



3315 West 12<sup>th</sup> Street  
 Houston, TX 77008  
[www.nusmile.com](http://www.nusmile.com)  
 Tel (713-861-0033  
 Fax (713) 861-1722

## 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	See Attachment B

MANUFACTURER		
Name of company	Address	Representative
NuSmile, Ltd.	3315 West 12th St. Houston, TX. 77008 USA	Mark Binford

AUTHORIZED REPRESENTATIVE		
Name of company	Address	Telephone/email
MDSS GmbH	Schiffgraben 41 30175 Hannover Germany	+49 511 62628630 – Phone +49 511 62628633 – Fax <a href="mailto:info@mdssar.com">info@mdssar.com</a>

REGISTRATION INFORMATION		
Notified Body and ID #	CE certificate number	
SGS 1639	US19/819943516 Valid from: 02 April 2020 until 24 May 2024	
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 <a href="mailto:Jaimy.Ealias@sgs.com">Jaimy.Ealias@sgs.com</a>



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CONFORMITY ASSESSMENT	
Device classification	Route to compliance
Class IIa Rule 8	Annex II, Excluding Section 4, of MDD 93/42/EEC Council Directive

**NuSmile, Ltd.** declares that the above-mentioned products meet the provision of the Council Directive 93/42/EEC for Medical Devices and Directive 93/42/EEC as transposed in the national laws of the Member States.

**COMPANY REPRESENTATIVE:** Diane Johnson Krueger

**TITLE:** President & CEO

**SIGNATURE:**

**DATE:** 04/01/2024

**Attachment A: NuSmile Products**

DI Number	Company Name	Brand Name	Description	Version or Model Number
00850008515002	NuSmile Ltd.	NuSmile NeoMTA 2	NeoMTA 2, 0.5 g Kit – 0.5 g Powder Bottle and 2 cc Gel Bottle	NMTA20.5
00850008515019	NuSmile Ltd.	NuSmile NeoMTA 2	NeoMTA 2, 1.0 g Kit – 1.0 g Powder Bottle and 2 cc Gel Bottle	NMTA21.0
00850008515026	NuSmile Ltd.	NuSmile NeoMTA 2	NeoMTA 2, 2.5 g Kit – 2.5 g Powder Bottle and 4 cc Gel Bottle	NMTA22.5
00850008515064	NuSmile Ltd.	NuSmile NeoPUTTY	NeoPUTTY, 0.5 g Kit – 0.5 g Syringe	NNPIK
00810092938279	NuSmile Ltd.	NuSmile NeoPUTTY	NeoPUTTY, 1.2 g Kit – 1.2 g Syringe	NNPMK
00850008515088	NuSmile Ltd.	NuSmile NeoPUTTY	NeoPUTTY, 2.4 g Kit – Two 1.2 g Syringes	NNPPK

**Attachment B: Avalon Biomed Products**

DI Number	Company Name	Brand Name	Description	Version or Model Number
00850008515033	NuSmile Ltd.	Avalon Biomed NeoMTA 2	NeoMTA 2, 0.5 g Kit – 0.5 g Powder Bottle and 2 cc Gel Bottle	N2050
00850008515040	NuSmile Ltd.	Avalon Biomed NeoMTA 2	NeoMTA 2, 1.0 g Kit – 1.0 g Powder Bottle and 2 cc Gel Bottle	N2100
00850008515057	NuSmile Ltd.	Avalon Biomed NeoMTA 2	NeoMTA 2, 2.5 g Kit – 2.5 g Powder Bottle and 4 cc Gel Bottle	N2250
00850008515095	NuSmile Ltd.	Avalon Biomed NeoPUTTY	NeoPUTTY, 0.5 g Kit – 0.5 g Syringe	ANPIK



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DI Number	Company Name	Brand Name	Description	Version or Model Number
00850008515101	NuSmile LTD.	Avalon Biomed NeoPUTTY	NeoPUTTY, 0.65 g Kit – 0.65 g Syringe	ANPSK
00850008515118	NuSmile LTD.	Avalon Biomed NeoPUTTY	NeoPUTTY, 1.2 g Kit – 1.2 g Syringe	ANPPK
00850008515248	NuSmile LTD.	Avalon Biomed NeoSEALER Flo	NeoSEALER Flo, 0.5 g Kit – 0.5 g Syringe & Flex Flo Tip 2 Pack, Basic Flex Tip 2 Pack, Flo Tip 2 Pack	ANSMK
00850008515255	NuSmile LTD.	Avalon Biomed NeoSEALER Flo	NeoSEALER Flo, 0.5 g Kit – 0.5 g Syringe & Flo Tip 10 Pack	ANSIMK
00850008515125	NuSmile LTD.	Avalon Biomed NeoSEALER Flo	NeoSEALER Flo, 2.2 g Kit – 2.2 g Syringe & Flo Tip 20 Pack	ANSIK
00850008515156	NuSmile LTD.	Avalon Biomed NeoSEALER Flo	NeoSEALER Flo, 2.2 g Kit – 2.2 g Syringe & Flex Flo Tip 20 Packs	ANSSK
00810092938286	NuSmile LTD.	Avalon Biomed NeoSEALER Flo	NeoSEALER Flo, 2.2 g Kit – 2.2 g Syringe	ANSRS
00850008515132	NuSmile LTD.	Avalon Biomed NeoSEALER Flo	NeoSEALER Flo, 4.4 g Kit – Two 2.2 g Syringe & Flex Flo Tip 40 Pack	ANSPK
00810092938620	NuSmile LTD.	Avalon Biomed NeoSEALER Flo	NeoSEALER Flo, 2.2 g Kit – 2.2 g Syringe & Two Flex Flo Tips 2 Packs	ANSFK
00810118101243	NuSmile LTD.	Avalon Biomed NeoSEALER Flo	NeoSEALER Flo, 0.5 g Kit – 0.5 g Syringe & Two Flex Flo Tip 2 Packs	ANSEMK
00850008515149	NuSmile LTD.	Avalon Biomed NeoSEALER Flo/ NeoPUTTY Combo Kit	NeoSEALER Flo/NeoPUTTY 2.85 g Kit – NeoSEALER Flo 2.2 g Syringe w/Flex Flo Tip 20 Pack & NeoPUTTY 0.65 g Syringe	ANSPCK