



Orthodontic Design and Production  
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<b>Registration Information</b>	
Notified Body, #:	BSI (2797)
Address:	Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam Netherlands
CE Certificate #	CE 649654
<b>Conformity Assessment</b>	
Applicable Council	93/42/EEC
Directive.....	(as amended by 2007/47/EC)
Classification.....	Class IIa (Rule 5, Annex IX)
Route to Compliance.	Annex V
Standards Applied.....	EN ISO 13485:2016/ISO 13485:2016 Certificate #: MD 702268
<b>European Authorized Representative</b>	
mdi Europa GmbH Langenhagen Str. 71 30855 Langenhagen Germany	

## DECLARATION OF CONFORMITY

### Class IIa Products

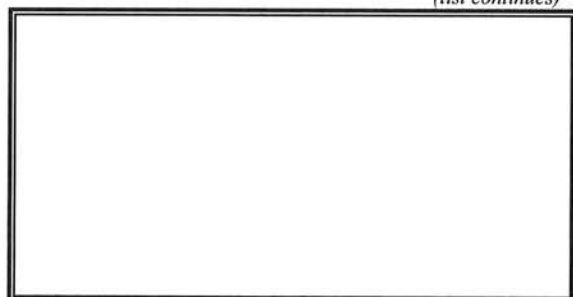
UMDNS Code	Product Family/Description	Part number Prefix (Part Number begins with...)				
11-394	<b><i>Non-latex Intraoral Elastics</i></b>					
	Non-latex Intraoral Elastics	LFH*	LFM*			
12-028	<b><i>Hooks</i></b>					
	Auxiliary J Hooks	M002-*				
	Ball Clasps	SSBC*				
	Crimpable Stops	CSTOP*	M022-*	M025-*		
	Extrusion Hooks	EXHK*				
	Eyelets	CME*	M005B*	M006B*		
	Lingual Buttons	M020-*	M021B-*	WLBC*	WLBF*	
	Lingual Cleats	270-*	M015-*	M015B-*	WLCLEAT*	
	Lugs	M011-*				
	Shepherds Hooks	SHPHK*				
	Surgical & Arch Hooks	ARHK*	M023-*	M024-*	SURHK*	
	Ceramic Lingual Button	CLB*				
	Ceramic Hooks	FCB-00-*				
	T-Hooks	THK*				
12-374	<b><i>Orthodontic Expanders</i></b>					
	Palatal Bars	PAB*				
	Lip Bumpers	CCLB*	M550-*			
14-457	<b><i>Ligature Wires</i></b>					
	Bulk Ligature Wire	SBLW*				
	Kobayashi Ties	KH01*	SKH*	TSKH*		
	Preformed Ligatures	LT*	SLT*	TCLT*	TCSLT*	
16-055	<b><i>Expansion Screws</i></b>					
	Expansion Screws	ESCR0*				
	Palatal Expansion Screws	2000/*	A0623*	A0625*	PALEXP*	X002*

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Orthodontic Design and Production EU Declaration of Conformity, Class IIa, *continued*

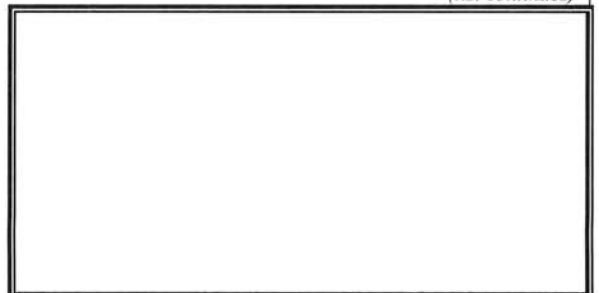
UMDNS Code	Product Family/Description	Part number Prefix (Part Number begins with...)				
16-190	<b>Elastic Bands, Orthodontic</b>					
	Archwire Protective Sleeve	ASPTG*	ASPTC*	M936-*	M937-*	
	Chain Elastic, Continuous	CDL*	M910-*			
	Chain Elastic, Long	LDL*	M913-*			
	Chain Elastic, Short	SDL*	M911-*			
	PowerLinx Chain Elastic	LPL*	SPL*			
	Enchanted Intraoral Elastics	14HV*	14LT*	14MD*	14ML*	14XH*
		18HV*	18LT*	18MD*	18XL*	36HV*
		36LT*	36MD*	36ML*	36XH*	38HV*
		38LT*	38MD*	38ML*	38XL*	56HV*
		56LT*	56MD*	56ML*	56XH*	56XL*
	Extreme Elastics	M931-*				
	PL Elastics	ACH*	ACM*	AML*	AMD*	AMH*
		AMX*				
	OC Elastics	OC14*	OC18*	OC36*	OC38*	OC56*
	Extraoral Elastics	AXH*	AX0*	305-*		
	Versa-Tie Patient Ties	VT*				
	Bambino Patient Ties	BT*				
	Mini Patient Ties	OCM*				
	Supreme Patient Ties	M920-*	M925-*			
	Select Patient Ties	OCS*				
	Designer Patient Ties	DTIE-*	DTIEK*	DTK*		
	Caned Patient Ties	CCL*	CGY*			
Bulk Patient Ties	BCL*	BGY*				
Threads, Hollow	TBCL*	TBGY*				
Threads, Solid	ETCL*	ETGY*	SNTC*	SNTG*		
Rotation Wedges	RWP*					
16-198	<b>Orthodontic Bands</b>					
	Titan Molar Bands	B10*	B11*	K10*	K11*	
	Saturn Molar Bands	B12*	B13*	K12*	K13*	
	Saturn Bicuspid Bands	B22*	B24*	K22*	K24*	
	PL Molar Bands	KMB*	MB*			
	PL Bicuspid Bands	OUB*				
16-199	<b>Orthodontic Tubes</b>					
	Viper Buccal Tubes	NS3*	NS3B*	NS4B*		
	Viper CV Buccal Tubes	CC3*	CC3B*	CS3*	CS3B*	
	Magnum Buccal Tubes	CC*	CCB*	CC1*	CC1B*	CD1*
		CD1B*	CL1*	CL1B*	CS1*	CS1B*
		CT1*	CT1B*	NC1*	NC1B*	NRD1*
		NRD1B*	NRT1*	NRT1B*	NS1*	NS1B*
		NS2B*	900-*			
	MiniPrevail Buccal Tubes	NS6*	NS6B*	NS7*	NS7B*	
	Coralex Buccal Tubes	NS3-036*				
Straight-Line Buccal Tubes	BBT*	WBT*				
Lingual Sheaths	M040-*	WLS05*	WLS15*			

(list continues)

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Orthodontic Design and Production EU Declaration of Conformity, Class IIa, *continued*

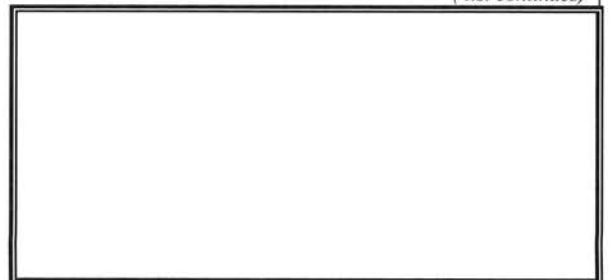
UMDNS Code	Product Family/Description	Part number Prefix (Part number begins with...)				
16-199	<b>Orthodontic Tubes (Continued.....)</b>					
	V-Tubes	V-T*				
	Tubes - Misc	M001*	M060*	M061*	M090*	045-*
16-204	<b>Orthodontic Wires</b>					
	Brass Wire	STBR*	AW820*			
	Colboly Blue Wire	CBBF*	CBF*	CBSTR*	CBTF*	STRCB*
	<b>Nickel Titanium Wire, includes coated wires</b>					
	G4 & Super Elastic Wires	G4ALL*	G4BF*	G4DYB*	G4EF*	G4GF*
		G4L*	G4MLU*	G4SF*	G4SL*	G4TF*
		G4XL*	HF*	PTEF*	PTNTF*	PTTF*
		SEBF*	SEEF*	SEL*	SEML*	SEMOM*
		SEOF*	SEOT*	SESF*	SESL*	SESM*
		SETF*	SEXL*	W1622*	W71*	W77*
		W83*	W90*	W93*	OSN*	ORC*
	M5 & Thermal Activated Wires	CUBF*	CUEF*	CUL*	CUSF*	CUTF*
		M1BF*	M1EF*	M1L*	M1SF*	M1TF*
		M5BF*	M5EF*	M5L*	M5SF*	M5TF*
		TBF*	TEF*	TLG*	TLL*	TLM*
		TLS*	TLXS*	TSF*	TSM*	TTF*
		W80*	W81*	W82*	W91*	
	G4 & Super Elastic Reverse Curve	G4RC*	PTNRC*	RC1*	RCD*	SERC*
		W68*	W78*			
	M5 & Thermal Reverse Curve	CURC*	MIRC*	M5RC*	TRC*	W88*
	Spooled & 7" Lengths	SENT*	SESP*	TNT*		
	Archwire Kits	PP*				
	<b>Stainless Steel Wire, including coated wires</b>					
	Australian Wire	AJW*	AW2*	AW6*	AW7*	AWSF*
		AWTF*				
	Stainless Steel Archwires	S3BF*	S3DYB*	S3EF*	S3L*	S3SF*
		S3TF*	SSBF*	SSEF*	SSL*	SSSF*
		SSTF*	W50*	W54*	W55*	W72*
		W92*	XRALL*	XRBF*	XREF*	XRSF*
		XRTF*	OCSB*	1037*		
	Stranded (Archwires, Spooled & 14")	CSF*	CTF*	MS3*	MS6*	MS7*
		MS8*	S6SF*	SSP*	SST3*	SST6*
SST7*						
Retraction Arches (Looped)	KHTF*	TLPTF*	TLTF*	031*	032*	
Posted Archwires	PSBF*	PSEF*	PSTF*	PXB*	W50LP*	
	W50UP*	1037*P				
14" Lengths	STSS*					
Soft Wire	SSSOF*					
<b>TitanMoly™ Titanium Molybdenum Wire / Beta BT3</b>						
TitanMoly Archwires	B3*	BEP*	BTEF*	BTL*	BTU*	
	TMBF*	TMEF*	TML*	TMML*	TMSF*	
	TMSL*	TMTF*	TMXL*	W60*	W61*	

(list continues)

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Orthodontic Design and Production EU Declaration of Conformity, Class IIa, *continued*

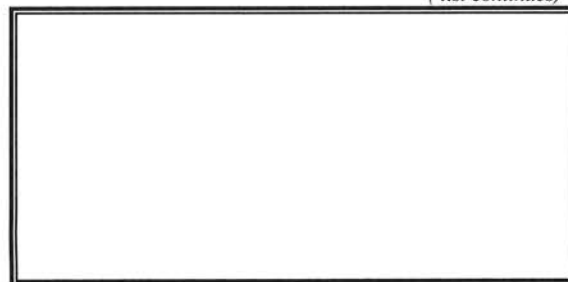
UMDNS Code	Product Family/Description	Part number Prefix (Part number begins with...)				
16-204	<b>TitanMoly™ Titanium Molybdenum Wire / Beta BT3(Continued.....)</b>					
	TitanMoly Archwires	W62*				
	Retraction Arches (Loops)	B3TL*	BTTL*	TMTL*		
	14" Lengths	BTSTR*	STB3*	STTM*		
16-360	<b>Orthodontic Brackets</b>					
	<b>Ceramic Brackets</b>					
	Clarion Ceramic Brackets	50-*	50K-*	51-*	51K-*	
		52-*	52K-*			
	Diamante Ceramic Brackets	55-*	55K-*	56-*	56K-*	
		57-*	57K-*	58-*	58K-*	
	Mirage Ceramic Brackets	60-*	60K-*	61-*	61K-*	
		62-*	62K-*	63-*	63K-*	
	Vapor Ceramic Brackets	75-*	75K-*	76-*	76K-*	
	Venus Ceramic Brackets	KTVCR*	VCR*			
	Zenith Ceramic Brackets	EDCR*	KTECR*	KTEDCR*	KTRCR*	
		RCR*				
	<b>Composite Brackets</b>					
	Lucent Composite Brackets	40-*	40K-*	41-*	41K-*	
		42-*	42K-*			
	Prism Composite Brackets	45-*	45K-*	46-*	46K-*	
		47-*	47K-*			
	Zenith Composite Brackets	EDCM*	KTEDCM*	KTRCM*	RCM*	
	<b>Stainless Steel Brackets</b>					
	Agility Brackets	14-*	14K-*	15-*	15K-*	
	Comfort Zone Brackets	16-*	16K-*	17-*	18-*	
		18K-*	26-*	26K-*	28-*	
		28K-*				
	Focus Brackets	19-*	19K-*	21-*	21K-*	
		22-*	22K-*	23-*	23K-*	
	Magnum Brackets	30-*	30K*	31-*	31K*	
		33-*	33K*	34-*	34K*	
	MiniPrevail	36-*	36K*	37-*	37K*	
		38-*	38K*	39-*	120-*	
		120K-*	121-*	121K-*		
	Bicuspid/Molar Brackets	BBB*	EDST*	WED*		
	Straight-line Brackets	EDSWM*	KTEDST*	KTNVE*	KTNVR*	
		KTVSR*	NVE*	NVR*	RXA*	
		RXB*	RXR*	VSR*		
	90-503	<b>Orthodontic Springs</b>				
		Closed Coil Nickel Titanium Springs	CCNT*	CCOF*	CCOT*	KTCCOF*
KTCCOT*			M140-*			
Closed Coil Stainless Steel Springs		M105-*	SSCC*			
Molar Distalizing Nickel Titanium Springs	OCNT2*	OCNT7*				
Open Coil Nickel Titanium Springs	M145-*	M146-*	OCNT0*	OCNT1*		

(list continues)

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Orthodontic Design and Production EU Declaration of Conformity, Class IIa, *continued*

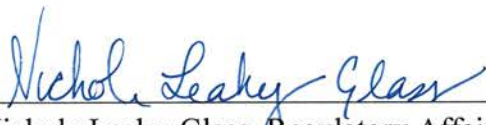
UMDNS Code	Product Family/Description	Part number Prefix (Part number begins with...)
90-503	<i>Orthodontic Springs (Continued.....)</i>	
	Open Coil Nickel Titanium Springs	OCNTS*
	Open Coil Stainless Steel Springs	M100-* SSOC*

We, G&H Wire Company of Franklin, Indiana, USA, declare with sole responsibility that the products listed above meet the essential requirements of the Council Directive 93/42/EEC, as amended by 2007/47/EC, pertaining to Medical Devices.

We hereby appoint mdi Europa GmbH, Langenhagener Str. 71, 30855 Langenhagen in Germany to act as European Authorized Representative, as explicitly stated in Article 1, §2(j) of Directive 93/42/EEC.

The above are necessary pre-requisites for placing the **CE 2797** mark on the above mentioned products, and marketing this in all Member States of the European Union.

Signed this 24<sup>th</sup> day of May, 2019 by

  
 \_\_\_\_\_  
 Nichole Leahy-Glass, Regulatory Affairs  
 Manager

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Name/Title

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