

EU Declaration of Conformity for Class_Ila_296103441


Document Information (OTCS)	
OTCS – Doc.-ID	296103441
Version	2.0

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)	NexxZr T NexxZr T 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)
745444	745444	NexxZr T Multi BL1 W98-16mm	Ila	8
745445	745445	NexxZr T Multi BL2 W98-16mm	Ila	8
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W-32094	697911	NexxZr T B4 W98-20mm	Ila	8
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W-32096	697927	NexxZr T B4 W98-25mm	Ila	8
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W-32104	697897	NexxZr T C1 W98-18mm	Ila	8
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W-32106	699373	NexxZr T C1 W98-22mm	Ila	8
W-32107	697928	NexxZr T C1 W98-25mm	Ila	8
W-32111	697841	NexxZr T C2 W98-10mm	Ila	8
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W-32122	697842	NexxZr T C3 W98-10mm	Ila	8
W-32123	697856	NexxZr T C3 W98-12mm	Ila	8
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W-32137	697900	NexxZr T C4 W98-18mm	Ila	8
W-32138	697915	NexxZr T C4 W98-20mm	Ila	8
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W-32140	697931	NexxZr T C4 W98-25mm	Ila	8
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W-32147	697886	NexxZr T D2 W98-16mm	Ila	8
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W-32162	697933	NexxZr T D3 W98-25mm	Ila	8
W-32166	697846	NexxZr T D4 W98-10mm	Ila	8
W-32167	697860	NexxZr T D4 W98-12mm	Ila	8
W-32168	697874	NexxZr T D4 W98-14mm	Ila	8
W-32169	697888	NexxZr T D4 W98-16mm	Ila	8
W-32170	697903	NexxZr T D4 W98-18mm	Ila	8
W-32171	697918	NexxZr T D4 W98-20mm	Ila	8
W-32172	699378	NexxZr T D4 W98-22mm	Ila	8
W-32173	697934	NexxZr T D4 W98-25mm	Ila	8
W-32177	691766	NexxZr T OM1 W98-10mm	Ila	8
W-32178	691770	NexxZr T OM1 W98 12mm	Ila	8
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W-32180	697889	NexxZr T OM1 W98-16mm	Ila	8
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W-32182	697919	NexxZr T OM1 W98-20mm	Ila	8
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W-32184	697935	NexxZr T OM1 W98-25mm	Ila	8

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W-32189	697861	NexxZr T OM2 W98-12mm	Ila	8
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W-32191	697890	NexxZr T OM2 W98-16mm	Ila	8
W-32192	697905	NexxZr T OM2 W98-18mm	Ila	8
W-32193	697920	NexxZr T OM2 W98-20mm	Ila	8
W-32194	699380	NexxZr T OM2 W98-22mm	Ila	8
W-32195	697936	NexxZr T OM2 W98-25mm	Ila	8
W-32199	697848	NexxZr T OM3 W98-10mm	Ila	8
W-32200	697862	NexxZr T OM3 W98-12mm	Ila	8
W-32201	697876	NexxZr T OM3 W98-14mm	Ila	8
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W-32203	697906	NexxZr T OM3 W98-18mm	Ila	8
W-32204	697921	NexxZr T OM3 W98-20mm	Ila	8
W-32205	699381	NexxZr T OM3 W98-22mm	Ila	8
W-32206	697937	NexxZr T OM3 W98-25mm	Ila	8
Z-31001	698098	NexxZr T WT Z95-10mm	Ila	8
Z-31002	698117	NexxZr T WT Z95-12mm	Ila	8
Z-31003	698136	NexxZr T WT Z95-14mm	Ila	8
Z-31004	698155	NexxZr T WT Z95-16mm	Ila	8
Z-31005	698174	NexxZr T WT Z95-18mm	Ila	8
Z-31006	698194	NexxZr T WT Z95-20mm	Ila	8
Z-31007	698213	NexxZr T WT Z95-22mm	Ila	8
Z-31008	698233	NexxZr T WT Z95-25mm	Ila	8
Z-31010	698253	NexxZr T WT Z95-30mm	Ila	8
Z-32001	698099	NexxZr T A1 Z95-10mm	Ila	8
Z-32002	697584	NexxZr T A1 Z95-12mm	Ila	8
Z-32003	697337	NexxZr T A1 Z95-14mm	Ila	8
Z-32004	697586	NexxZr T A1 Z95-16mm	Ila	8
Z-32005	698175	NexxZr T A1 Z95-18mm	Ila	8
Z-32006	698195	NexxZr T A1 Z95-20mm	Ila	8
Z-32007	698214	NexxZr T A1 Z95-22mm	Ila	8
Z-32008	698234	NexxZr T A1 Z95-25mm	Ila	8
Z-32012	698100	NexxZr T A2 Z95-10mm	Ila	8
Z-32013	698118	NexxZr T A2 Z95-12mm	Ila	8
Z-32014	698137	NexxZr T A2 Z95-14mm	Ila	8
Z-32015	698156	NexxZr T A2 Z95-16mm	Ila	8
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Z-32019	698235	NexxZr T A2 Z95-25mm	Ila	8
Z-32023	698101	NexxZr T A3 Z95-10mm	Ila	8
Z-32024	698119	NexxZr T A3 Z95-12mm	Ila	8
Z-32025	698138	NexxZr T A3 Z95-14mm	Ila	8
Z-32026	698157	NexxZr T A3 Z95-16mm	Ila	8

Z-32027	698177	NexxZr T A3 Z95-18mm	Ila	8
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Z-32029	698216	NexxZr T A3 Z95-22mm	Ila	8
Z-32030	698236	NexxZr T A3 Z95-25mm	Ila	8
Z-32034	698102	NexxZr T A3.5 Z95-10mm	Ila	8
Z-32035	698120	NexxZr T A3.5 Z95-12mm	Ila	8
Z-32036	698139	NexxZr T A3.5 Z95-14mm	Ila	8
Z-32037	698158	NexxZr T A3.5 Z95-16mm	Ila	8
Z-32038	698178	NexxZr T A3.5 Z95-18mm	Ila	8
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Z-32041	698237	NexxZr T A3.5 Z95-25mm	Ila	8
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Z-32046	698121	NexxZr T A4 Z95-12mm	Ila	8
Z-32047	698140	NexxZr T A4 Z95-14mm	Ila	8
Z-32048	698159	NexxZr T A4 Z95-16mm	Ila	8
Z-32049	698179	NexxZr T A4 Z95-18mm	Ila	8
Z-32050	698199	NexxZr T A4 Z95-20mm	Ila	8
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Z-32056	698104	NexxZr T B1 Z95-10mm	Ila	8
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Z-32058	698141	NexxZr T B1 Z95-14mm	Ila	8
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Z-32100	698108	NexxZr T C1 Z95-10mm	Ila	8
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Z-32162	698248	NexxZr T D3 Z95-25mm	Ila	8
Z-32166	698114	NexxZr T D4 Z95-10mm	Ila	8
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Z-32173	698249	NexxZr T D4 Z95-25mm	Ila	8
Z-32177	699612	NexxZr T OM1 Z95-10mm	Ila	8
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Z-32191	698172	NexxZr T OM2 Z95-16mm	Ila	8
Z-32192	698192	NexxZr T OM2 Z95-18mm	Ila	8
Z-32193	698212	NexxZr T OM2 Z95-20mm	Ila	8
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Z-32199	698116	NexxZr T OM3 Z95-10mm	Ila	8
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Z-32205	698232	NexxZr T OM3 Z95-22mm	Ila	8
Z-32206	698252	NexxZr T OM3 Z95-25mm	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

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