EU Declaration of Conformity for Class_Class IIa_6622771

Document Information (OTCS)	
OTCS – Doc.-ID	6622771
Version	7.0

Signatures	
Author(s)	**The signatures of all involved signatories are added on the last page of this document.**
Reviewer(s)	
Approver(s)	

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)	**Variolink Esthetic DC**
Basic-UDI-DI	76152082ACEME001DV

Legal manufacturer		
ivoclar	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 (Legal Manufacturer)	LI-MF-000000522
Intended Purpose	Adhesive cementation of indirect anterior and posterior restorations
Category (MDCG 2019-14)	MDN 1103 Non-active dental implants and dental materials
EMDN Code + term	Q0101010201 Dental Base Cements
MDS Code	MDS 1007
MDT Code	MDT 2006 MDT 2011
EU Classification	☒ Medical Device ☐ Accessory for Medical Device
EU Risk Class (MDR Annex VIII)	Class IIa CE 0123
Conformity Assessment Procedure (MDR Annex IX)	☒ Quality Management System ☐ Assessment of the Technical Documentation
Notified Body Address	**TÜV SÜD Product Service GmbH** Ridlerstrasse 65 80339 Munich Germany
EC Certificate No.	G15 043306 0282 Rev. 02
Valid until	2031-05-04

Attachment to EU Declaration of Conformity

Article No.	Description	MDR Classification (EU)	Rule MDR (EU)
666117WW	Variolink Esthetic DC Refill 1x5g light+	IIa	8
666118WW	Variolink Esthetic DC Refill 1x5g light	IIa	8
666119WW	Variolink Esthetic DC Ref. 1x5g neutral	IIa	8
666120WW	Variolink Esthetic DC Refill 1x5g warm	IIa	8
666121WW	Variolink Esthetic DC Refill 1x5g warm+	IIa	8
666122WW	Variolink Esthetic DC Refill 1x9g light	IIa	8
666123WW	Variolink Esthetic DC Ref. 1x9g neutral	IIa	8
666124WW	Variolink Esthetic DC Refill 1x9g warm	IIa	8
692424WW	Variolink Esth. DC Refill 3x9g light	IIa	8
692425WW	Variolink Esth. DC Refill 3x9g neutral	IIa	8
692426WW	Variolink Esth. DC Refill 3x9g warm	IIa	8
762062WW	Variolink Esth DC Ref 1x5g White opaque	IIa	8

Revision History			
Version	**Date**	**Author**	**Remark**
1.0	2022-11-28	R. Ritter	First MDR Version
2.0	2024-02-08	R. Ritter	DR494 OTCS134759899
3.0	2025-06-27	R. Ritter	APM111056
4.0	2025-11-18	R. Ritter	APM112430
5.0	2026-03-24	R. Tsolova	APM112346
6.0	2026-04-27	R. Ritter	Update MDR TüV Certificate
7.0	2026-06-25	R. Ritter	APM113151

Signing Page

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Document Approval (OTCS)

UserName: Regina Ritter (RITTREG)
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Meaning: I have reviewed and hereby APPROVE the content
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UserName: Sandro Sbicego (LISBC)
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