



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
NuSmile NeoMTA 2 NuSmile NeoPUTTY	See Attachment A
Avalon Biomed NeoMTA 2 Avalon Biomed NeoPUTTY Avalon Biomed NeoSEALER Flo Avalon Biomed NeoSEALER EZ Flo	See Attachment B

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

Device Classification: 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

Standards Applied:

European Medical Device Directive 93/42/EEC Council Directive

European Medical Device Regulation 2017/745

United Kingdom Medical Device Regulation 2002

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: 06/22/2026



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Attachment A: NuSmile Products

Basic-UDI-DI	DI Number	Company Name	Brand Name	Version or Model Number
0850008515NNPIKV8	00850008515002	NuSmile LTD.	NuSmile NeoMTA 2	NMTA20.5
0850008515NNPIKV8	00850008515019	NuSmile LTD.	NuSmile NeoMTA 2	NMTA21.0
0850008515NNPIKV8	00850008515026	NuSmile LTD.	NuSmile NeoMTA 2	NMTA22.5
0850008515NNPIKV8	00850008515064	NuSmile LTD.	NuSmile NeoPUTTY	NNPIK
0850008515NNPIKV8	00850008515088	NuSmile LTD.	NuSmile NeoPUTTY	NNPPK
0850008515NNPIKV8	00810092938279	NuSmile LTD.	NuSmile NeoPUTTY	NNPMK

Attachment B: Avalon Biomed Products

Basic-UDI-DI	DI Number	Company Name	Brand Name	Version or Model Number
0850008515NNPIKV8	00850008515033	NuSmile LTD.	Avalon Biomed NeoMTA 2	N2050
0850008515NNPIKV8	00850008515040	NuSmile LTD.	Avalon Biomed NeoMTA 2	N2100
0850008515NNPIKV8	00850008515057	NuSmile LTD.	Avalon Biomed NeoMTA 2	N2250
0850008515NNPIKV8	00850008515095	NuSmile LTD.	Avalon Biomed NeoPUTTY	ANPIK
0850008515NNPIKV8	00850008515118	NuSmile LTD.	Avalon Biomed NeoPUTTY	ANPPK
0850008515NMTA20.5CE	00810118101243	NuSmile LTD.	Avalon Biomed NeoSEALER Flo	ANSEMK
0850008515NNPIKV8	00810092938286	NuSmile LTD.	Avalon Biomed NeoSEALER Flo	ANSRS
0850008515NMTA20.5CE	00810092938620	NuSmile LTD.	Avalon Biomed NeoSEALER Flo	ANSFK
0850008515NMTA20.5CE	00810118105586	NuSmile LTD.	Avalon Biomed NeoSEALER Flo	ANSBK
0850008515NMTA20.5CE	00810118106569	NuSmile LTD.	Avalon Biomed NeoSEALER EZFlo	ANSEZCFMK
0850008515NMTA20.5CE	00810118106514	NuSmile LTD.	Avalon Biomed NeoSEALER EZFlo	ANSEZCF
0850008515NNPIKV8	00810118106576	NuSmile LTD.	Avalon Biomed NeoSEALER EZFlo	ANSEZRF