

EU Declaration of Conformity for Class_Ilb_12157490

Document Information (OTCS)	
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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 Press
Basic-UDI-DI	76152082BABUT003JC

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	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.
Category (MDCG 2019-14)	MDN 1103 Non-active dental implants and dental materials
EMDN Code + term	P01020101 Dental Implants
MDS Code	MDS 1005
MDT Code	MDT 2003 MDT 2011
EU Classification	☒ Medical Device ☐ Accessory for Medical Device
EU Risk Class (MDR Annex VIII)	Class IIb 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. 02
Valid until	2031-05-04

Attachment to EU Declaration of Conformity

Article No.	Description	MDR Classification (EU)	Rule MDR (EU)
596753	IPS e.max Press HO 0 5 pcs	IIb	8
596754	IPS e.max Press HO 0 L/3 pcs	IIb	8
596756	IPS e.max Press MO 0 5 pcs	IIb	8
596757	IPS e.max Press MO 1 5 pcs	IIb	8
596758	IPS e.max Press MO 2 5 pcs	IIb	8
596759	IPS e.max Press MO 3 5 pcs	IIb	8
596760	IPS e.max Press MO 4 5 pcs	IIb	8
596762	IPS e.max Press MO 0 L/3 pcs	IIb	8
596763	IPS e.max Press MO 1 L/3 pcs	IIb	8
596764	IPS e.max Press MO 2 L/3 pcs	IIb	8
596765	IPS e.max Press MO 3 L/3 pcs	IIb	8
596766	IPS e.max Press MO 4 L/3 pcs	IIb	8
605273	IPS e.max Press LT A1 5 pcs.	IIb	8
605274	IPS e.max Press LT A2 5 pcs.	IIb	8
605275	IPS e.max Press LT A3 5 pcs.	IIb	8
605276	IPS e.max Press LT A3,5 5 pcs.	IIb	8
605277	IPS e.max Press LT B1 5 pcs.	IIb	8
605278	IPS e.max Press LT B2 5 pcs.	IIb	8
605279	IPS e.max Press LT B3 5 pcs.	IIb	8
605280	IPS e.max Press LT C2 5 pcs.	IIb	8
605281	IPS e.max Press LT D3 5 pcs.	IIb	8
605283	IPS e.max Press LT A1 L/3 pcs.	IIb	8
605284	IPS e.max Press LT A2 L/3 pcs.	IIb	8
605285	IPS e.max Press LT A3 L/3 pcs.	IIb	8
605286	IPS e.max Press LT A3,5 L/3 pcs.	IIb	8
605287	IPS e.max Press LT B1 L/3 pcs.	IIb	8
605288	IPS e.max Press LT B2 L/3 pcs.	IIb	8
605289	IPS e.max Press LT B3 L/3 pcs.	IIb	8
605290	IPS e.max Press LT C2 L/3 pcs.	IIb	8
605291	IPS e.max Press LT D3 L/3 pcs.	IIb	8
605293	IPS e.max Press LT BL1 5 pcs.	IIb	8
605294	IPS e.max Press LT BL2 5 pcs.	IIb	8
605295	IPS e.max Press LT BL3 5 pcs.	IIb	8
605296	IPS e.max Press LT BL4 5 pcs.	IIb	8
605298	IPS e.max Press LT BL1 L/3 pcs.	IIb	8
605299	IPS e.max Press LT BL2 L/3 pcs.	IIb	8
605300	IPS e.max Press LT BL3 L/3 pcs.	IIb	8
605301	IPS e.max Press LT BL4 L/3 pcs.	IIb	8
626302	IPS e.max Press HO 1 5 pcs	IIb	8
626303	IPS e.max Press HO 2 5 pcs	IIb	8
626304	IPS e.max Press HO 1 L/3 pcs	IIb	8
626305	IPS e.max Press HO 2 L/3 pcs	IIb	8

626306	IPS e.max Press LT A4 5 pcs	IIb	8
626307	IPS e.max Press LT B4 5 pcs	IIb	8
626308	IPS e.max Press LT C1 5 pcs	IIb	8
626309	IPS e.max Press LT C3 5 pcs	IIb	8
626310	IPS e.max Press LT C4 5 pcs	IIb	8
626311	IPS e.max Press LT D2 5 pcs	IIb	8
626312	IPS e.max Press LT D4 5 pcs	IIb	8
626313	IPS e.max Press LT A4 L/3 pcs	IIb	8
626314	IPS e.max Press LT B4 L/3 pcs	IIb	8
626315	IPS e.max Press LT C1 L/3 pcs	IIb	8
626316	IPS e.max Press LT C3 L/3 pcs	IIb	8
626317	IPS e.max Press LT C4 L/3 pcs	IIb	8
626318	IPS e.max Press LT D2 L/3 pcs	IIb	8
626319	IPS e.max Press LT D4 L/3 pcs	IIb	8
626320	IPS e.max Press HT A1 5 pcs	IIb	8
626321	IPS e.max Press HT A2 5 pcs	IIb	8
626322	IPS e.max Press HT A3 5 pcs	IIb	8
626323	IPS e.max Press HT A3,5 5 pcs	IIb	8
626324	IPS e.max Press HT A4 5 pcs	IIb	8
626325	IPS e.max Press HT B1 5 pcs	IIb	8
626326	IPS e.max Press HT B2 5 pcs	IIb	8
626327	IPS e.max Press HT B3 5 pcs	IIb	8
626328	IPS e.max Press HT B4 5 pcs	IIb	8
626329	IPS e.max Press HT C1 5 pcs	IIb	8
626330	IPS e.max Press HT C2 5 pcs	IIb	8
626331	IPS e.max Press HT C3 5 pcs	IIb	8
626332	IPS e.max Press HT C4 5 pcs	IIb	8
626333	IPS e.max Press HT D2 5 pcs	IIb	8
626334	IPS e.max Press HT D3 5 pcs	IIb	8
626335	IPS e.max Press HT D4 5 pcs	IIb	8
626336	IPS e.max Press HT A1 L/3 pcs	IIb	8
626337	IPS e.max Press HT A2 L/3 pcs	IIb	8
626338	IPS e.max Press HT A3 L/3 pcs	IIb	8
626339	IPS e.max Press HT A3,5 L/3 pcs	IIb	8
626340	IPS e.max Press HT A4 L/3 pcs	IIb	8
626341	IPS e.max Press HT B1 L/3 pcs	IIb	8
626342	IPS e.max Press HT B2 L/3 pcs	IIb	8
626343	IPS e.max Press HT B3 L/3 pcs	IIb	8
626344	IPS e.max Press HT B4 L/3 pcs	IIb	8
626345	IPS e.max Press HT C1 L/3 pcs	IIb	8
626346	IPS e.max Press HT C2 L/3 pcs	IIb	8
626347	IPS e.max Press HT C3 L/3 pcs	IIb	8
626348	IPS e.max Press HT C4 L/3 pcs	IIb	8
626349	IPS e.max Press HT D2 L/3 pcs	IIb	8
626350	IPS e.max Press HT D3 L/3 pcs	IIb	8
626351	IPS e.max Press HT D4 L/3 pcs	IIb	8
626352	IPS e.max Press HT BL1 5 pcs	IIb	8

626353	IPS e.max Press HT BL2 5 pcs	IIb	8
626354	IPS e.max Press HT BL3 5 pcs	IIb	8
626355	IPS e.max Press HT BL4 5 pcs	IIb	8
626356	IPS e.max Press HT BL1 L/3 pcs	IIb	8
626357	IPS e.max Press HT BL2 L/3 pcs	IIb	8
626358	IPS e.max Press HT BL3 L/3 pcs	IIb	8
626359	IPS e.max Press HT BL4 L/3 pcs	IIb	8
635560	IPS e.max Press Impulse Opal 1 5pcs.	IIb	8
635561	IPS e.max Press Impulse Opal 2 5pcs.	IIb	8
635569	IPS e.max Press Impulse Opal 1 L/3pcs.	IIb	8
635570	IPS e.max Press Impulse Opal 2 L/3Stk.	IIb	8
638036	IPS e.max Press Multi A1 5 pcs.	IIb	8
638147	IPS e.max Press Multi A2 5 pcs.	IIb	8
638148	IPS e.max Press Multi A3 5 pcs.	IIb	8
638149	IPS e.max Press Multi A3.5 5 pcs.	IIb	8
638151	IPS e.max Press Multi B1 5 pcs.	IIb	8
638152	IPS e.max Press Multi B2 5 pcs.	IIb	8
638155	IPS e.max Press Multi C1 5 pcs.	IIb	8
638156	IPS e.max Press Multi C2 5 pcs.	IIb	8
638159	IPS e.max Press Multi D2 5 pcs.	IIb	8
638638	IPS e.max Press Multi BL2 5 pcs.	IIb	8
668756	IPS e.max Press MT A1 5 Stk.	IIb	8
668757	IPS e.max Press MT A2 5 Stk.	IIb	8
668758	IPS e.max Press MT A3 5 Stk.	IIb	8
668759	IPS e.max Press MT B1 5 Stk.	IIb	8
668760	IPS e.max Press MT B2 5 Stk.	IIb	8
668761	IPS e.max Press MT C1 5 Stk.	IIb	8
668762	IPS e.max Press MT D2 5 Stk.	IIb	8
668763	IPS e.max Press MT A1 L/3 Stk.	IIb	8
668764	IPS e.max Press MT A2 L/3 Stk.	IIb	8
668765	IPS e.max Press MT A3 L/3 Stk.	IIb	8
668766	IPS e.max Press MT B1 L/3 Stk.	IIb	8
668767	IPS e.max Press MT B2 L/3 Stk.	IIb	8
668768	IPS e.max Press MT C1 L/3 Stk.	IIb	8
668769	IPS e.max Press MT D2 L/3 Stk.	IIb	8
668770	IPS e.max Press MT BL3 5 Stk.	IIb	8
668771	IPS e.max Press MT BL4 5 Stk.	IIb	8
668772	IPS e.max Press MT BL3 L/3 Stk.	IIb	8
668773	IPS e.max Press MT BL4 L/3 Stk.	IIb	8
668891	IPS e.max Press MT BL2 5 Stk.	IIb	8
668892	IPS e.max Press MT BL2 L/3 Stk.	IIb	8
711981	IPS e.max Press MT A3.5 L/3 Stk.	IIb	8
716624	IPS e.max Press MT C2 L/3 Stk.	IIb	8
716625	IPS e.max Press MT A3.5 5 Stk.	IIb	8
716626	IPS e.max Press MT C2 5 Stk.	IIb	8
763445	IPS e.max Press MO 1 10 pcs	IIb	8
764026	IPS e.max Press LT A1 10 pcs	IIb	8

764027	IPS e.max Press LT A2 10 pcs	IIb	8
764028	IPS e.max Press LT A3 10 pcs	IIb	8
764029	IPS e.max Press LT B1 10 pcs	IIb	8
764030	IPS e.max Press LT BL1 10 pcs	IIb	8
764031	IPS e.max Press LT BL2 10 pcs	IIb	8
764032	IPS e.max Press LT BL3 10 pcs	IIb	8
764033	IPS e.max Press LT BL4 10 pcs	IIb	8
764034	IPS e.max Press HT A1 10 pcs	IIb	8
764035	IPS e.max Press HT A2 10 pcs	IIb	8
764036	IPS e.max Press HT A3 10 pcs	IIb	8
764037	IPS e.max Press HT B1 10 pcs	IIb	8
764038	IPS e.max Press HT BL1 10 pcs	IIb	8
764039	IPS e.max Press HT BL2 10 pcs	IIb	8
764040	IPS e.max Press HT BL3 10 pcs	IIb	8
764041	IPS e.max Press HT BL4 10 pcs	IIb	8
764042	IPS e.max Press MT A1 10 pcs	IIb	8
764043	IPS e.max Press MT A2 10 pcs	IIb	8
764044	IPS e.max Press MT A3 10 pcs	IIb	8
764045	IPS e.max Press MT B1 10 pcs	IIb	8
764046	IPS e.max Press MT BL3 10 pcs	IIb	8
764047	IPS e.max Press MT BL4 10 pcs	IIb	8
764048	IPS e.max Press MT BL2 10 pcs	IIb	8
605273CN	IPS e.max Press LT A1 5 pcs.	IIb	8
605274CN	IPS e.max Press LT A2 5 pcs.	IIb	8
605275CN	IPS e.max Press LT A3 5 pcs.	IIb	8
605276CN	IPS e.max Press LT A3,5 5 pcs.	IIb	8
605277CN	IPS e.max Press LT B1 5 pcs.	IIb	8
605293CN	IPS e.max Press LT BL1 5 pcs.	IIb	8
605294CN	IPS e.max Press LT BL2 5 pcs.	IIb	8
605295CN	IPS e.max Press LT BL3 5 pcs.	IIb	8
605296CN	IPS e.max Press LT BL4 5 pcs.	IIb	8
626302CN	IPS e.max Press HO 1 5 pcs	IIb	8
626320CN	IPS e.max Press HT A1 5 pcs	IIb	8
626323CN	IPS e.max Press HT A3,5 5 pcs	IIb	8
626326CN	IPS e.max Press HT B2 5 pcs	IIb	8
626329CN	IPS e.max Press HT C1 5 pcs	IIb	8
626333CN	IPS e.max Press HT D2 5 pcs	IIb	8
626334CN	IPS e.max Press HT D3 5 pcs	IIb	8
626352CN	IPS e.max Press HT BL1 5 pcs	IIb	8
626353CN	IPS e.max Press HT BL2 5 pcs	IIb	8
626354CN	IPS e.max Press HT BL3 5 pcs	IIb	8
626355CN	IPS e.max Press HT BL4 5 pcs	IIb	8
635560CN	IPS e.max Press Impulse Opal 1 5pcs.	IIb	8
668756CN	IPS e.max Press MT A1 5 Stk.	IIb	8
668757CN	IPS e.max Press MT A2 5 Stk.	IIb	8
668891CN	IPS e.max Press MT BL2 5 Stk.	IIb	8
750789CI	IPS e.max Press Multi A1 5 pcs.	IIb	8

750790CI	IPS e.max Press Multi A2 5 pcs.	IIb	8
750791CI	IPS e.max Press Multi A3.5 5 pcs.	IIb	8
750792CI	IPS e.max Press Multi B1 5 pcs.	IIb	8
750793CI	IPS e.max Press Multi B2 5 pcs.	IIb	8
750795CI	IPS e.max Press Multi C1 5 pcs.	IIb	8
750796CI	IPS e.max Press Multi C2 5 pcs.	IIb	8
750797CI	IPS e.max Press Multi D2 5 pcs.	IIb	8
750798CI	IPS e.max Press Multi BL2 5 pcs.	IIb	8
750799CI	IPS e.max Press Multi A3 5 pcs.	IIb	8

Revision History			
Version	Date	Author	Remark
1.0	2024-07-09	R. Ritter	First MDR Version
2.0	2024-08-12	R. Ritter	APM110118, APM110864
3.0	2025-01-13	R. Ritter	GSPR updated
4.0	2025-05-22	R. Ritter	APM111689
5.0	2025-07-29	R. Ritter	APM112091
6.0	2025-08-14	R. Ritter	APM112024
7.0	2026-01-09	R. Ritter	APM111821
8.0	2026-04-27	R. Ritter	Update MDR TÜV Certificate
9.0	2026-06-30	R. Ritter	APM113151

Signing Page

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Document Approval (OTCS)

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Title: Senior Technical Assistant - Regulatory Affairs
Date: Tuesday, 30 June 2026, 15:03 W. Europe Daylight Time
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UserName: Sandro Sbicego (LISBC)
Title: Director Regulatory Affairs & Corporate Quality Control / PRRC /
Date: Tuesday, 30 June 2026, 17:58 W. Europe Daylight Time
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