

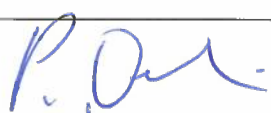
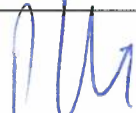
EU Declaration of Conformity according to Medical Device Regulation MDR 2017/745 Annex IV

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 CAD
Basic-UDI-DI	76152082ACERA001EQ
Document-ID	LL3400442
Document Version	2.0

Legal manufacturer		
	Ivoclar Vivadent AG Bendererstrasse 2 9494 Schaan/Liechtenstein www.ivoclarvivadent.com	Phone +423 / 235 35 35, Fax +423 / 235 33 60 www.ivoclarvivadent.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	Anterior and posterior single-tooth restorations, restoration of teeth with 3-unit bridges up to the second premolar as the terminal abutment.
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 2011
EU Risk Classification (MDR Annex VIII)	Medical Device Class IIa  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. 00
Place and date of issue	Schaan, 2022-05-04
Valid until	2026-05-04

Document Control		
Name	Date	Signature
Approver (PRRC): Patrik Oehri	04.05.2022	
Approver (CTO): Dr. Thomas Hirt	04.05.2022	

Revision History			
Version	Date	Author	Remark
1.0	2022-04-27	Regina Ritter	First MDR Version
2.0	2022-05-03	Regina Ritter	Correction of Validity Date