EU Declaration of Conformity for Class I_I_6083953

Document Information (OTCS)	
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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)	**OptraGate**
Basic-UDI-DI	76152081XDAMS001US

Legal manufacturer		
ivoclar	Ivoclar Vivadent AG Benderer Strasse 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	Access to the oral cavity of the patient
EU Risk Classification (MDR Annex VIII)	Medical Device Class I CE
Conformity Assessment Procedure (MDR Annex IX)	Quality Management System
EC Certificate No.	N/A
Valid until	2029-11-28

Attachment to EU Declaration of Conformity

Article No.	Description	MDR Classification (EU)	Rule MDR (EU)
577275RU	OptraGate Assortment	I	5
577275WW	OptraGate Assortment	I	5
590850RU	OptraGate Regular Refill / 80	I	5
590850WW	OptraGate Regular Refill / 80	I	5
590851RU	OptraGate Small Refill / 80	I	5
590851WW	OptraGate Small Refill / 80	I	5
591451RU	OptraGate Junior Refill/80	I	5
591451WW	OptraGate Junior Refill/80	I	5
669088WW	OptraGate Small Assort./blue+pink/20+20	I	5
669089WW	OptraGate Junior Assort./blue+pink/20+20	I	5
683376WW	OptraGate Junior Refill/40	I	5
683377WW	OptraGate Regular Refill/40	I	5
683378WW	OptraGate Small Refill/40	I	5
695568WW	OptraGate Test Pack/4	I	5
762773WW	OptraGate Test Pack 2x1	I	5

Revision History			
Version	**Date**	**Author**	**Remark**
1.0	2020-04-02	A. Remm	First MDR Version
2.0	2022-10-26	R. Ritter	SRN added Update of Basic-UDI-DI Update of EMDN-term
3.0	2023-08-18	R. Tsolova	APM108280
4.0	2024-02-27	D. Kuljici	AM1001191
5.0	2024-04-18	R. Ritter	APM109593
6.0	2024-12-16	R. Ritter	APM111426
7.0	2025-01-03	R. Ritter	APM1001527

Signing Page

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Document Approval (OTCS)

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Date: Thursday, 02 January 2025, 17:13 W. Europe Daylight Time
Meaning: I have reviewed and hereby APPROVE the content
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UserName: Thomas Hirt (LIHIT)
Title: CTO
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UserName: Sandro Sbicego (LISBC)
Title: Director Regulatory Affairs & Corporate Quality Control / PRRC
Date: Tuesday, 07 January 2025, 18:21 W. Europe Daylight Time
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