

G&H® Wire Company  
 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	
Self-Certified	
Conformity Assessment	
Applicable Council	93/42/EEC
Directive.....	(as amended by 2007/47/EC)
Classification.....	Class I (Rule 5, Annex IX)
Route to Compliance.	Annex VII
Standards Applied.....	EN ISO 13485:2016 / ISO 13485:2016
	Certificate #: MD 635659
European Authorized Representative	
mdi Europa GmbH	
Langenhagen Str. 71 30855 Langenhagen	
Germany	

## DECLARATION OF CONFORMITY

### Class I Products

UMDNS Code	Product Family/Description	Part number Prefix (Part Number begins with...)				
13-370	<b>Orthodontic Retainers</b>					
	Tooth Positioners	PFTP*				
13-380	<b>Dental Retractors</b>					
	Check Retractors	BPR-* M987-*	CH* M993-*	CR* M995-*	EX-9* M996-*	M986-* M997-*
	Photo Retractors	TLC*	PCKE-*			
	Lip Retractors	LR*	M984-*	M985-*		
	Bite Blocks	TBU*				
	Tongue Blocks	TB-*				
16-189	<b>Dental Wax</b>					
	Bite Wax	BWX*				
	Brace Guard/Silicone	79*				
	Patient Wax/Flavor Wax	M200-*	M201-*	PWX*	WB*	
	Utility Wax	UWX*	700-*			
	Bite Therapy Wafer	EB-*	M350-*			
16-191	<b>Extraoral Headgear</b>					
	Facemasks	M54*	PFM*	RPFM*		
	Highpull Headcaps	HPL*	HPS*	SOF*		
	Neckpads	CP*				
	Safety Modules	SRD*	SRB*			
16-192	<b>Facebows</b>					
	Stainless Steel Coated	CCFB*	M500-*			
	Stainless Steel Non-Coated	STFB*				
16-201	<b>Dental Polishing Strips</b>					
	Diamond Disks	DISC*	129*	183*	314*	699*
		710*	790*	913*	101*	303*
		406*	700*			
	Burs	5500*	9630*	916*	917*	927*
1201*		1202*	1300*	R133*	R368*	
R379*		R909*	780*	G/*		
Lightning Strip Abrasive	LSDS*	LSSS*	620*	630*	635*	
16-223	<b>Positioning Aids</b>					
	Gauges/Placers	BRKTP*	BRPL*	KBTP*	SSBR*	ISP-05*
	Rulers	CCOF*	CCOT*	OP*	RULER*	
	Zand Gauges	ZDG*				
	Arch Evaluator Templates	AE*	AET*	GH*		

G&H Wire Company Declaration of Conformity, Class I, *continued*

UMDNS Code	Product Family/Description	Part number Prefix (Part Number begins with...)					
16-350	<b>Impression Trays</b>						
	Disposable Trays	DIT*	GIT*				
	Stainless Steel	TRAY*					
16-370	<b>Dental Matrix Band Wedge</b>						
	NEET Separating Springs	M125-*	M126-*	M130*	NEET*		
	Elastomeric Separators	M926-*	M927-*	ROSP10*	SEP0*	500-*	
16-664	<b>Orthodontic Hand Instruments</b>						
	Applicator Brushes	BND*	BDB*	BB2*	BT2*		
	Hand Instruments	BSEAT*	BSHH*	DEDEB*	EPT*	EXPKY*	
		INTPR*	IRT-*	ISP-*	LIGDIR*	MBP*	
		PL*	THS*	TS-1*	TWEEZ*	TWIRL*	
		080	097	0161	0158-*	018*	
		097-*	601-*	PRH*	PRS*	077-*	
	Mixing Spatulas	S*	030*				
	Wax Marking Pencils	AMP0*					
	Mini Mold Products	MMAS*	MMB*	MMH*	MMM*	MMT*	
		MMW*	MMC*	MML*	MMP*	MMU*	
	Mirrors	PRMR*	SSMR*	011-*	QM5*	07-4*	
		200M*					
	Mirror Handles	SGP*	SGS*	SGH*	SG*		
	Paragon Instruments	IPL1-*					
	Armada Instruments	IPL2-*					
Excelsior Instruments	IPL-*						
Pliers and Cutters	GH0*	MNH*	MOSQ*	ODG*	SEPP*		
	018*	026*	034	044	052		
	012-*	016-*	020-*				
16-680	<b>Dental Impression Materials, Other</b>						
	Alginate Flavorings	ALFL*					
17-595	<b>Protectors, Teeth</b>						
	Lip Protectors	M410-*					
	Mouthguards	5800*	MGS-*	5810*	MG-*	SMG*	
	Patient Care Kits	M340-*					

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.

Signed this 23<sup>rd</sup> day of December, 2019  
by

  
 Nichole Leahy-Glass, Global Regulatory Affairs Manager

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(g) of Directive 98/79/EC.

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