DECLARATION OF CONFORMITY

OPALUSTRE

Ultradent Products Inc., 505 West Ultradent Drive (10200 South), South Jordan, UT, 84095, has evaluated this product by using the Conformity Assessment Procedure of Annex IX of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Devices, and confirms that this product is compliant with the General Safety and Performance Requirements of Annex I of the Regulation (EU) 2017/745. Technical documentation is located in the Regulatory Affairs Department.

Identified Legislations:	Regulation (EU) 2017/745 – European Parliament and of the Council of 5 April 2017 on medical devices
EC Representative:	Ultradent Products GmbH Am Westhover Berg 30 51149 Cologne Germany
Device Classification:	This product system is classified as a Class I medical device according to Regulation (EU) 2017/745, Annex VIII, Chapter III, Section 5.1, Rule 5.
Intended Purpose:	For removal of superficial (<0.2mm depth) imperfections, including mild fluorosis discoloration.
UMDNS Code:	16699; Prophy Pastes
GMDN Code:	11168-Dentifrice
EMDN Code:	Q01010403 DENTAL ABRASIVE AND POLISHING MATERIALS
Basic UDI-DI:	0883205-TF042AT
Eudamed SRN:	US-MF-000013697
Common Specifications:	Not applicable
Model Numbers:	554-, 555-, 5554-
Images:	

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This Declaration of Conformity is issued under the sole responsibility of the manufacturer and is in force as long as the following certificate is valid:

DIN EN ISO 13485:2021 Reg.-No. 44 221 090234 valid until 05 March 2029

Adam Black, RAC
Director - Regulatory Affairs & Clinical Operations

23 Feb 2026
Date

State of Utah, County of Salt Lake
Subscribed and sworn to before me on this

23 **day of** February **20**26

By Adam Black

Amy Henderson-Neilson, **Notary Public**

AMY HENDERSON-NIELSON
Notary Public State of Utah
My Commission Expires on:
July 15, 2028
Comm. Number: 738155

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