasse 2 9494 Schaan/Liechtenstein www.ivoclar.com	Phone +423 / 235 35 35, Fax +423 / 235 33 60 www.ivoclar.com Legal Form: Joint Stock Company Corporate Headquarters: 9494 Schaan Registration No.: FL-0001.001.595-7 VAT No.: 50639

EU Declaration of Conformity Information	
SRN	LI-MF-000000522
Intended Purpose	Crowns and bridges in the anterior and posterior region.
Category (MDCG 2019-14)	MDN 1103 Non-active dental implants and dental materials
EMDN Code + term	Q010699 Materials for the preparation of custom-made dental devices - other
MDS Code	---
MDT Code	MDT 2003 MDT 2006 MDT 2011
EU Risk Classification (MDR Annex VIII)	Medical Device Class IIa CE 0123
Conformity Assessment Procedure (MDR Annex IX)	☒ Quality Management System ☐ Assessment of the Technical Documentation
Notified Body Address	TÜV SÜD Product Service GmbH Ridlerstrasse 65 80339 München Deutschland
EC Certificate No.	G10 043306 0270 Rev. 01
Valid until	2026-05-04

Document Control			
Name	Place of issue	Date of issue	Signature
Approver (PRRC): Patrik Oehri	Schaan, LI	08.01.2024	
Approver (CTO): Dr. Thomas Hirt	Schaan, LI	11.01.2024	

Revision History			
Version	Date	Author	Remark
1.0	2022-12-20	R. Ritter	First MDR Version
2.0	2023-08-17	R. Ritter	Add ZrO2 Speed-Sinter-Blocks (Design Review OTCS12017618)
3.0	2024-01-03	R. Ritter	APM108876 PMS 2023