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Single Registration Number

US-MF-000012129

Conformity Assessment

Device Classification	Class IIa
Conformity Assessment Route	Annex IX, (Rule 5 Annex VIII)
Quality Management Certificate #:	MD 635659

Notified Body

BSI (2797)
Say Building, John M. Keynesplein 9,
1066 EP, Amsterdam, Netherlands
CE Certificate# MDR 761486 R000

European Authorized Representative

G&H Europe BV
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- I. The EU Declaration of Conformity is issued under the sole responsibility of the manufacturer.
- II. The quality management system of the manufacturer has been approved by the notified body BSI according to European Medical Device Regulation 2017/745 Annex IX and EN ISO 13485:2016 compliant system.
- III. Please reference the Summary Technical Document for a list of all applicable standards and common specifications.

UMD NS Code	Intended Purpose	Product Family / Description	Part number Prefix (Part Number begins with...)
12-028	<i>Hooks provide a method to transfer force from a wire, spring, elastic, or other force containing device to a tooth in order to facilitate orthodontic treatment</i>	Hooks	Basic UDI-DI: 0190886AuxiliariesFG
		<i>Balls Clasps</i>	SSBC* A1G*
		<i>Crimpable Stops</i>	CSTOP* M022-* A2T*
		<i>Eyelets</i>	M005B* M006B* OM-0*
		<i>Lingual Buttons</i>	M021B-*
		<i>Lingual Cleats</i>	M015B-*
		<i>Surgical & Arch Hooks</i>	SURHK* M024-* A2H*
14-457	<i>Ligature wires assist in creating the forces necessary to move teeth during orthodontic treatment.</i>	Ligature Wires	Basic UDI-DI: 0190886LigatureWiresWK
		<i>Bulk Ligature Wire</i>	SBLW* GW* A1L*
		<i>Kobayashi Ties</i>	KH01* SKH* GWKH* GWSKH* A1LK*
			L08* L09* OMLK*
		<i>Preformed Ligatures</i>	LT* SLT* GWL* GWS* A1LM*
			L62*



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16-190	Orthodontic elastics are used in orthodontic treatment to exert a force. Elastomeric chain is placed around the tie wings on the bracket to retain the archwire in the bracket slot and extended to other teeth to provide force.	Elastic Chain, Orthodontic	Basic UDI-DI: 0190886ElasticChainBM				
		Chain Elastic	CDL* GWS*	LDL* ECD*	SDL* ECF*	GWC* L81*	GWL*
		PowerLinx Chain Elastic	LPL*	SPL*	GWL*	ECE*	
	Orthodontic elastics are used in orthodontic treatment to exert a force.	Elastic Bands, Orthodontic	Basic UDI-DI: 0190886ElasticBandsBM				
		Enchanted Intraoral Elastics	14HV*	14LT*	14MD*	14XH*	18HV*
			18LT*	18MD*	36HV*	36LT*	36MD*
			36XH*	38HV*	38LT*	38MD*	56HV*
			56LT*	56MD*	56XH*		
		Extreme Intraoral Elastics	M931*				
		Doctor Intraoral Elastics	OC14*	OC18*	OC36*	OC38*	OC56*
		Bulk Intraoral Elastics	AC**B	AM**B			
		Custom Elastics	LANOD*	L81*	03-0*		
		Extraoral Elastics	AXH*	AX0*	GWAX*	EEIL*	
	Ligature ties are intended to be placed around the tie wings on the bracket to retain the archwire in the bracket slot.	Elastic Ligature Tie, Orthodontic	Basic UDI-DI: 019886LigatureTiesVN				
		Versa-Tie Patient Ties	VT*	GWVT*	L81*		
		Bambino Patient Ties	BT*	ELB*			
		Mini Patient Ties	OCM*	GWOCM*			
		Select Patient Ties	OCS*				
		Designer Patient Ties	DTIE-*	DTIEK*	DTKEY*		
		Caned Patient Ties	CCL*	CGY*	GWC*		
		Bulk Patient Ties	BCL*	BGY*			
	Elastomeric threads, hollow, solid and slip-not are used to tie appliances and auxiliaries into place.	Elastic Thread, Orthodontic	Basic UDI-DI: 0190886ThreadMJ				
		Elastomeric Thread	TBCL*	TBGY*	ETC*	ETGY*	SNT*
			ET*	GW4*	GWS*		



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18-082	Elastomeric separators are placed between adjacent teeth to assist in creating space between them.	Separators, Orthodontic	Basic UDI-DI: 0190886SeparatorsX2				
		Elastomeric Separators	325-*	500-*	GW3*	GW5*	ESM*
16-198	Orthodontic bands provide a base to affix weldable attachments such as buccal tubes, sheaths, cleats and hugs.	Orthodontic Bands	Basic UDI-DI: 0190886MolarBandsFU				
		Titan Molar Bands	B10*	B11*	K10*	K11*	
		Saturn Molar Bands	B12*	B13*	K12*	K13*	
16-199	Tubes are intended to be affixed to the teeth, molar bands or slide onto the archwire to provide an anchor for a wire or other appliance.	Orthodontic Tubes	Basic UDI-DI: 0190886MetalTubesKR				
		Agility Buccal Tubes	AC1*	AC*	AL1*	AS1*	
		Viper Buccal Tubes	CC3*	CS3*	NS3*	NS4*	GWNS*
		Magnum Buccal Tubes	CC*	CC1*	CD1*	CL1*	CS1*
			CT1*	NC1*	NRD1*	NRT1*	NS1*
			NS2*	GWNR*			
		MiniPrevail Buccal Tubes	NS6*	NS7*			
		Lingual Sheaths	M040-*				
		V-Tubes	V-T*	A2HV*			
16-204	Wires provide force to move the teeth into the desired Class I bite and to maintain the formation of the teeth until the roots of the teeth remain in the preferred position.	Orthodontic Wires					
		Type 2 Wire	Basic UDI-DI: 0190886Type2Orthowires43				
		Nickel Titanium Archwires	G4BF*	G4DYB*	G4EF*	G4GF*	G4L*
			G4M*	G4SF*	G4SL*	G4TF*	G4XL*
			PTEF*	PTTF*	SEBF*	SEEF*	SEL*
			SEML*	SEMOM*	SEOF*	SESF*	SESL*
			SESM*	SETF*	SEXL*	VSEBF*	NT*
			VNT*	KNT*	GWSE*	A1NS*	A1NP*
			L05*	L30*	L32*	OMS*	
		Thermal Nickel Thermal Archwires	CUBF*	CUEF*	CUL*	CUSF*	CUTF*
			M5BF*	M5EF*	M5L*	M5SF*	M5TF*
			TBF*	TEF*	TLG*	TLL*	TLM*
			TLS*	TLXS*	TS*	TTF*	TNE*
			TNT*	VTNT*	GWT*	A1CN*	A1NT*
			L08*	L51*	L99*	OMC*	OML*
		Nickel Titanium Reverse Curve	G4RC*	RC1*	RCD*	SER*	RCS*
			A1NS*	A1NP*	L05*	OMR*	
		Thermal Nickel Titanium Reverse Curve	CURC*	M5RC*	TRC*	GWT*	A1CN*
			OML*				
		Spools & Straight Lengths	SENT*	SESP*	GWSE*	A1NS*	
		Archwire Kits	PP*				



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		Type 1 Wire	Basic UDI-DI: 019886Type1Orthowire34						
		Australian Archwire	AWSF*	AWTF*					
		Stainless Steel Archwires	S3BF*	S3DYB*	S3EF*	S3L*	S3SF*		
			S3TF*	SSBF*	SSEF*	SSL*	SSSF*		
			SSTF*	XRBF*	XREF*	XRSF*	XRTF*		
			SD*	GWS*	A1A*	L05*	L06*		
			L09*	L62*	OMT*				
		Stranded (Archwires, Spooled, & Straight Lengths	CSF*	CTF*	MS3*	MS6*	MS7*		
			MS8*	SST3*	SST6*	SST7*	GWC*		
			GWM*	GWSS*	A1AT*	L06*	L07*		
			L08*						
		Retraction Archwes (Looped)	KHTF*	TLTF*	031*	032*	033*		
			GWKH*	GWTL*	A1AL*	L07*	L95*		
		Posted Archwires	PSEF*	PSTF*	PXB*	GWP*	A1AP*		
			A1AB*	OMT*					
		Straight Lengths	STSS*	GWST*	A1AC*	L07*	OMT*		
		Soft Wire	SSSOF*						
		Brass Wire	STBR*	GWS*					
		Colboloy Archwires & Straight Lengths	CBBF*	CBTF*	STRCB*	GWC*	GWSTR*		
			A1CL*	L11*	L30*	OMO*			
		TitanMoly Archwires	B3BF3*	B3DYB*	B3EF*	B3L*	B3M*		
			B3SF*	B3SL*	B3TF*	B3X*	TMBF*		
			TMEF*	TML*	TMML*	TMSF*	TMSL*		
			TMTF*	TMXL*	GWTM*	A1BT*			
		Retraction Arches (Loops)	B3TL*	TMTL*	GWTMTL*				
		Straight Lengths	STB3*	STTM*	GWST*	A1BT*			
16-360	Orthodontic brackets provide a base to create force to move a tooth in order to facilitate orthodontic treatment.	Orthodontic Brackets							
		Ceramic Brackets	Basic UDI-DI: 0190886CeramicBrackets7H						
		Agility Ceramic Brackets	125*	126*					
		Vapor Ceramic Brackets	GW7*	BNU*	OHC*				
		Stainless Steel Brackets	Basic UDI-DI: 019886MetalBrackets7C						
		Marquis Brackets	10*	11*	12*				
		Agility Brackets	14*	15*	127*	128*			
		Comfort Zone Brackets	16*	17*	18*	26*	28*		
		Magnum Brackets	30*	31*	33*	34*	GW3*		
		MiniPrevail	36*	37*	38*	39*	120*		
			121*	GW3*	BBP*				
		33-907	Springs are intended to open or close a space between teeth or to prevent molar tipping.	Orthodontic Springs					
				Nickel Titanium Springs	Basic UDI-DI: 0190886NiTiSpringsPV				
				Closed Coil Nickel Titanium Springs	CCNT*	CCOF*	CCOT*	KTCCOF*	KTCCOT*
GWC*	A2N*				L08*	L11*	L12*		
Molar Distalizing Nickel Titanium Springs	OCNT2*			OCNT7*	GWO*	A2N*	L08*		
	OMC*								
Open Coil Nickel Titanium Springs	OCNT0*			OCNT1*	GWO*	A2NA*	L08*		
	OMCD*								



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		<i>Stainless Steel Springs</i>	<i>Basic UDI-DI: 0190886SSSprings8X</i>			
		<i>Closed Coil Stainless Steel Springs</i>	SSCC*	GWR*	A2AC*	
		<i>Open Coil Stainless Steel Springs</i>	SSOC*	GWSSO*	GWR*	A2AA*

We, G&H Wire Company, Inc. of Franklin, Indiana, USA, hereby declare with sole responsibility that the medical devices listed above conform to the applicable standards identified above and the provision of European Medical Device Regulation (MDR) 2017/745 Annex IX.

Signed this 20 day of December, 2022 by

John Browder
Director, RA/QA