

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)	SR Nexco (Paste, Liner, Stains, Opaquer) SR Link SR Modelling Liquid
Basic-UDI-DI	76152082ACOMP004LJ
Document-ID	OTCS8820077
Document Version	1.0

Legal manufacturer		
	Ivoclar Vivadent AG Bendererstrasse 2 9494 Schaan/Liechtenstein www.ivoclar.com	Phone +423 / 235 35 35, Fax +423 / 235 33 60 www.ivoclar.com Legal Form: Joint Stock Company Corporate Headquarters: 9494 Schaan Registration No.: FL-0001.001.595-7 VAT No.: 50639

EU Declaration of Conformity Information					
SRN	LI-MF-000000522				
Intended Purpose	Veneering of metal-based and zirconium oxide-based frameworks in the fabrication of indirect restorations in anterior and posterior teeth; Inlays/onlays, veneers and anterior crowns; Modification/characterization of resin teeth and denture base materials				
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	MDS 1007 Devices incorporating or consisting of nanomaterial applies to the following articles: <table border="1" style="margin-left: 20px;"> <tr> <td> SR Nexco Paste SR Nexco Paste Dentin SR Nexco Paste Incisal SR Nexco Paste Margin SR Nexco Paste Gingiva SR Nexco Paste Basic Gingiva SR Nexco Paste Int. Gingiva SR Nexco Paste Effect SR Nexco Pontic Fill </td> </tr> <tr> <td>SR Nexco Liner</td> </tr> <tr> <td>SR Nexco Stains</td> </tr> <tr> <td> SR Nexco Opaquer SR Nexco Opaquer SR Nexco Gingiva Opaquer </td> </tr> </table>	SR Nexco Paste SR Nexco Paste Dentin SR Nexco Paste Incisal SR Nexco Paste Margin SR Nexco Paste Gingiva SR Nexco Paste Basic Gingiva SR Nexco Paste Int. Gingiva SR Nexco Paste Effect SR Nexco Pontic Fill	SR Nexco Liner	SR Nexco Stains	SR Nexco Opaquer SR Nexco Opaquer SR Nexco Gingiva Opaquer
SR Nexco Paste SR Nexco Paste Dentin SR Nexco Paste Incisal SR Nexco Paste Margin SR Nexco Paste Gingiva SR Nexco Paste Basic Gingiva SR Nexco Paste Int. Gingiva SR Nexco Paste Effect SR Nexco Pontic Fill					
SR Nexco Liner					
SR Nexco Stains					
SR Nexco Opaquer SR Nexco Opaquer SR Nexco Gingiva Opaquer					
MDT Code	MDT 2006 MDT 2011				

EU Risk Classification (MDR Annex VIII)	Medical Device Class IIa CE 0123 Applies to the following articles: <table border="1" data-bbox="794 367 1420 815"> <tr> <td data-bbox="794 367 1420 629"> SR Nexco Paste SR Nexco Paste Dentin SR Nexco Paste Incisal SR Nexco Paste Margin SR Nexco Paste Gingiva SR Nexco Paste Basic Gingiva SR Nexco Paste Int. Gingiva SR Nexco Paste Effect SR Nexco Pontic Fill </td> </tr> <tr> <td data-bbox="794 629 1420 674"> SR Nexco Liner </td> </tr> <tr> <td data-bbox="794 674 1420 719"> SR Nexco Stains </td> </tr> <tr> <td data-bbox="794 719 1420 815"> SR Nexco Opaquer SR Nexco Opaquer SR Nexco Gingiva Opaquer </td> </tr> </table>	SR Nexco Paste SR Nexco Paste Dentin SR Nexco Paste Incisal SR Nexco Paste Margin SR Nexco Paste Gingiva SR Nexco Paste Basic Gingiva SR Nexco Paste Int. Gingiva SR Nexco Paste Effect SR Nexco Pontic Fill	SR Nexco Liner	SR Nexco Stains	SR Nexco Opaquer SR Nexco Opaquer SR Nexco Gingiva Opaquer
SR Nexco Paste SR Nexco Paste Dentin SR Nexco Paste Incisal SR Nexco Paste Margin SR Nexco Paste Gingiva SR Nexco Paste Basic Gingiva SR Nexco Paste Int. Gingiva SR Nexco Paste Effect SR Nexco Pontic Fill					
SR Nexco Liner					
SR Nexco Stains					
SR Nexco Opaquer SR Nexco Opaquer SR Nexco Gingiva Opaquer					
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 Deutschland				
EC Certificate No.	G10 043306 0270 Rev. 01				
Valid until	2026-05-04				

Document Control			
Name	Place of issue	Date of issue	Signature
Approver (PRRC): Patrik Oehri	Schaan, LI	04.12.2023	
Approver (CTO): Dr. Thomas Hirt	Schaan, LI	05.12.2023	

Revision History			
Version	Date	Author	Remark
1.0	2023-12-04	R. Ritter	First MDR Version

Attachment to EU Declaration of Conformity (MDR) of
SR NEXCO, SR LINK, SR MOD. LIQ

Article No.	Description	MDR Classification (EU)	Rule MDR (EU)
000545872	SR Link 5 ml	CLASS IIA	8
000640401	SR Nexco Paste Margin 2.5 g 1	CLASS IIA	8
000640402	SR Nexco Paste Margin 2.5 g 2	CLASS IIA	8
000640403	SR Nexco Paste Margin 2.5 g 3	CLASS IIA	8
000640404	SR Nexco Paste Margin 2.5 g 4	CLASS IIA	8
000640405	SR Nexco Paste Margin 2.5 g 5	CLASS IIA	8
000640406	SR Nexco Paste Dentin 2.5 g A1	CLASS IIA	8
000640407	SR Nexco Paste Dentin 2.5 g A2	CLASS IIA	8
000640408	SR Nexco Paste Dentin 2.5 g A3	CLASS IIA	8
000640409	SR Nexco Paste Dentin 2.5 g A3.5	CLASS IIA	8
000640410	SR Nexco Paste Dentin 2.5 g A4	CLASS IIA	8
000640411	SR Nexco Paste Dentin 2.5 g B1	CLASS IIA	8
000640412	SR Nexco Paste Dentin 2.5 g B2	CLASS IIA	8
000640413	SR Nexco Paste Dentin 2.5 g B3	CLASS IIA	8
000640414	SR Nexco Paste Dentin 2.5 g B4	CLASS IIA	8
000640415	SR Nexco Paste Dentin 2.5 g C1	CLASS IIA	8
000640416	SR Nexco Paste Dentin 2.5 g C2	CLASS IIA	8
000640417	SR Nexco Paste Dentin 2.5 g C3	CLASS IIA	8
000640418	SR Nexco Paste Dentin 2.5 g C4	CLASS IIA	8
000640419	SR Nexco Paste Dentin 2.5 g D2	CLASS IIA	8
000640420	SR Nexco Paste Dentin 2.5 g D3	CLASS IIA	8
000640421	SR Nexco Paste Dentin 2.5 g D4	CLASS IIA	8
000640422	SR Nexco Paste Dentin 2.5 g BL3	CLASS IIA	8
000640423	SR Nexco Paste Dentin 2.5 g BL4	CLASS IIA	8
000640424	SR Nexco Paste Incisal 2.5 g I1	CLASS IIA	8
000640425	SR Nexco Paste Incisal 2.5 g I2	CLASS IIA	8
000640426	SR Nexco Paste Incisal 2.5 g I3	CLASS IIA	8
000640427	SR Nexco Paste Incisal 2.5 g I4	CLASS IIA	8
000640428	SR Nexco Paste Incisal 2.5 g I5	CLASS IIA	8

The suffix of the article number (e.g. "AN", "EN", "AL", "WW") is only used for in-house reference and relates to the language version and/or electrical plug of the product. The suffix does not belong to the official article number.

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Article No.	Description	MDR Classification (EU)	Rule MDR (EU)
000640429	SR Nexco Paste Incisal 2.5 g BL	CLASS IIA	8
000640430	SR Nexco Opaquer 2 ml A1	CLASS IIA	8
000640431	SR Nexco Opaquer 2 ml A2	CLASS IIA	8
000640432	SR Nexco Opaquer 2 ml A3	CLASS IIA	8
000640433	SR Nexco Opaquer 2 ml A3.5	CLASS IIA	8
000640434	SR Nexco Opaquer 2 ml A4	CLASS IIA	8
000640435	SR Nexco Opaquer 2 ml B1	CLASS IIA	8
000640436	SR Nexco Opaquer 2 ml B2	CLASS IIA	8
000640437	SR Nexco Opaquer 2 ml B3	CLASS IIA	8
000640438	SR Nexco Opaquer 2 ml B4	CLASS IIA	8
000640439	SR Nexco Opaquer 2 ml C1	CLASS IIA	8
000640440	SR Nexco Opaquer 2 ml C2	CLASS IIA	8
000640441	SR Nexco Opaquer 2 ml C3	CLASS IIA	8
000640442	SR Nexco Opaquer 2 ml C4	CLASS IIA	8
000640443	SR Nexco Opaquer 2 ml D2	CLASS IIA	8
000640444	SR Nexco Opaquer 2 ml D3	CLASS IIA	8
000640445	SR Nexco Opaquer 2 ml D4	CLASS IIA	8
000640446	SR Nexco Opaquer 2 ml BL3	CLASS IIA	8
000640447	SR Nexco Opaquer 2 ml BL4	CLASS IIA	8
000640448	SR Nexco Paste Effect OD 2.5 g orange	CLASS IIA	8
000640449	SR Nexco Paste Effect OD 2.5 g brown	CLASS IIA	8
000640450	SR Nexco Paste Effect M 2.5 g light	CLASS IIA	8
000640451	SR Nexco Paste Effect M 2.5 g yellow-ora	CLASS IIA	8
000640452	SR Nexco Paste Effect T 2.5 g blue	CLASS IIA	8
000640453	SR Nexco Paste Effect T 2.5 g brown-grey	CLASS IIA	8
000640454	SR Nexco Paste Effect T 2.5 g orange-gre	CLASS IIA	8
000640455	SR Nexco Paste Effect Opal 2.5 g E1	CLASS IIA	8
000640456	SR Nexco Paste Effect Opal 2.5 g E2	CLASS IIA	8
000640457	SR Nexco Paste Effect Opal 2.5 g E3	CLASS IIA	8

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Article No.	Description	MDR Classification (EU)	Rule MDR (EU)
000640458	SR Nexco Paste Effect Opal 2.5 g E4	CLASS IIA	8
000640459	SR Nexco Paste Effect T 2.5g clear	CLASS IIA	8
000640460	SR Nexco Stains 1 ml clear	CLASS IIA	8
000640461	SR Nexco Stains 1 ml white	CLASS IIA	8
000640462	SR Nexco Stains 1 ml blue	CLASS IIA	8
000640463	SR Nexco Stains 1 ml orange	CLASS IIA	8
000640464	SR Nexco Stains 1 ml mahogany	CLASS IIA	8
000640465	SR Nexco Stains 1 ml maroon	CLASS IIA	8
000640466	SR Nexco Gingiva Opaquer 2 ml pink	CLASS IIA	8
000640467	SR Nexco Paste Gingiva 2.5 g G1	CLASS IIA	8
000640468	SR Nexco Paste Gingiva 2.5 g G2	CLASS IIA	8
000640469	SR Nexco Paste Gingiva 2.5 g G3	CLASS IIA	8
000640470	SR Nexco Paste Gingiva 2.5 g G4	CLASS IIA	8
000640471	SR Nexco Paste Gingiva 2.5 g G5	CLASS IIA	8
000640472	SR Nexco Paste Int. Gingiva 2.5g IG 1	CLASS IIA	8
000640473	SR Nexco Paste Int. Gingiva 2.5g IG 2	CLASS IIA	8
000640474	SR Nexco Paste Int. Gingiva 2.5g IG 3	CLASS IIA	8
000640475	SR Nexco Paste Int. Gingiva 2.5g IG 4	CLASS IIA	8
000640476	SR Nexco Liner 2 ml L1	CLASS IIA	8
000640477	SR Nexco Liner 2 ml L2	CLASS IIA	8
000640478	SR Nexco Liner 2 ml L3	CLASS IIA	8
000640479	SR Nexco Liner 2 ml L4	CLASS IIA	8
000640480	SR Nexco Liner 2 ml L5	CLASS IIA	8
000640481	SR Nexco Liner 2 ml BL	CLASS IIA	8
000640482	SR Nexco Liner 2 ml clear	CLASS IIA	8
000640483	SR Nexco Liner 2 ml incisal	CLASS IIA	8
000640485	SR Nexco Pontic Fill Refill 2.5 g	CLASS IIA	8
000640500	SR Modelling Liquid 5 ml	CLASS IIA	8
000642319	SR Nexco Paste Int. Gingiva 2.5g IG 5	CLASS IIA	8

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Article No.	Description	MDR Classification (EU)	Rule MDR (EU)
000642453	SR Nexco Paste Basic Gingiva 2.5g BG34	CLASS IIA	8
000645933	SR Nexco Paste Promo Kit A2	CLASS IIA	8
000648973	SR Nexco Paste Gingiva Kit	CLASS IIA	8
000649796	SR Nexco Stains 1 ml red	CLASS IIA	8
000656157	SR Nexco Stains 1 ml chili	CLASS IIA	8
640399DN	SR Nexco Paste Starter Kit A-D	CLASS IIA	8
640399EN	SR Nexco Paste Starter Kit A-D	CLASS IIA	8
640399FN	SR Nexco Paste Starter Kit A-D	CLASS IIA	8
640399IN	SR Nexco Paste Starter Kit A-D	CLASS IIA	8
640399PN	SR Nexco Paste Starter Kit A-D	NO CE	8
640399SN	SR Nexco Paste Starter Kit A-D	CLASS IIA	8

Schaan, 13.02.2024

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