

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.

Manufacturer Address	Sagemax Bioceramics, Inc. 34210 9th Ave S. Suite 118 Federal Way, WA 98003, USA Phone: +1 (253) 214 0389 www.sagemax.com	
SRN (Manufacturer)	US-MF-000008180	
Authorized Representative	DSSM AG Im alten Riet 9 9494 Schaan Liechtenstein Phone: +423 (235) 3766 www.dssm.group	
SRN (EC Representative)	LI-AR-000024947	
Product(s)	NexxZr® + Multi 2.0	
Basic-UDI-DI	084227112ACERA0143P	
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
EU Risk Classification (MDR Annex VIII)	Medical Device Class IIa	CE 0123

Document ID: TEFO-04673-EN
Document title: EU Declaration of Conformity Ila_Ilb
Module: Product Conformity
Module owner: Director QA & RA

**Conformity Assessment
Procedure (MDR Annex IX)**

Quality Management System without chapter II Assessment
of 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

Date, Signature

03/15/2024 Lucina Celeste

Approver Name and Position

Lucina Celeste Director of QA/RA, Sagemax Bioceramics, Inc.

Date, Signature

03/15/2024 [Signature]

Approver Name and Position

Louis Liu, Director of Product/General Manager, Sagemax
Bioceramics, Inc.

List of Products

Product REF	Description	Brand Name
760336	NexxZr Plus Multi 2.0 BL1 W98-14mm	NexxZr Plus Multi 2.0
760337	NexxZr Plus Multi 2.0 BL2 W98-14mm	NexxZr Plus Multi 2.0
760338	NexxZr Plus Multi 2.0 BL3 W98-14mm	NexxZr Plus Multi 2.0
760339	NexxZr Plus Multi 2.0 BL4 W98-14mm	NexxZr Plus Multi 2.0
760340	NexxZr Plus Multi 2.0 A1 W98-14mm	NexxZr Plus Multi 2.0
760341	NexxZr Plus Multi 2.0 A2 W98-14mm	NexxZr Plus Multi 2.0
760342	NexxZr Plus Multi 2.0 A3 W98-14mm	NexxZr Plus Multi 2.0
760343	NexxZr Plus Multi 2.0 A3.5 W98-14mm	NexxZr Plus Multi 2.0
760344	NexxZr Plus Multi 2.0 A4 W98-14mm	NexxZr Plus Multi 2.0
760345	NexxZr Plus Multi 2.0 B1 W98-14mm	NexxZr Plus Multi 2.0
760346	NexxZr Plus Multi 2.0 B2 W98-14mm	NexxZr Plus Multi 2.0
760347	NexxZr Plus Multi 2.0 B3 W98-14mm	NexxZr Plus Multi 2.0
760348	NexxZr Plus Multi 2.0 B4 W98-14mm	NexxZr Plus Multi 2.0
760349	NexxZr Plus Multi 2.0 C1 W98-14mm	NexxZr Plus Multi 2.0
760350	NexxZr Plus Multi 2.0 C2 W98-14mm	NexxZr Plus Multi 2.0
760351	NexxZr Plus Multi 2.0 C3 W98-14mm	NexxZr Plus Multi 2.0
760352	NexxZr Plus Multi 2.0 C4 W98-14mm	NexxZr Plus Multi 2.0
760353	NexxZr Plus Multi 2.0 D2 W98-14mm	NexxZr Plus Multi 2.0
760354	NexxZr Plus Multi 2.0 D3 W98-14mm	NexxZr Plus Multi 2.0
760355	NexxZr Plus Multi 2.0 D4 W98-14mm	NexxZr Plus Multi 2.0
760356	NexxZr Plus Multi 2.0 BL1 W98-16mm	NexxZr Plus Multi 2.0
760357	NexxZr Plus Multi 2.0 BL2 W98-16mm	NexxZr Plus Multi 2.0
760358	NexxZr Plus Multi 2.0 BL3 W98-16mm	NexxZr Plus Multi 2.0
760359	NexxZr Plus Multi 2.0 BL4 W98-16mm	NexxZr Plus Multi 2.0
760360	NexxZr Plus Multi 2.0 A1 W98-16mm	NexxZr Plus Multi 2.0
760361	NexxZr Plus Multi 2.0 A2 W98-16mm	NexxZr Plus Multi 2.0
760362	NexxZr Plus Multi 2.0 A3 W98-16mm	NexxZr Plus Multi 2.0
760363	NexxZr Plus Multi 2.0 A3.5 W98-16mm	NexxZr Plus Multi 2.0
760364	NexxZr Plus Multi 2.0 A4 W98-16mm	NexxZr Plus Multi 2.0
760365	NexxZr Plus Multi 2.0 B1 W98-16mm	NexxZr Plus Multi 2.0
760366	NexxZr Plus Multi 2.0 B2 W98-16mm	NexxZr Plus Multi 2.0
760367	NexxZr Plus Multi 2.0 B3 W98-16mm	NexxZr Plus Multi 2.0
760368	NexxZr Plus Multi 2.0 B4 W98-16mm	NexxZr Plus Multi 2.0

Product REF	Description	Brand Name
760369	NexxZr Plus Multi 2.0 C1 W98-16mm	NexxZr Plus Multi 2.0
760370	NexxZr Plus Multi 2.0 C2 W98-16mm	NexxZr Plus Multi 2.0
760371	NexxZr Plus Multi 2.0 C3 W98-16mm	NexxZr Plus Multi 2.0
760372	NexxZr Plus Multi 2.0 C4 W98-16mm	NexxZr Plus Multi 2.0
760373	NexxZr Plus Multi 2.0 D2 W98-16mm	NexxZr Plus Multi 2.0
760374	NexxZr Plus Multi 2.0 D3 W98-16mm	NexxZr Plus Multi 2.0
760375	NexxZr Plus Multi 2.0 D4 W98-16mm	NexxZr Plus Multi 2.0
760376	NexxZr Plus Multi 2.0 BL1 W98-20mm	NexxZr Plus Multi 2.0
760377	NexxZr Plus Multi 2.0 BL2 W98-20mm	NexxZr Plus Multi 2.0
760378	NexxZr Plus Multi 2.0 BL3 W98-20mm	NexxZr Plus Multi 2.0
760379	NexxZr Plus Multi 2.0 BL4 W98-20mm	NexxZr Plus Multi 2.0
760380	NexxZr Plus Multi 2.0 A1 W98-20mm	NexxZr Plus Multi 2.0
760381	NexxZr Plus Multi 2.0 A2 W98-20mm	NexxZr Plus Multi 2.0
760382	NexxZr Plus Multi 2.0 A3 W98-20mm	NexxZr Plus Multi 2.0
760383	NexxZr Plus Multi 2.0 A3.5 W98-20mm	NexxZr Plus Multi 2.0
760384	NexxZr Plus Multi 2.0 A4 W98-20mm	NexxZr Plus Multi 2.0
760385	NexxZr Plus Multi 2.0 B1 W98-20mm	NexxZr Plus Multi 2.0
760386	NexxZr Plus Multi 2.0 B2 W98-20mm	NexxZr Plus Multi 2.0
760387	NexxZr Plus Multi 2.0 B3 W98-20mm	NexxZr Plus Multi 2.0
760388	NexxZr Plus Multi 2.0 B4 W98-20mm	NexxZr Plus Multi 2.0
760389	NexxZr Plus Multi 2.0 C1 W98-20mm	NexxZr Plus Multi 2.0
760390	NexxZr Plus Multi 2.0 C2 W98-20mm	NexxZr Plus Multi 2.0
760391	NexxZr Plus Multi 2.0 C3 W98-20mm	NexxZr Plus Multi 2.0
760392	NexxZr Plus Multi 2.0 C4 W98-20mm	NexxZr Plus Multi 2.0
760393	NexxZr Plus Multi 2.0 D2 W98-20mm	NexxZr Plus Multi 2.0
760394	NexxZr Plus Multi 2.0 D3 W98-20mm	NexxZr Plus Multi 2.0
760395	NexxZr Plus Multi 2.0 D4 W98-20mm	NexxZr Plus Multi 2.0