

EU Declaration of Conformity for Class_Ila_6155473

Document Information (OTCS)	
OTCS – Doc.-ID	6155473
Version	9.0

Signatures	
Author(s)	The signatures of all involved signatories are added on the last page of this document.
Reviewer(s)	
Approver(s)	

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

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 (Legal Manufacturer)	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 Classification	☒ Medical Device ☐ Accessory for Medical Device
EU Risk Class (MDR Annex VIII)	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 Munich Germany
EC Certificate No.	G15 043306 0282 Rev. 01
Valid until	2031-05-04

Attachment to EU Declaration of Conformity

Article No.	Description	MDR Classification (EU)	Rule MDR (EU)
596797	IPS e.max CAD for inLab MO 0 C14/5 pcs	Ila	8
596798	IPS e.max CAD for inLab MO 1 C14/5 pcs	Ila	8
596799	IPS e.max CAD for inLab MO 2 C14/5 pcs	Ila	8
596800	IPS e.max CAD for inLab MO 3 C14/5 pcs	Ila	8
596801	IPS e.max CAD for inLab MO 4 C14/5 pcs	Ila	8
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686541	IPS e.max CAD PrograMill LT D2 C16/5	Ila	8
686542	IPS e.max CAD PrograMill LT BL2 B32/3	Ila	8
686543	IPS e.max CAD PrograMill LT A1 B32/3	Ila	8
686544	IPS e.max CAD PrograMill LT A2 B32/3	Ila	8
686545	IPS e.max CAD PrograMill LT A3 B32/3	Ila	8
686546	IPS e.max CAD PrograMill LT A3,5 B32/3	Ila	8
686547	IPS e.max CAD PrograMill LT B1 B32/3	Ila	8
686548	IPS e.max CAD PrograMill LT B2 B32/3	Ila	8
686549	IPS e.max CAD PrograMill LT C1 B32/3	Ila	8
686550	IPS e.max CAD PrograMill LT C2 B32/3	Ila	8
686551	IPS e.max CAD PrograMill LT D2 B32/3	Ila	8
686552	IPS e.max CAD PrograMill MT BL2 C14/5	Ila	8
686553	IPS e.max CAD PrograMill MT BL3 C14/5	Ila	8
686554	IPS e.max CAD PrograMill MT BL4 C14/5	Ila	8
686555	IPS e.max CAD PrograMill MT A1 C14/5	Ila	8
686556	IPS e.max CAD PrograMill MT A2 C14/5	Ila	8
686557	IPS e.max CAD PrograMill MT A3 C14/5	Ila	8
686558	IPS e.max CAD PrograMill MT B1 C14/5	Ila	8
686559	IPS e.max CAD PrograMill HT BL1 I12/5	Ila	8
686560	IPS e.max CAD PrograMill HT BL2 I12/5	Ila	8
686561	IPS e.max CAD PrograMill HT BL3 I12/5	Ila	8
686562	IPS e.max CAD PrograMill HT BL4 I12/5	Ila	8
686563	IPS e.max CAD PrograMill HT A1 I12/5	Ila	8
686564	IPS e.max CAD PrograMill HT A2 I12/5	Ila	8
686565	IPS e.max CAD PrograMill HT A3 I12/5	Ila	8
686566	IPS e.max CAD PrograMill HT A3,5 I12/5	Ila	8
686567	IPS e.max CAD PrograMill HT A4 I12/5	Ila	8
686568	IPS e.max CAD PrograMill HT B1 I12/5	Ila	8
686569	IPS e.max CAD PrograMill HT B2 I12/5	Ila	8
686570	IPS e.max CAD PrograMill HT B3 I12/5	Ila	8
686571	IPS e.max CAD PrograMill HT B4 I12/5	Ila	8
686572	IPS e.max CAD PrograMill HT C1 I12/5	Ila	8
686573	IPS e.max CAD PrograMill HT C2 I12/5	Ila	8
686574	IPS e.max CAD PrograMill HT C3 I12/5	Ila	8
686575	IPS e.max CAD PrograMill HT C4 I12/5	Ila	8
686576	IPS e.max CAD PrograMill HT D2 I12/5	Ila	8
686577	IPS e.max CAD PrograMill HT D3 I12/5	Ila	8
686578	IPS e.max CAD PrograMill HT D4 I12/5	Ila	8
686579	IPS e.max CAD PrograMill HT BL1 C14/5	Ila	8
686580	IPS e.max CAD PrograMill HT BL2 C14/5	Ila	8
686581	IPS e.max CAD PrograMill HT BL3 C14/5	Ila	8
686582	IPS e.max CAD PrograMill HT BL4 C14/5	Ila	8
686583	IPS e.max CAD PrograMill HT A1 C14/5	Ila	8
686584	IPS e.max CAD PrograMill HT A2 C14/5	Ila	8
686585	IPS e.max CAD PrograMill HT A3 C14/5	Ila	8

686586	IPS e.max CAD PrograMill HT A3,5 C14/5	Ila	8
686587	IPS e.max CAD PrograMill HT A4 C14/5	Ila	8
686588	IPS e.max CAD PrograMill HT B1 C14/5	Ila	8
686589	IPS e.max CAD PrograMill HT B2 C14/5	Ila	8
686590	IPS e.max CAD PrograMill HT B3 C14/5	Ila	8
686591	IPS e.max CAD PrograMill HT B4 C14/5	Ila	8
686592	IPS e.max CAD PrograMill HT C1 C14/5	Ila	8
686593	IPS e.max CAD PrograMill HT C2 C14/5	Ila	8
686594	IPS e.max CAD PrograMill HT C3 C14/5	Ila	8
686595	IPS e.max CAD PrograMill HT C4 C14/5	Ila	8
686596	IPS e.max CAD PrograMill HT D2 C14/5	Ila	8
686597	IPS e.max CAD PrograMill HT D3 C14/5	Ila	8
686598	IPS e.max CAD PrograMill HT D4 C14/5	Ila	8
740257	IPS e.max CAD CER/inLab MT A2 C14/1	Ila	8
605318US	IPS e.max CAD CEREC/inLab LT A1 I12/5	Ila	8
605319CN	IPS e.max CAD CEREC/inLab LT A2 I12/5	Ila	8
605319US	IPS e.max CAD CEREC/inLab LT A2 I12/5	Ila	8
605320CN	IPS e.max CAD CEREC/inLab LT A3 I12/5	Ila	8
605320US	IPS e.max CAD CEREC/inLab LT A3 I12/5	Ila	8
605328CN	IPS e.max CAD CEREC/inLab LT A1 C14/5	Ila	8
605328US	IPS e.max CAD CEREC/inLab LT A1 C14/5	Ila	8
605329CN	IPS e.max CAD CEREC/inLab LT A2 C14/5	Ila	8
605329US	IPS e.max CAD CEREC/inLab LT A2 C14/5	Ila	8
605330CN	IPS e.max CAD CEREC/inLab LT A3 C14/5	Ila	8
605330US	IPS e.max CAD CEREC/inLab LT A3 C14/5	Ila	8
605331CN	IPS e.max CAD CEREC/inLab LTA3,5 C14/5	Ila	8
605331US	IPS e.max CAD CEREC/inLab LTA3,5 C14/5	Ila	8
605332CN	IPS e.max CAD CEREC/inLab LT B1 C14/5	Ila	8
605332US	IPS e.max CAD CEREC/inLab LT B1 C14/5	Ila	8
605333CN	IPS e.max CAD CEREC/inLab LT B2 C14/5	Ila	8
605335CN	IPS e.max CAD CEREC/inLab LT C2 C14/5	Ila	8
605335US	IPS e.max CAD CEREC/inLab LT C2 C14/5	Ila	8
605336US	IPS e.max CAD CEREC/inLab LT D3 C14/5	Ila	8
605343CN	IPS e.max CAD CEREC/inLab LT BL1 C14/5	Ila	8
605344CN	IPS e.max CAD CEREC/inLab LT BL2 C14/5	Ila	8
605345CN	IPS e.max CAD CEREC/inLab LT BL3 C14/5	Ila	8
626389US	IPS e.max CAD CEREC/inLab LT D2 C14/5	Ila	8
626392CN	IPS e.max CAD CEREC/inLab HT A2 I12/5	Ila	8
626392US	IPS e.max CAD CEREC/inLab HT A2 I12/5	Ila	8
626393CN	IPS e.max CAD CEREC/inLab HT A3 I12/5	Ila	8
626393US	IPS e.max CAD CEREC/inLab HT A3 I12/5	Ila	8
626407CN	IPS e.max CAD CEREC/inLab HT A1 C14/5	Ila	8
626407US	IPS e.max CAD CEREC/inLab HT A1 C14/5	Ila	8
626408CN	IPS e.max CAD CEREC/inLab HT A2 C14/5	Ila	8
626408US	IPS e.max CAD CEREC/inLab HT A2 C14/5	Ila	8
626409CN	IPS e.max CAD CEREC/inLab HT A3 C14/5	Ila	8
626409US	IPS e.max CAD CEREC/inLab HT A3 C14/5	Ila	8

626410CN	IPS e.max CAD CEREC/inLab HT A3,5 C14/5	Ila	8
626410US	IPS e.max CAD CEREC/inLab HT A3,5 C14/5	Ila	8
626412CN	IPS e.max CAD CEREC/inLab HT B1 C14/5	Ila	8
626413CN	IPS e.max CAD CEREC/inLab HT B2 C14/5	Ila	8
626417CN	IPS e.max CAD CEREC/inLab HT C2 C14/5	Ila	8
626420CN	IPS e.max CAD CEREC/inLab HT D2 C14/5	Ila	8
626427CN	IPS e.max CAD CEREC/inLab HT BL1 C14/5	Ila	8
626428CN	IPS e.max CAD CEREC/inLab HT BL2 C14/5	Ila	8
626429CN	IPS e.max CAD CEREC/inLab HT BL3 C14/5	Ila	8
648190CN	IPS e.max CAD CEREC/inLab LT A3 C16/5	Ila	8
648205CN	IPS e.max CAD CEREC/inLab LT A2 B32/3	Ila	8
648205US	IPS e.max CAD CEREC/inLab LT A2 B32/3	Ila	8
648206CN	IPS e.max CAD CEREC/inLab LT A3 B32/3	Ila	8
648206US	IPS e.max CAD CEREC/inLab LT A3 B32/3	Ila	8
680028CN	IPS e.max CAD CEREC/inLab MT A1 C14/5	Ila	8
680028US	IPS e.max CAD CEREC/inLab MT A1 C14/5	Ila	8
680029CN	IPS e.max CAD CEREC/inLab MT A2 C14/5	Ila	8
680029US	IPS e.max CAD CEREC/inLab MT A2 C14/5	Ila	8
680030CN	IPS e.max CAD CEREC/inLab MT A3 C14/5	Ila	8
680030US	IPS e.max CAD CEREC/inLab MT A3 C14/5	Ila	8
680032CN	IPS e.max CAD CEREC/inLab MT BL2 C14/5	Ila	8

Revision History			
Version	Date	Author	Remark
1.0	2022-04-27	R. Ritter	First MDR Version
2.0	2022-05-03	R. Ritter	Correction of Validity Date
3.0	2023-12-18	R. Ritter	APM108102
4.0	2024-10-31	R. Ritter	APM109774
5.0	2025-05-22	R. Ritter	APM111615
6.0	2025-07-29	R. Ritter	APM112091
7.0	2025-08-18	R. Ritter	APM112018
8.0	2026-02-12	R. Ritter	APM111931, APM111934
9.0	2026-04-27	R. Ritter	Update MDR TÜV Certificate and APM111902

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