

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	SR Ivolen
Basic-UDI-DI	++DIVO1XTRAY002KF
Document-ID	LL3456014
Document Version	2.0

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	Tray material
Category (MDCG 2019-14)	MDA n.a.
	MDN 1209 Non-active non-implantable dental materials
EMDN Code + term	Q010699 Materials for the preparation of custom-made devices - other
MDS Code	MDS n.a.
MDT Code	MDT 2006 MDT 2011
EU Risk Classification (MDR Annex VIII)	Medical Device Class I 
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.	<input type="checkbox"/> G10 043306 0270 Rev. 00 <input type="checkbox"/> not yet available <input checked="" type="checkbox"/> N/A
Valid until	2025-05-25

Document Control			
Name	Place of issue	Date of issue	Signature
Approver (PRRC): Patrik Oehri	Schaan, LI	27.10.2022	
Approver (CTO): Dr. Thomas Hirt	Schaan, LI	27.10.2022	

Revision History			
Version	Date	Author	Remark
1.0	2020-07-01	Evi Vogt	First MDR Version
2.0	2022-10-26	Regina Ritter	SRN added Update of Basic-UDI-DI Update of EMDN-term

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

Article No.	Description	MDR Classification (EU)	Rule MDR (EU)
000530363	SR Ivolen Powder 2x500 g	CLASS I	5
000530367	SR Ivolen Liquid 500 ml	CLASS I	5
000530368	SR Ivolen Liquid 2500 ml	CLASS I	5
530359AN	SR Ivolen Standard Kit	CLASS I	5
530364AN	SR Ivolen Powder 10x500 g	CLASS I	5
530365AN	SR Ivolen Powder 20x500 g	CLASS I	5

Schaan, 13.02.2024

(this document is valid without signature)