

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.

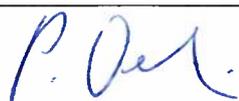
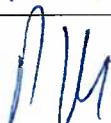
Product(s)	SR Ivocron (Dentin, Incisal, Opaquer, Intensiv, Gingiva, Opaquer Liquid, Cold Liquid, Hot Liquid, Press Liquid)
Basic-UDI-DI	76152082ACOMP002LE
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Document Version	1.0

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	Fabrication of temporary and fixed crowns and bridges by veneering alloy frameworks as well as framework-free. Modification of acrylic 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 Ivocron Dentin</td></tr> <tr><td>SR Ivocron Incisal</td></tr> <tr><td>SR Ivocron Opaquer</td></tr> <tr><td>SR Ivocron Intensiv</td></tr> <tr><td>SR Ivocron Gingiva</td></tr> </table>	SR Ivocron Dentin	SR Ivocron Incisal	SR Ivocron Opaquer	SR Ivocron Intensiv	SR Ivocron Gingiva
SR Ivocron Dentin						
SR Ivocron Incisal						
SR Ivocron Opaquer						
SR Ivocron Intensiv						
SR Ivocron Gingiva						
MDT Code	MDT 2006 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 Deutschland					

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 Module owner: Head of Department Regulatory Documentation and Clinical Affairs

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	18.12.2023	
Approver (CTO): Dr. Thomas Hirt	Schaan, LI	19.12.2023	

Revision History			
Version	Date	Author	Remark
1.0	2023-12-18	R. Ritter	First MDR Version

Attachment to EU Declaration of Conformity (MDR) of
SR IVOCRON

Article No.	Description	MDR Classification (EU)	Rule MDR (EU)
000550078	SR Ivocron Opaquer Liquid 30 ml	CLASS IIA	8
549903AN	SR Ivocron Body 30 g 110	CLASS IIA	8
549904AN	SR Ivocron Body 30 g 120	CLASS IIA	8
549905AN	SR Ivocron Body 30 g 130	CLASS IIA	8
549906AN	SR Ivocron Body 30 g 140	CLASS IIA	8
549907AN	SR Ivocron Body 30 g 210	CLASS IIA	8
549908AN	SR Ivocron Body 30 g 220	CLASS IIA	8
549909AN	SR Ivocron Body 30 g 230	CLASS IIA	8
549910AN	SR Ivocron Body 30 g 240	CLASS IIA	8
549911AN	SR Ivocron Body 30 g 310	CLASS IIA	8
549912AN	SR Ivocron Body 30 g 320	CLASS IIA	8
549913AN	SR Ivocron Body 30 g 330	CLASS IIA	8
549914AN	SR Ivocron Body 30 g 340	CLASS IIA	8
549915AN	SR Ivocron Body 30 g 410	CLASS IIA	8
549916AN	SR Ivocron Body 30 g 420	CLASS IIA	8
549917AN	SR Ivocron Body 30 g 430	CLASS IIA	8
549918AN	SR Ivocron Body 30 g 440	CLASS IIA	8
549919AN	SR Ivocron Body 30 g 510	CLASS IIA	8
549920AN	SR Ivocron Body 30 g 520	CLASS IIA	8
549921AN	SR Ivocron Body 30 g 530	CLASS IIA	8
549922AN	SR Ivocron Body 30 g 540	CLASS IIA	8
549924AN	SR Ivocron Body 100 g 110	CLASS IIA	8
549925AN	SR Ivocron Body 100 g 120	CLASS IIA	8
549926AN	SR Ivocron Body 100 g 130	CLASS IIA	8
549927AN	SR Ivocron Body 100 g 140	CLASS IIA	8
549928AN	SR Ivocron Body 100 g 210	CLASS IIA	8
549929AN	SR Ivocron Body 100 g 220	CLASS IIA	8
549930AN	SR Ivocron Body 100 g 230	CLASS IIA	8
549931AN	SR Ivocron Body 100 g 240	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.

Attachment to EU Declaration of Conformity (MDR) of
SR IVOCRON

Article No.	Description	MDR Classification (EU)	Rule MDR (EU)
549932AN	SR Ivocron Body 100 g 310	CLASS IIA	8
549933AN	SR Ivocron Body 100 g 320	CLASS IIA	8
549934AN	SR Ivocron Body 100 g 330	CLASS IIA	8
549935AN	SR Ivocron Body 100 g 340	CLASS IIA	8
549936AN	SR Ivocron Body 100 g 410	CLASS IIA	8
549937AN	SR Ivocron Body 100 g 420	CLASS IIA	8
549938AN	SR Ivocron Body 100 g 430	CLASS IIA	8
549939AN	SR Ivocron Body 100 g 440	CLASS IIA	8
549940AN	SR Ivocron Body 100 g 510	CLASS IIA	8
549941AN	SR Ivocron Body 100 g 520	CLASS IIA	8
549942AN	SR Ivocron Body 100 g 530	CLASS IIA	8
549943AN	SR Ivocron Body 100 g 540	CLASS IIA	8
549945AN	SR Ivocron Incisal 30 g 1	CLASS IIA	8
549946AN	SR Ivocron Incisal 30 g 2	CLASS IIA	8
549947AN	SR Ivocron Incisal 30 g 3	CLASS IIA	8
549948AN	SR Ivocron Incisal 30 g 4	CLASS IIA	8
549950AN	SR Ivocron Incisal 100 g 1	CLASS IIA	8
549951AN	SR Ivocron Incisal 100 g 2	CLASS IIA	8
549952AN	SR Ivocron Incisal 100 g 3	CLASS IIA	8
549953AN	SR Ivocron Incisal 100 g 4	CLASS IIA	8
549975AN	SR Ivocron Gingiva 100 g pink	CLASS IIA	8
549977AN	SR Ivocron Intensive 15 g 1	CLASS IIA	8
549978AN	SR Ivocron Intensive 15 g 2	CLASS IIA	8
549980AN	SR Ivocron Intensive 15 g 4	CLASS IIA	8
549981AN	SR Ivocron Intensive 15 g 5	CLASS IIA	8
549982AN	SR Ivocron Intensive 15 g 6	CLASS IIA	8
549983AN	SR Ivocron Intensive 15 g 7	CLASS IIA	8
549985AN	SR Ivocron Intensive 15 g 9	CLASS IIA	8
549988BN	SR Ivocron Opaquer 5 g 11	CLASS IIA	8

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Attachment to EU Declaration of Conformity (MDR) of
SR IVOCRON

Article No.	Description	MDR Classification (EU)	Rule MDR (EU)
549989BN	SR Ivocron Opaquer 5 g 12	CLASS IIA	8
549990BN	SR Ivocron Opaquer 5 g 13	CLASS IIA	8
549991BN	SR Ivocron Opaquer 5 g 14	CLASS IIA	8
549992BN	SR Ivocron Opaquer 5 g 15	CLASS IIA	8
549993BN	SR Ivocron Opaquer 5 g 16	CLASS IIA	8
549994BN	SR Ivocron Opaquer 5 g 23	CLASS IIA	8
549995BN	SR Ivocron Opaquer 5 g 24	CLASS IIA	8
549996BN	SR Ivocron Opaquer 5 g 26	CLASS IIA	8
550080AN	SR Ivocron Cold Liquid 100 ml	CLASS IIA	8
550081AN	SR Ivocron Cold Liquid 500 ml	CLASS IIA	8
550082AN	SR Ivocron Hot Liquid 100 ml	CLASS IIA	8
550083AN	SR Ivocron Press Liquid 100 ml	CLASS IIA	8

Schaan, 13.02.2024

(this document is valid without signature)