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EU Declaration of Conformity – OptraDam Plus

Product	OptraDam Plus
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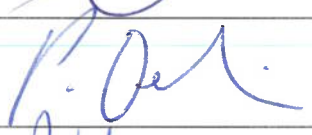
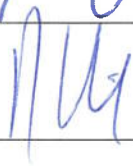
Document Control		
Name	**Date**	**Signature**
Author (Project Manager, RSR): Annina Remm	2020-07-01	
Reviewer (Research Associate, RSC): Dr. Ovidiu Pentelescu	01-07-2020	
Approver (PRRC): Patrik Oehri	01.07.2020	
Approver (CTO): Dr. Thomas Hirt	01.07.2020	

Revision History			
Version	**Date**	**Author**	**Remark**
1.0	2020-07-01	Annina Remm	First MDR Version

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.

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Legal Manufacturer information	**Ivoclar Vivadent AG** Bendererstrasse 2 9494 Schaan Liechtenstein	Phone +423 / 235 35 35 Fax +423 / 235 33 60 www.ivoclarvivadent.com Legal Form: Joint Stock Company Corporate Headquarters: 9494 Schaan Registration No.: FL-0001.001.595-7 VAT No.: 50639
SRN	not yet available	
Basic UDI-DI	DIVO1xDams002	
Product	**OptraDam Plus**	
Category (NBOG F 2017-3)	MDA Code: ☐ MDA 0311 Active non-implantable dental devices ☐ MDA 0315 Software	
	MDN Code: ☐ MDN 1103 Non-active dental implants and dental materials ☒ MDN 1208 Non-active non-implantable instruments ☐ MDN 1209 Non-active non-implantable dental materials ☐ MDN 1214 General non-active non-implantable devices used in health care and non-active non-implantable devices	
EMDN Code + term	Dental devices – various: ☒ Q019002 Dental devices, rubber dam and hooks	
EU Risk Classification (MDR Annex VIII)	☒ Medical Device Class I CE ☐ Medical Device Class IIa CE 0123 ☐ Medical Device Class IIb CE 0123 ☐ Medical Device Class III CE 0123	see Notified Body below
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 München Deutschland	
EC Certificate No.	☐ not yet available ☒ N/A	
Place and date of issue	Schaan, 2020-07-01	
Valid until	2025-05-06	