

EU Declaration of Conformity for Class I_I_247218909


Document Information (OTCS)	
OTCS – Doc.-ID	247218909
Version	2.0

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)	VivaDent Polishing Paste
Basic-UDI-DI	++DIVO1XPOLI002GD

Legal manufacturer		
	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	Prophy paste
EU Classification	<input checked="" type="checkbox"/> Medical Device <input type="checkbox"/> Accessory for Medical Device
EU Risk Class (MDR Annex VIII)	Class I CE
Conformity Assessment Procedure (MDR Annex II and III)	Quality Management System
EC Certificate No.	N/A
Valid until	2030-10-14

Attachment to EU Declaration of Conformity

Article No.	Description	MDR Classification (EU)	Rule MDR (EU)
759502	VD Polishing Paste fine Apple 80g	I	5
759515	VD Polishing Paste fine BGum 80g	I	5
759516	VD Polishing Paste medium Apple 80g	I	5
759517	VD Polishing Paste medium BGum 80g	I	5
759518	VD Polishing Paste coarse Apple 80g	I	5
759519	VD Polishing Paste coarse BGum 80g	I	5
760115	VD Polishing Paste fine Apple 200x1.8g	I	5
760116	VD Polishing Paste fine BGum 200x1.8g	I	5
760117	VD Polishing Paste coarse BGum 200x1.8g	I	5
760119	VD Polishing Paste medium ff 200x1.8g	I	5
760120	VD Polishing Paste medium Apple 200x1.8g	I	5
760121	VD Polishing Paste Test Pack 6x1.8g	I	5
761376	VD Polishing Paste fine Mint 80g	I	5
761377	VD Polishing Paste medium Mint 80g	I	5
761378	VD Polishing Paste medium ff 80g	I	5
761379	VD Polishing Paste coarse Mint 80g	I	5
761380	VD Polishing Paste fine Mint 200x1.8g	I	5
761381	VD Polishing Paste coarse Mint 200x1.8g	I	5

Revision History			
Version	Date	Author	Remark
1.0	2024-09-25	R. Ritter	First MDR Version
2.0	2025-10-27	R. Ritter	GSPR updated

Signing Page

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Document Approval (OTCS)

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