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G&H Wire Company, Inc.
40 Linville Way
Franklin, IN 46131, United States

T: +1 (317) 346-6655
F: +1 (317) 346-6663
E-mail: orders@ghortho.com

Single Registration Number

US-MF-000012129

Conformity Assessment

Device Classification	Class IIa
Conformity Assessment Route	Annex VIII, Rule 5
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**SRN:** NL-AR-000022839

G&H Europe BV
Edisonstraat 3 3861 Nijkerk
Netherlands

- I. The EU Declaration of Conformity is issued under the sole responsibility of the manufacturer.
- II. Manufacturer declares, under its sole responsibility, that the product(s) covered in this document are in conformance with the Medical Devices Regulations (EU) 2017/745 Annex IX Chapter I and III and carried out according to the Quality Management System ISO 13485:2016.
- III. Please reference the General Safety and Performance Requirements 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	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.	Hooks	Basic UDI-DI: 0190886AuxiliariesFG
		Balls Clasps	SSBC* A1G*
		Crimpable Stops	CSTOP* M022-* A2T*
		Eyelets	M005B* M006B* OM-0*
		Lingual Buttons	M021B-*
		Lingual Cleats	M015B-* WLC*
		Surgical & Arch Hooks	SURHK* M024-* A2H*
14-457	Ligature wires assist in creating the forces necessary to move teeth during orthodontic treatment.	Ligature Wires	Basic UDI-DI: 0190886LigatureWiresWK
		Bulk Ligature Wire	SBLW* GW* A1L*
		Kobayashi Ties	KH01* SKH* GWKH* GWSKH* A1LK*
			L08* L09* OMLK*
		Preformed Ligatures	LT* SLT* GWL* GWS* A1LM*
			L62*

16-190	Orthodontic elastics are used	Elastic Chain, Orthodontic	Basic UDI-DI: 0190886ElasticChainBM
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	<i>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.</i>	<i>Chain Elastic</i>	CDL* GWS*	LDL* ECD*	SDL* ECF*	GWC* L81*	GWL*
		<i>PowerLinx Chain Elastic</i>	LPL*	SPL*	GWL*	ECE*	
	<i>Orthodontic elastics are used in orthodontic treatment to exert a force.</i>	Elastic Bands, Orthodontic	Basic UDI-DI: 0190886ElasticBandsBM				
		<i>Enchanted Intraoral Elastics</i>	14HV*	14LT*	14MD*	14XH*	18HV*
			18LT*	18MD*	36HV*	36LT*	36MD*
			36XH*	38HV*	38LT*	38MD*	56HV*
			56LT*	56MD*	56XH*		
		<i>Extreme Intraoral Elastics</i>	M931*				
		<i>Doctor Intraoral Elastics</i>	OC14*	OC18*	OC36*	OC38*	OC56*
		<i>Bulk Intraoral Elastics</i>	AC**B	AM**B			
		<i>Custom Elastics</i>	LANOD*	L81*	03-0*		
		<i>Extraoral Elastics</i>	AXH*	AX0*	GWAX*	EEIL*	
	<i>Ligature ties are intended to be placed around the tie wings on the bracket to retain the archwire in the bracket slot.</i>	Elastic Ligature Tie, Orthodontic	Basic UDI-DI: 0190886LigatureTiesVN				
		<i>Versa-Tie Patient Ties</i>	VT*	GWVT*	L81*		
		<i>Bambino Patient Ties</i>	BT*	ELB*			
		<i>Mini Patient Ties</i>	OCM*	GWOCM*			
		<i>Select Patient Ties</i>	OCS*				
		<i>Designer Patient Ties</i>	DTIE-*	DTIEK*	DTKEY*		
		<i>Caned Patient Ties</i>	CCL*	CGY*	GWC*		
		<i>Bulk Patient Ties</i>	BCL*	BGY*			
	<i>Elastomeric threads, hollow, solid and slip-not are used to tie appliances and auxiliaries into place.</i>	Elastic Thread, Orthodontic	Basic UDI-DI: 0190886ThreadMJ				
		<i>Elastomeric Thread</i>	TBCL*	TBGY*	ETC*	ETGY*	SNT*
			ET*	GW4*	GWS*		
18-082	<i>Elastomeric separators are placed between</i>	Separators, Orthodontic	Basic UDI-DI: 0190886SeparatorsX2				
			325-*	500-*	GW3*	GW5*	ESM*



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	<i>adjacent teeth to assist in creating space between them.</i>	<i>Elastomeric Separators</i>	OM*				
16-198	<i>Orthodontic bands provide a base to affix weldable attachments such as buccal tubes, sheaths, cleats and lugs.</i>	Orthodontic Bands	Basic UDI-DI: 0190886MolarBandsFU				
		<i>Titan Molar Bands</i>	B10*	B11*	K10*	K11*	
		<i>Saturn Molar Bands</i>	B12*	B13*	K12*	K13*	
16-199	<i>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.</i>	Orthodontic Tubes	Basic UDI-DI: 0190886MetalTubesKR				
		<i>Agility Buccal Tubes</i>	AC1*	AC*	AL1*	AS1*	
		<i>Viper Buccal Tubes</i>	CC3*	CS3*	NS3*	NS4*	GWNS*
		<i>Magnum Buccal Tubes</i>	CC*	CC1*	CD1*	CL1*	CS1*
			CT1*	NC1*	NRD1*	NRT1*	NS1*
			NS2*	GWNR*			
		<i>MiniPrevail Buccal Tubes</i>	NS6*	NS7*			
		<i>Lingual Sheaths</i>	M040-*				
		<i>V-Tubes</i>	V-T*	A2HV*			
		<i>Tubes-Misc</i>	045-*	140*			
		<i>Custom Tubes</i>	HODI*	INSBBP*	INSBBSP*	NS2BBP*	CSBBP*
			CSBBSP*	INSBW*	CSBWF*	CDBBL*	CDBWF*
			CTBWF*	BBTN*			
16-204	<i>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.</i>	Orthodontic Wires					
		Type 2 Wire	Basic UDI-DI: 0190886Type2Orthowires43				
		<i>Nickel Titanium Archwires</i>	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*	
		<i>Thermal Nickel Thermal Archwires</i>	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*
		<i>Nickel Titanium Reverse Curve</i>	G4RC*	RC1*	RCD*	SER*	RCS*
			A1NS*	A1NP*	L05*	OMR*	
		<i>Thermal Nickel Titanium Reverse Curve</i>	CURC*	M5RC*	TRC*	GWT*	A1CN*
			OML*				
		<i>Spools & Straight Lengths</i>	SENT*	SESP*	GWSE*	A1NS*	
		<i>Archwire Kits</i>	PP*				
		Type 1 Wire	Basic UDI-DI: 0190886Type1Orthowires34				



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		<i>Australian Archwire</i>	AWSF*	AWTF*			
		<i>Stainless Steel Archwires</i>	S3BF*	S3DYB*	S3EF*	S3L*	S3SF*
			S3TF*	SSBF*	SSEF*	SSL*	SSSF*
			SSTF*	XRBF*	XREF*	XRSF*	XRTF*
			SD*	GWS*	A1A*	L05*	L06*
			L09*	L62*	OMT*		
		<i>Stranded (Archwires, Spooled, & Straight Lengths)</i>	CSF*	CTF*	MS3*	MS6*	MS7*
			MS8*	SST3*	SST6*	SST7*	GWC*
			GWM*	GWSS*	A1AT*	L06*	L07*
			L08*				
		<i>Retraction Archwires (Looped)</i>	KHTF*	TLTF*	031*	032*	033*
			GWKH*	GWTL*	A1AL*	L07*	L95*
		<i>Posted Archwires</i>	PSEF*	PSTF*	PXB*	GWP*	A1AP*
			A1AB*	OMT*			
		<i>Straight Lengths</i>	STSS*	GWST*	A1AC*	L07*	OMT*
		<i>Soft Wire</i>	SSSOF*				
		<i>Brass Wire</i>	STBR*	GWS*			
		<i>Colboloy Archwires & Straight Lengths</i>	CBBF*	CBTF*	STRCB*	GWC*	GWSTR*
			A1CL*	L11*	L30*	OMO*	
		<i>TitanMoly Archwires</i>	B3BF3*	B3DYB*	B3EF*	B3L*	B3M*
			B3SF*	B3SL*	B3TF*	B3X*	TMBF*
			TMEF*	TML*	TMML*	TMSF*	TMSL*
			TMTF*	TMXL*	GWTM*	A1BT*	
		<i>Retraction Arches (Loops)</i>	B3TL*	TMTL*	GWTMTL*		
		<i>Straight Lengths</i>	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				
		<i>Agility Ceramic Brackets</i>	125*	126*			
		<i>Vapor Ceramic Brackets</i>	GW7*	BNU*	OHC*		
		Stainless Steel Brackets	Basic UDI-DI: 0190886MetalBrackets7C				
		<i>Marquis Brackets</i>	10*	11*	12*		
		<i>Agility Brackets</i>	14*	15*	127*	128*	
		<i>Comfort Zone Brackets</i>	16*	17*	18*	26*	28*
		<i>Magnum Brackets</i>	30*	31*	33*	34*	GW3*
		<i>Cannon Brackets</i>	84*	85*	86*	87*	
		<i>MiniPrevail</i>	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				
		<i>Closed Coil Nickel Titanium Springs</i>	CCNT*	CCOF*	CCOT*	KTCCOF*	KTCCOT*
			GWC*	A2N*	L08*	L11*	L12*
		<i>Molar Distalizing Nickel Titanium Springs</i>	OCNT2*	OCNT7*	GWO*	A2N*	L08*
			OMC*				
			OCNT0*	OCNT1*	GWO*	A2NA*	L08*



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		<i>Open Coil Nickel Titanium Springs</i>	OMCD*
		<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*

Signed in Franklin 2024-February-06 on behalf of G&H Wire Company, Inc.

John Browder

Director, RA/QA

Person Responsible for Regulatory Compliance