

## EU Declaration of Conformity for Class\_Ila\_172601031


Document Information (OTCS)	
<b>OTCS – Doc.-ID</b>	172601031
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Signatures	
<b>Author(s)</b>	<b>The signatures of all involved signatories are added on the last page of this document.</b>
<b>Reviewer(s)</b>	
<b>Approver(s)</b>	

## 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.

<b>Product(s)</b>	<b>NexxZr+ Multi 2.0</b>
<b>Basic-UDI-DI</b>	084227112ACERA0143P

Legal manufacturer		
	Sagemax Bioceramics Inc. 34210 9 <sup>th</sup> 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	
<b>EC-REP</b>	SRN: LI-AR-000024947 DSSM AG Im alten Riet 9 9494 Schaan Liechtenstein
<b>SRN (Legal Manufacturer)</b>	US-MF-000008180
<b>Intended Purpose</b>	Crowns and bridges in the anterior and posterior region
<b>Category (MDCG 2019-14)</b>	MDN 1103      Non-active dental implants and dental materials
<b>EMDN Code + term</b>	Q010699      Materials for the preparation of custom-made dental devices - other
<b>MDS Code</b>	---
<b>MDT Code</b>	MDT 2003 MDT 2011
<b>EU Classification</b>	<input checked="" type="checkbox"/> Medical Device <input type="checkbox"/> Accessory for Medical Device
<b>EU Risk Class (MDR Annex VIII)</b>	Class IIa <span style="border: 1px solid black; padding: 2px;">CE 0123</span>
<b>Conformity Assessment Procedure (MDR Annex IX)</b>	<input checked="" type="checkbox"/> Quality Management System <input type="checkbox"/> Assessment of the Technical Documentation
<b>Notified Body Address</b>	<b>TÜV SÜD Product Service GmbH</b> Ridlerstrasse 65 80339 Munich Germany
<b>EC Certificate No.</b>	G10 101492 0004 Rev. 00
<b>Valid until</b>	2028-10-08

**Attachment to EU Declaration of Conformity**

<b>Article No.</b>	<b>Description</b>	<b>MDR Classification (EU)</b>	<b>Rule MDR (EU)</b>
760336	NexxZr Plus Multi 2.0 BL1 W98-14mm	Ila	8
760337	NexxZr Plus Multi 2.0 BL2 W98-14mm	Ila	8
760338	NexxZr Plus Multi 2.0 BL3 W98-14mm	Ila	8
760339	NexxZr Plus Multi 2.0 BL4 W98-14mm	Ila	8
760340	NexxZr Plus Multi 2.0 A1 W98-14mm	Ila	8
760341	NexxZr Plus Multi 2.0 A2 W98-14mm	Ila	8
760342	NexxZr Plus Multi 2.0 A3 W98-14mm	Ila	8
760343	NexxZr Plus Multi 2.0 A3.5 W98-14mm	Ila	8
760344	NexxZr Plus Multi 2.0 A4 W98-14mm	Ila	8
760345	NexxZr Plus Multi 2.0 B1 W98-14mm	Ila	8
760346	NexxZr Plus Multi 2.0 B2 W98-14mm	Ila	8
760347	NexxZr Plus Multi 2.0 B3 W98-14mm	Ila	8
760348	NexxZr Plus Multi 2.0 B4 W98-14mm	Ila	8
760349	NexxZr Plus Multi 2.0 C1 W98-14mm	Ila	8
760350	NexxZr Plus Multi 2.0 C2 W98-14mm	Ila	8
760351	NexxZr Plus Multi 2.0 C3 W98-14mm	Ila	8
760352	NexxZr Plus Multi 2.0 C4 W98-14mm	Ila	8
760353	NexxZr Plus Multi 2.0 D2 W98-14mm	Ila	8
760354	NexxZr Plus Multi 2.0 D3 W98-14mm	Ila	8
760355	NexxZr Plus Multi 2.0 D4 W98-14mm	Ila	8
760356	NexxZr Plus Multi 2.0 BL1 W98-16mm	Ila	8
760357	NexxZr Plus Multi 2.0 BL2 W98-16mm	Ila	8
760358	NexxZr Plus Multi 2.0 BL3 W98-16mm	Ila	8
760359	NexxZr Plus Multi 2.0 BL4 W98-16mm	Ila	8
760360	NexxZr Plus Multi 2.0 A1 W98-16mm	Ila	8
760361	NexxZr Plus Multi 2.0 A2 W98-16mm	Ila	8
760362	NexxZr Plus Multi 2.0 A3 W98-16mm	Ila	8
760363	NexxZr Plus Multi 2.0 A3.5 W98-16mm	Ila	8
760364	NexxZr Plus Multi 2.0 A4 W98-16mm	Ila	8
760365	NexxZr Plus Multi 2.0 B1 W98-16mm	Ila	8
760366	NexxZr Plus Multi 2.0 B2 W98-16mm	Ila	8
760367	NexxZr Plus Multi 2.0 B3 W98-16mm	Ila	8
760368	NexxZr Plus Multi 2.0 B4 W98-16mm	Ila	8
760369	NexxZr Plus Multi 2.0 C1 W98-16mm	Ila	8
760370	NexxZr Plus Multi 2.0 C2 W98-16mm	Ila	8
760371	NexxZr Plus Multi 2.0 C3 W98-16mm	Ila	8
760372	NexxZr Plus Multi 2.0 C4 W98-16mm	Ila	8
760373	NexxZr Plus Multi 2.0 D2 W98-16mm	Ila	8
760374	NexxZr Plus Multi 2.0 D3 W98-16mm	Ila	8
760375	NexxZr Plus Multi 2.0 D4 W98-16mm	Ila	8
760376	NexxZr Plus Multi 2.0 BL1 W98-20mm	Ila	8
760377	NexxZr Plus Multi 2.0 BL2 W98-20mm	Ila	8
760378	NexxZr Plus Multi 2.0 BL3 W98-20mm	Ila	8
760379	NexxZr Plus Multi 2.0 BL4 W98-20mm	Ila	8
760380	NexxZr Plus Multi 2.0 A1 W98-20mm	Ila	8
760381	NexxZr Plus Multi 2.0 A2 W98-20mm	Ila	8

760382	NexxZr Plus Multi 2.0 A3 W98-20mm	Ila	8
760383	NexxZr Plus Multi 2.0 A3.5 W98-20mm	Ila	8
760384	NexxZr Plus Multi 2.0 A4 W98-20mm	Ila	8
760385	NexxZr Plus Multi 2.0 B1 W98-20mm	Ila	8
760386	NexxZr Plus Multi 2.0 B2 W98-20mm	Ila	8
760387	NexxZr Plus Multi 2.0 B3 W98-20mm	Ila	8
760388	NexxZr Plus Multi 2.0 B4 W98-20mm	Ila	8
760389	NexxZr Plus Multi 2.0 C1 W98-20mm	Ila	8
760390	NexxZr Plus Multi 2.0 C2 W98-20mm	Ila	8
760391	NexxZr Plus Multi 2.0 C3 W98-20mm	Ila	8
760392	NexxZr Plus Multi 2.0 C4 W98-20mm	Ila	8
760393	NexxZr Plus Multi 2.0 D2 W98-20mm	Ila	8
760394	NexxZr Plus Multi 2.0 D3 W98-20mm	Ila	8
760395	NexxZr Plus Multi 2.0 D4 W98-20mm	Ila	8

Revision History			
Version	Date	Author	Remark
1.0	2024-03-15	L. Celeste	First MDR Version
2.0	2024-12-11	R. Ritter	New GSPR
3.0	2025-03-03	R. Ritter	APM111179

## Signing Page

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**Document Approval (OTCS)**

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