

Doc. No. - DOC004	Revision: 0	Effective Date: February 6, 2024	DCR: 24-016
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Single Registration Number

US-MF-000013090

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 768187 R000

European Authorized Representative

SRN:	NL-AR-000022839
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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: 0195291AuxiliariesA9
		Ball Clasps	SSBC* 122*
		Crimpable Stops	CSTOP* M022-* OP-MICRO* ACC.CSR* LBO CST*
			SCC* OFCST* 1172* VWCSTO* 762*
		Eyelets	M005B* M006B* ES00* LBE* BBU*
			OFBE* VWM0* 762*
		Lingual Buttons	M021B-* ES00* LBO LIN* LBM* BBR*
			OFBM* VWM0* 60XM* 762*
		Lingual Cleats	M015B-* WLC* BBU* CBS*
14-457	Ligature wires assist in creating the forces necessary to move teeth during orthodontic treatment.	Surgical & Arch Hooks	Basic UDI-DI: 0195291LigatureWiresQL
			SURHK M024-* OP-GA* ES00* ACC.S*
			LBO SU* SHO* OFS* VWS* 762*
		Ligature Wires	Basic UDI-DI: 0195291LigatureWiresQL
		Bulk Ligature Wire	SBLW* OP-LE* ES00* LBO* OFS*
			762* 122*
		Kobayashi Ties	KH01* SKH* OP-LE* ES00* LIG.K*
			LBO* KL0* SKL0* OFK* OFSK*
			VWK* 312-* 60XS* 762* 122*
	Performed Ligature	LT*	SLT* OP-L* 2050* ES00*
		LIG.*	LBO* PFL* OF* VWL*
		60XS*	GH02* 762* LP02* 121*

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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: 0195291ElasticChain62
		Chain Elastic	CDL* LDL* SDL* 205* DL5*
			ES00* CHAIN* LBO* ST* SC*
			SDC* PC* VW* 60X* 762*
			OD-C* SL* AU* LIG* STS*
			SS* 88-* 89-* 340*
		PowerLinx Chain Elastic	LPL* SPL* CHAIN* LBO CH* PTL*
			VWL* PTS* CH* VWS*
	Orthodontic elastics are used in orthodontic treatment to exert a force.	Elastic Bands, Orthodontic	Basic UDI-DI: 0195291ElasticBands62
		Bulk Intraoral Elastics	AC**B AM**B
		Intraoral Elastics	ACH* ACM* AML* AMD* AMH*
			AMX* ELAST* 340*
		Custom Elastics	205* 463* DL5* ELAST* ET*
			EH* G7* ES0* LBO* FB*
			60XA* 85-*
		Extraoral Elastics	AXH* AX0* OP-EX* ES00* ELA*
			1000* VWAX*
11-394	Orthodontic elastics are used in orthodontic treatment to exert a force.	Non-Latex Elastic Bands	
		Intraoral Elastics	LFH* LFM* ELA* 60XL* GH0*
			762-2* DL5* 205* UNL* FB*
			85-*
16-190	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: 0195291LigatureTiesQ3
		Versa-Tie Patient Ties	VT* OD-L* 205* DL5* ES00*
			61* LBO EL* LT* VWV* M920*
			60XV* 762-2* 87-*
		Bambino Patient Ties	BT* KT* VWB* 762-2*
		Mini Patient Ties	OCM* 611G* VWOC*
		Select Patient Ties	OCS* 610* 61S* 61P* LBO EL*
		S-Ties	ST*
		Caned Patient Ties	CCL* CGY* T0* VWOC*
		Bulk Patient Ties	BCL* BGY* OP-LEG* LIG.C* 60XC*
	Elastomeric threads, hollow, solid and slip-not are used to tie appliances and auxiliaries into place.	Elastic Thread, Orthodontic	Basic UDI-DI: 0195291ThreadKP
		Elastomeric Thread	TBCL* TBGY* ETC* ETGY* SNT*
			OP* 205* 104* VWS* PT*
			LBO* 89-*

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18-082	<i>Elastomeric separators are placed between adjacent teeth to assist in creating space between them.</i>	Separators, Orthodontic	Basic UDI-DI: 0195291SeparatorsSD				
		<i>Elastomeric Separators</i>	325-*	500-*	AU-5*	LBO EL*	SEP*
			LBO S*	SH5*	SR5*	VW5*	762-2*
			89-*				
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: 0195291MolarBandsB7				
		<i>Titan Molar Bands</i>	B10*	B11*	K10*	K11*	OD-B*
			MB6*	MB7*	MK6*	MK7*	
		<i>Saturn Molar Bands</i>	B12*	B13*	K12*	K13*	OD-B*
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: 0195291MetalTubesF4				
		<i>Agility Buccal Tubes</i>	AC1*	AC*	AL1*	AS1*	
		<i>Viper Buccal Tubes</i>	CC3*	CS3*	NS3*	NS4*	OBT*
			CBT*	WCVB*	BCVB*	OF3B*	OD-T*
			714*	TUB*	LBO M*	OBT*	WBT*
			BBT*	VWN*	OF4B*	GH NS*	40-*
		<i>Magnum Buccal Tubes</i>	CC*	CC1*	CD1*	CL1*	CS1*
			CT1*	NC1*	NRD1*	NRT1*	NS1*
			NS2*	900-*	OD-T*	WBT*	BBT*
			TUB*				
		<i>miniPrevail Buccal Tubes</i>	NS6*	NS7*			
		<i>Lingual Sheaths</i>	M040-*	OD-L*	OP-L*	WB*	
		<i>V-Tubes</i>	V-T*				
		<i>Tubes – Misc</i>	045-*	140*	40-*	HS1*	
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: 0195291Type2OrthowiresUK				
		<i>Nickel Titanium Archwires</i>	PTEF*	PTTF*	SEBF*	SEEF*	SEL*
			SEML*	SEMOM*	SEOF*	SESF*	SESL*
			SESM*	SETF*	SEXL*	ARC*	PTN*
			OFPT*	762*	GH0*	OP*	ES00*
			LBO*	GHP*	OFSE*	OF-SE*	VWBF*
			60X*	AI0*	OA02*	SE*	NTE*
			083*	089*	VWS*	VWT*	VNT*
			204*	NTT*	091*	W83*	111*
		<i>Heat-Activated/ Thermal Nickel Titanium Archwires</i>	CUBF*	CUEF*	CUL*	CUSF*	CUTF*
			TBF*	TEF*	TLG*	TLL*	TLM*
			TLS*	TLXS*	TS*	TTF*	ES0*
			CUN*	762*	CNT*	VWCU*	60X*
			OP-TE*	OFHA*	OF-T*	VWT*	ARC*
			082*	084*	LBO*	040*	112*
		<i>Nickel Titanium Reverse Curve</i>	RC1*	RCD*	SER*	ARC*	60X*
			762*	AI0*	ES0*	ETR*	GH*
			LBO*	NR*	OFSE*	OP*	VWS*
		<i>Heat-Activated/ Thermal Nickel</i>	CURC*	TRC*	OP*	083*	762*

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		Titanium Reverse Curve					
		Spools & Straight Lengths	SENT*	SESP*	OP*	60X*	FEL*
			VWS*	762*	GH*	FIL*	111*
			112*				
		Archwire Kits	PP*				
		Type 1 Wire	Basic UDI-DI: 0195291Type1OrthowiresTL				
		Stainless Steel Archwires	SSBF*	SSEF*	SSL*	SSSF*	SSTF*
			762*	OF-S*	OF*	OP*	VWS*
			3U*	60X*	ARC*	ES0*	LBO*
			SS*	204*	W83*	122*	123*
			78-*				
		Stranded (Archwires, Spooled, & Straight Lengths)	CSF*	CTF*	MS3*	MS6*	MS7*
			MS8*	SST3*	SST6*	SST7*	OP*
			ARC*	081*	762*	ES0*	SSF*
			VW*	FIL*	3IS*	TSS*	OFS*
		Retraction Arches (Looped)	KHTF*	TLTF*	090*	60X*	762*
			ES0*	OP*	VWK*	ARC*	78-*
		Posted Archwires	PSEF*	PSTF*	PXB*	762*	ARC*
			OF*	OP*	SSP*	VWP*	090*
			60X*	ES0*	LBO*	78-*	
		Straight Lengths	STSS*	31S*	762*	ES0*	OF*
			OP*	VWS*	122*	127*	
		Soft Wire	SSSOF*				
		Brass Wire	STBR*				
		Colboloy Archwires & Straight Lengths	CBBF*	CBTF*	STRCB*	ARC*	089*
			891*	ES0*	NCB*	OP*	VWS*
		TitanMoly Archwires	TMBF*	TMEF*	TML*	TMML*	TMSF*
			TMSL*	TMTF*	TMXL*	OF*	762*
			ARC*	OP*	VWT*	204*	60X*
			BTA*	ES0*	LBO*	B3DYB*	130*
		Retraction Arches (Loops)	TMTL*	086*	OP*	ARC*	762*
		Straight Lengths	STB3*	STTM*	OP*	FIL*	60X*
			762*	VWS*	130*		
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: 0195291CeramicBracketsXZ				
		Agility Ceramic Brackets	125*	126*	A1*	BRA*	LBO*
			VW7*	A2*			
		Ceramic Brackets	97*	99*			
		Stainless Steel Brackets	Basic UDI-DI: 0195291MetalBracketsZA				
		Agility Brackets	14*	15*	127*	128*	B1*
			LBO*	B5*	OD*	B6*	
		Comfort Zone Brackets	16*	17*	18*	26*	28*
			B2*	OD*	B4*		
		Magnum Brackets	30*	31*	33*	34*	B7*
			OD*				
		MiniPrevail Brackets	36*	37*	38*	39*	120*
			121*	LBO*	B3*	B4*	SLB*

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		<i>Metal Brackets</i>	98*	100*	101*	102*	150*
33-907	<i>Springs are intended to open or close a space between teeth or to prevent molar tipping.</i>	<i>Orthodontic Springs</i>					
		<i>Nickel Titanium Springs</i>	<i>Basic UDI-DI: 0195291NiTiSpringsJN</i>				
		<i>Closed Coil Nickel Titanium Springs</i>	CCNT*	OP*	ES0*	220*	VWS*
			60X*	762*	AI0*	CCOT*	CCOF*
			111*				
		<i>Molar Distalizing Nickel Titanium Springs</i>	OCNT2*	OCNT7*	OP*	RESS*	NTD*
			VWO*	60X*	GH0*		
		<i>Open Coil Nickel Titanium Springs</i>	OCNT0*	OCNT1*	OP*	OF*	VWS*
			762*	3SN*	60X*	AI0*	ES0*
			RESS*	LBO*	NTO*	VWO*	
		<i>Stainless Steel Springs</i>	<i>Basic UDI-DI: 0195291SSSprings4U</i>				
		<i>Closed Coil Stainless Steel Springs</i>	SSCC*	OP*	OF*	117*	VWS*
			762*				
		<i>Open Coil Stainless Steel Springs</i>	SSO*	OP*	OF*	117*	VWS*

Signed in Franklin 2024-February-06 on behalf of Flexmedics



John Browder

Director, RA/QA

Person Responsible for Regulatory Compliance