

FlexMedics
 2165 Earlywood Drive
 Franklin, IN 46131, United States

T: +1 (317) 346-6655
 F: +1 (317) 346-6663

E-mail: orders@ghortho.com

Registration Information

Notified Body, #: BSI (2797)
 Address: Say Building, John M. Keynesplein 9,
 1066 EP, Amsterdam
 Netherlands
 CE Certificate # CE 635656

Conformity Assessment

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 635662

European Authorized Representative

mdi Europa GmbH
 Langenhagen Str. 71 30855 Langenhagen
 Germany

DECLARATION OF CONFORMITY

Class IIa Products

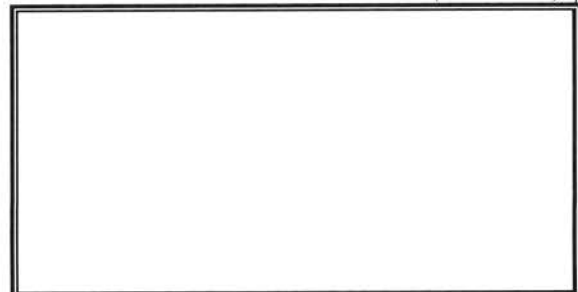
UMDNS Code	Product Family/Description	Part number Prefix (Part Number begins with...)			
11-394	Non-latex Intraoral Elastics				
	Non-latex Intraoral Elastics	LFH*	LFM*		
12-028	Hooks				
	Auxiliary J Hooks	M002-*			
	Ball Clasps	SSBC*			
	Crimpable Stops	CSTOP*	M022-*	M025-*	
	Extrusion Hooks	EXHK*			
	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	Orthodontic Expanders				
	Palatal Bars	PAB*			
	Lip Bumpers	CCLB*	M550-*		
14-457	Ligature Wires				
	Bulk Ligature Wire	SBLW*			
	Kobayashi Ties	KH01*	SKH*	TSKH*	
	Preformed Ligatures	LT*	SLT*	TCLT*	TCSLT*
16-055	Expansion Screws				
	Expansion Screws	ESCR0*			
	Palatal Expansion Screws	2000/*	A0623*	A0625*	PALEXP* X002*

(list continues)

 Name/Title

 Signature

 Date



FlexMedics EU Declaration of Conformity, Class IIa, *continued*

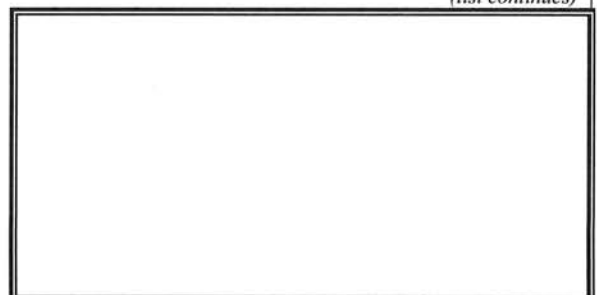
UMDNS Code	Product Family/Description	Part number Prefix (Part Number begins with...)				
16-190	Elastic Bands, Orthodontic					
	Archwire Protective Sleeve	ASPTG*	ASPTC*	M936-*	M937-*	
	Chain Elastic, Continuous	CDL*	M910-*			
	Chain Elastic, Long	LDL*	M913-*			
	Chain Elastic, Short	SDL*	M911-*			
	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	Orthodontic Bands					
	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	Orthodontic Tubes					
	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)

Name/Title

Signature

Date



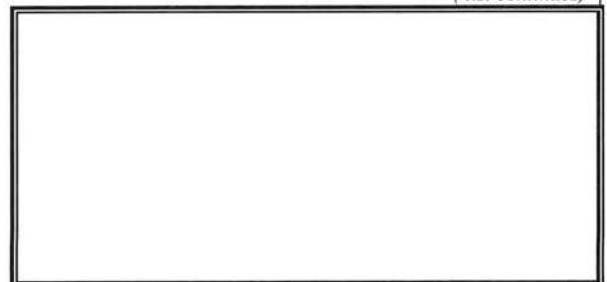
UMDNS Code	Product Family/Description	Part number Prefix (Part number begins with...)				
16-199	Orthodontic Tubes (Continued....)					
	V-Tubes	V-T*				
	Tubes - Misc	M001*	M060*	M061*	M090*	045-*
16-204	Orthodontic Wires					
	Brass Wire	STBR*	AW820*			
	Colboly Blue Wire	CBBF*	CBF*	CBSTR*	CBTF*	STRCB*
	Nickel Titanium Wire, includes coated wires					
	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*				
	Stainless Steel Wire, including coated wires					
	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*					
TitanMoly™ Titanium Molybdenum Wire / Beta BT3						
TitanMoly Archwires	B3*	BEF*	BTEF*	BTL*	BTU*	
	TMBF*	TMEF*	TML*	TMML*	TMSF*	
	TMSL*	TMTF*	TMXL*	W60*	W61*	

(list continues)

Name/Title

Signature

Date



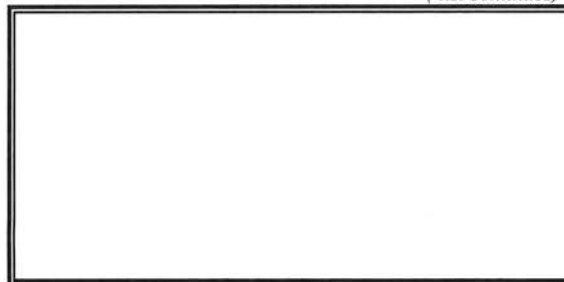
UMDNS Code	Product Family/Description	Part number Prefix (Part number begins with...)				
16-204	TitanMoly™ Titanium Molybdenum Wire / Beta BT3(Continued.....)					
	TitanMoly Archwires	W62*				
	Retraction Arches (Loops)	B3TL*	BTTL*	TMTL*		
	14" Lengths	BTSTR*	STB3*	STTM*		
16-360	Orthodontic Brackets					
	Ceramic Brackets					
	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*				
	Composite Brackets					
	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*	
	Stainless Steel Brackets					
	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	Orthodontic Springs				
		Closed Coil Nickel Titanium Springs	CCNT*	CCOF*	CCOT*	KTCCOF*
KTCCOT*			M140-*			
Closed Coil Stainless Steel Springs		M105-*	S SCC*			
Molar Distalizing Nickel Titanium Springs	OCNT2*	OCNT7*				
Open Coil Nickel Titanium Springs	M145-*	M146-*	OCNT0*	OCNT1*		

(list continues)

Name/Title

Signature

Date



FlexMedics 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 24th day of May, 2019 by



 Nichole Leahy-Glass
 Regulatory Affairs Manager

 Name/Title

 Signature

 Date

