

EU Declaration of Conformity for Class_Ilb_163150490

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)	PressCeramic
Basic-UDI-DI	084227112BABUT0077A

Legal manufacturer		
sagemax[®]	Sagemax Bioceramics Inc. 34210 9 th Ave. S, Suite 118 Federal Way, WA 98003, USA www.sagemax.com	Phone: +1 (253) 214 0389 www.sagemax.com Legal Form: C Corporation Headquarters: Federal Way, WA 98003, USA Registration No.: 12-101044-00-BL Tax ID: 35-2271727

EU Declaration of Conformity Information	
EC-REP	SRN: LI-AR-000024947 DSSM AG Im alten Riet 9 9494 Schaan Liechtenstein
SRN (Legal Manufacturer)	US-MF-000008180
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.	G10 101492 0004 Rev. 00
Valid until	2028-10-08

Attachment to EU Declaration of Conformity

Article No.	Description	MDR Classification (EU)	Rule MDR (EU)
742817	PressCeramic HT A1 /4	IIb	8
742818	PressCeramic HT A2 /4	IIb	8
742819	PressCeramic HT A3 /4	IIb	8
742820	PressCeramic HT A3.5 /4	IIb	8
742821	PressCeramic HT A4 /4	IIb	8
742822	PressCeramic HT B1 /4	IIb	8
742823	PressCeramic HT B2 /4	IIb	8
742824	PressCeramic HT B3 /4	IIb	8
742825	PressCeramic HT B4 /4	IIb	8
742826	PressCeramic HT C1 /4	IIb	8
742827	PressCeramic HT C2 /4	IIb	8
742828	PressCeramic HT C3 /4	IIb	8
742829	PressCeramic HT C4 /4	IIb	8
742830	PressCeramic HT D2 /4	IIb	8
742831	PressCeramic HT D3 /4	IIb	8
742832	PressCeramic HT D4 /4	IIb	8
742833	PressCeramic HT BL1 /4	IIb	8
742834	PressCeramic HT BL2 /4	IIb	8
742835	PressCeramic HT BL3 /4	IIb	8
742836	PressCeramic HT BL4 /4	IIb	8
742837	PressCeramic MT A1 /4	IIb	8
742838	PressCeramic MT A2 /4	IIb	8
742839	PressCeramic MT A3 /4	IIb	8
742840	PressCeramic MT A3.5 /4	IIb	8
742841	PressCeramic MT B1 /4	IIb	8
742842	PressCeramic MT B2 /4	IIb	8
742843	PressCeramic MT C1 /4	IIb	8
742844	PressCeramic MT C2 /4	IIb	8
742845	PressCeramic MT D2 /4	IIb	8
742846	PressCeramic MT BL2 /4	IIb	8
742847	PressCeramic MT BL3 /4	IIb	8
742848	PressCeramic MT BL4 /4	IIb	8
742849	PressCeramic LT BL1 /4	IIb	8
742850	PressCeramic LT BL2 /4	IIb	8
742851	PressCeramic LT BL3 /4	IIb	8
742852	PressCeramic LT BL4 /4	IIb	8
742853	PressCeramic LT A1 /4	IIb	8
742854	PressCeramic LT A2 /4	IIb	8
742855	PressCeramic LT A3 /4	IIb	8
742856	PressCeramic LT A3.5 /4	IIb	8
742857	PressCeramic LT A4 /4	IIb	8
742858	PressCeramic LT B1 /4	IIb	8

742859	PressCeramic LT B2 /4	IIb	8
742860	PressCeramic LT B3 /4	IIb	8
742861	PressCeramic LT B4 /4	IIb	8
742862	PressCeramic LT C1 /4	IIb	8
742863	PressCeramic LT C2 /4	IIb	8
742864	PressCeramic LT C3 /4	IIb	8
742865	PressCeramic LT C4 /4	IIb	8
742866	PressCeramic LT D2 /4	IIb	8
742867	PressCeramic LT D3 /4	IIb	8
742868	PressCeramic LT D4 /4	IIb	8
742869	PressCeramic MO 0 /4	IIb	8
742870	PressCeramic MO 1 /4	IIb	8
742871	PressCeramic MO 2 /4	IIb	8
742872	PressCeramic MO 3 /4	IIb	8
742873	PressCeramic MO 4 /4	IIb	8
742874	PressCeramic Opal 1 /4	IIb	8
742875	PressCeramic Opal 2 /4	IIb	8

Revision History			
Version	Date	Author	Remark
1.0	2024-01-02	L. Celeste	First MDR Version
2.0	2025-01-22	R. Ritter	APM110375
3.0	2025-04-16	R. Ritter	APM111262, APM111516

Signing Page

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Document Approval (OTCS)

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