3315 West 12th Street
Houston, TX 77008
www.nusmile.com
Tel (713) 861-0033
Fax (713) 861-1722
1-800-346-5133

Declaration of Conformity

PRODUCT IDENTIFICATION	
Product name	**Model/number**
Dentsply ProRoot Bio Sealer	See Attachment A

MANUFACTURER			
Name of company	**Single Registration Number (SRN)**	**Address**	**Representative**
NuSmile, Ltd.	US-MF-000021910	3315 West 12th St. Houston, TX. 77008 USA	Priscilla Lara

AUTHORIZED REPRESENTATIVE			
Name of company	**Single Registration Number (SRN)**	**Address**	**Telephone/email**
MDSS GmbH	DE-AR-000005430	Schiffgraben 41 30175 Hannover Germany	+49 511 62628630 – Phone +49 511 62628633 — Fax info@mdssar.com

REGISTRATION INFORMATION		
Notified Body and ID #	**CE certificate number**	
SGS 1639	US25/00000460 Valid from: 06 November 2025 until 06 November 2030	
Name of company	**Address**	**Telephone/email**
SGS Belgium NV SGS House	Noorderlaan 87 Antwerp 2030 Belgium	+32 (0)3 545 44 00 - Phone +32 (0)3 545 44 49 - Fax Jaimy.Ealias@sgs.com

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CONFORMITY ASSESSMENT
Class IIa Rule 8 Annex IX, Excluding Section 5&6, of MDR 2017/745.
EMDN Code & Term: Q01010299 – Dental Devices-Canal Filling-Others GMDN Code & Term: 60510 – Hygroscopic Dental Cement
European Medical Device Directive 93/42/EEC Council Directive European Medical Device Regulation 2017/745 ISO 13485:2016 Medical Devices — Quality Management Systems — Requirements for Regulatory Purposes ISO 14971:2019 Medical Devices – Application of Risk Management to Medical Devices ISO 15223-1:2021, Symbols To Be Used With Medical Device Labels, labelling and Information To Be Supplied. ISO 20417: 2021 Medical Devices – Information to be supplied by the manufacturer ISO 7405:2018 Dentistry – Evaluation of biocompatibility of medical devices used in dentistry ISO 10993-1:2018 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process ISO 10993-5:2009 Biological Evaluation of medical devices—Part 5: Tests for in vitro cytotoxicity ISO 10993-6:2007 Biological Evaluation of medical devices – Part 6: Tests for local effects after implantation ISO 10993-12:2012 Biological Evaluation of Medical Devices - Part 12: Sample Preparation and Reference Materials ISO 9917-1:2007 Dentistry – Water-based Cements – Part 1: Power/liquid acid-base cements ISO 6876:2012 Dentistry – Root canal sealing materials ADA 57:2012 Endodontic Sealing Materials

INTENDED PURPOSE
The MTA Products are designed for use in dental procedures that contact pulp tissue or periradicular tissue.

NuSmile, Ltd. declares that the above-mentioned products meet the provision of the Council covered by the present EU declaration is in conformity with the EU MDR 2017/745 and is issued under the sole responsibility of the manufacturer.

PLACE OF ISSUE: 3315 West 12th St. Houston, TX. 77008 USA

COMPANY REPRESENTATIVE: Diane Johnson Krueger

TITLE: President & CEO **SIGNATURE:**  **DATE:** 02/27/2026

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Attachment A: Dentsply Products

Basic-UDI-DI	DI Number	Company Name	Brand Name	Version or Model Number
0850008515NMTA20.5CE	00810118106491	NuSmile LTD.	Dentsply ProRoot Bio Sealer	60620140