1-800-346-5133
www.nusmilecrowns.com
3315 West 12th St. | Houston, TX 77008
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 info@mdssar.com

REGISTRATION INFORMATION		
Notified Body and ID #	**CE certificate number**	
SGS 1639	US19/819943516 Valid from: 16 December 2019 until 01 April 2024	
Name of company	**Address**	**Telephone/email**
SGS Belgium NV SGS House	Noorderlaan 87 Antwerp 2030 Belgium	+32 (0)3 545 44 48 - Phone +32 (0)3 545 44 49 - Fax josephine.obidigbo@sgs.com

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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:** 06/29/2022

Attachment A: NuSmile Products

DI Number	Company Name	Brand Name	Version or Model Number
00850008515002	NuSmile LTD.	NuSmile NeoMTA 2	NMTA20.5
00850008515019	NuSmile LTD.	NuSmile NeoMTA 2	NMTA21.0
00850008515026	NuSmile LTD.	NuSmile NeoMTA 2	NMTA22.5
00850008515064	NuSmile LTD.	NuSmile NeoPUTTY	NNPIK
00850008515071	NuSmile LTD.	NuSmile NeoPUTTY	NNPSK
00850008515088	NuSmile LTD.	NuSmile NeoPUTTY	NNPPK
00810092938279	NuSmile LTD.	NuSmile NeoPUTTY	NNPMK

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Attachment B: Avalon Biomed Products

DI Number	Company Name	Brand Name	Version or Model Number
00850008515033	NuSmile LTD.	Avalon Biomed NeoMTA 2	N2050
00850008515040	NuSmile LTD.	Avalon Biomed NeoMTA 2	N2100
00850008515057	NuSmile LTD.	Avalon Biomed NeoMTA 2	N2250
00850008515095	NuSmile LTD.	Avalon Biomed NeoPUTTY	ANPIK
00850008515101	NuSmile LTD.	Avalon Biomed NeoPUTTY	ANPSK
00850008515118	NuSmile LTD.	Avalon Biomed NeoPUTTY	ANPPK
00850008515248	NuSmile LTD.	Avalon Biomed NeoSEALER Flo	ANSMK
00850008515255	NuSmile LTD.	Avalon Biomed NeoSEALER Flo	ANSIMK
00850008515125	NuSmile LTD.	Avalon Biomed NeoSEALER Flo	ANSIK
00850008515156	NuSmile LTD.	Avalon Biomed NeoSEALER Flo	ANSSK
00810092938286	NuSmile LTD.	Avalon Biomed NeoSEALER Flo	ANSRS
00850008515132	NuSmile LTD.	Avalon Biomed NeoSEALER Flo	ANSPK
00810092938620	NuSmile LTD.	Avalon Biomed NeoSEALER Flo	ANSFK
00850008515149	NuSmile LTD.	Avalon Biomed NeoSEALER Flo/ NeoPUTTY Combo Kit	ANSPCK