

EU Declaration of Conformity for Class_Ila_100927223


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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)	NexxZr+ NexxZr+ Multi
Basic-UDI-DI	084227112ACERA0143P

Legal manufacturer		
	Sagemax Bioceramics Inc. 34210 9 th Ave. S, Suite 118 Federal Way, WA 98003, USA www.sagemax.com	Phone: +46 / 859441257 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	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 2011
EU Risk Classification (MDR Annex VIII)	Medical Device Class IIa CE 0123
Conformity Assessment Procedure (MDR Annex IX)	<input checked="" type="checkbox"/> Quality Management System <input type="checkbox"/> Assessment of the Technical Documentation
Notified Body Address	TÜV SÜD Product Service GmbH Ridlerstrasse 65 80339 München Germany
EC Certificate No.	G10 101492 0004 Rev. 00
Valid until	2028-10-08

Attachment to EU Declaration of Conformity

REF Number	SAP Number	Description	MDR Classification (EU)	Rule MDR (EU)
W-21001	691609	NexxZr Plus WT W98-10mm	Ila	8
W-21002	691610	NexxZr Plus WT W98-12mm	Ila	8
W-21003	691611	NexxZr Plus WT W98-14mm	Ila	8
W-21004	691612	NexxZr Plus WT W98-16mm	Ila	8
W-21005	691613	NexxZr Plus WT W98-18mm	Ila	8
W-21006	691614	NexxZr Plus WT W98-20mm	Ila	8
W-21007	691615	NexxZr Plus WT W98-22mm	Ila	8
W-21008	691616	NexxZr Plus WT W98-25mm	Ila	8
W-21010	699582	NexxZr Plus WT W98-30mm	Ila	8
W-22001	699382	NexxZr Plus A1 W98-10mm	Ila	8
W-22002	699401	NexxZr Plus A1 W98-12mm	Ila	8
W-22003	699420	NexxZr Plus A1 W98-14mm	Ila	8
W-22004	699439	NexxZr Plus A1 W98-16mm	Ila	8
W-22005	699458	NexxZr Plus A1 W98-18mm	Ila	8
W-22006	699477	NexxZr Plus A1 W98-20mm	Ila	8
W-22007	699496	NexxZr Plus A1 W98-22mm	Ila	8
W-22008	699563	NexxZr Plus A1 W98-25mm	Ila	8
W-22012	699383	NexxZr Plus A2 W98-10mm	Ila	8
W-22013	699402	NexxZr Plus A2 W98-12mm	Ila	8
W-22014	699421	NexxZr Plus A2 W98-14mm	Ila	8
W-22015	699440	NexxZr Plus A2 W98-16mm	Ila	8
W-22016	699459	NexxZr Plus A2 W98-18mm	Ila	8
W-22017	699478	NexxZr Plus A2 W98-20mm	Ila	8
W-22018	699497	NexxZr Plus A2 W98-22mm	Ila	8
W-22019	699564	NexxZr Plus A2 W98-25mm	Ila	8
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W-22024	699403	NexxZr Plus A3 W98-12mm	Ila	8
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W-22036	699423	NexxZr Plus A3.5 W98-14mm	Ila	8
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W-22039	699480	NexxZr Plus A3.5 W98-20mm	Ila	8
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W-23070	702244	NexxZr Plus Multi B2 W98- 16mm	Ila	8
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W-23116	702252	NexxZr Plus Multi C2 W98- 20mm	Ila	8
W-23147	702246	NexxZr Plus Multi D2 W98- 16mm	Ila	8
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Z-22017	699714	NexxZr Plus A2 Z95-20mm	Ila	8
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Z-22023	699616	NexxZr Plus A3 Z95-10mm	Ila	8
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Z-22073	699739	NexxZr Plus B2 Z95-22mm	Ila	8
Z-22074	699759	NexxZr Plus B2 Z95-25mm	Ila	8
Z-23004	702282	NexxZr Plus Multi A1 Z95- 16mm	Ila	8
Z-23006	702289	NexxZr Plus Multi A1 Z95- 20mm	Ila	8

Z-23015	702283	NexxZr Plus Multi A2 Z95- 16mm	Ila	8
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Z-23026	702284	NexxZr Plus Multi A3 Z95- 16mm	Ila	8
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Z-23072	702293	NexxZr Plus Multi B2 Z95- 20mm	Ila	8
Z-23114	702287	NexxZr Plus Multi C2 Z95- 16mm	Ila	8
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Z-23147	702288	NexxZr Plus Multi D2 Z95- 16mm	Ila	8
Z-23149	702295	NexxZr Plus Multi D2 Z95- 20mm	Ila	8

Revision History			
Version	Date	Author	Remark
1.0	2024-01-25	L. Celeste	First MDR Version
2.0	2024-12-19	R. Ritter	APM110378, APM110525

Signing Page

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Document Approval (OTCS)

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Title: Technical Assistant - Regulatory Affairs
Date: Friday, 20 December 2024, 08:01 W. Europe Daylight Time
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UserName: Lucina Celeste (USCELU)
Title: Director, QA/RA
Date: Friday, 20 December 2024, 14:58 W. Europe Daylight Time
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UserName: Yuanfan Liu (LIULOU)
Title: General Manager & Director of Products
Date: Saturday, 21 December 2024, 02:12 W. Europe Daylight Time
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