



Orthodontic Design and Production

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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.....	ISO 13485:2016
	Certificate #: FM 659830
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	Orthodontic Retainers					
	Tooth Positioners	PFTP*				
13-380	Dental Retractors					
	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*				
16-189	Dental Wax					
	Bite Wax	BWX*				
	Brace Guard/Silicone	79*				
	Patient Wax/Flavor Wax	M200-*	M201-*	PWX*	WB*	
	Utility Wax	UWX*	700-*			
16-191	Extraoral Headgear					
	Facemasks	M545-*	M540-*	PFM*	RPFM*	
	Highpull Headcaps	HPL*	HPS*	SOF*		
	Neckpads	CP*				
16-192	Facebows					
	Stainless Steel Coated	CCFB*	M500-*			
	Stainless Steel Non-Coated	STFB*				
16-201	Dental Polishing Strips					
	Diamond Disks	DISC*	129*	183*	314*	699*
			710*	790*	913*	
	Burs	5500*	9630*	916*	917*	927*
		1201*	1202*	1300*	R133*	R368*
R379*		R909*				
Lightning Strip Abrasive	LSDS*	LSSS*	620-*	630-*		
16-223	Positioning Aids					
	Gauges/Placers	BRKTP*	BRPL*	KBTP*	SSBR*	ISP-05*
	Rulers	CCOF*	CCOT*	OP*	RULER*	
	Zand Gauges	ZDG*				
16-350	Arch Evaluator Templates	AE*	AET*	GH*		
	Impression Trays					
	Disposable Trays	DIT*	GIT*	S310-*		
	Stainless Steel	TRAY*				

G&H Orthodontics Declaration of Conformity, Class I *continued*

UMDNS Code	Product Family/Description	Part number Prefix (Part Number begins with...)				
16-370	Dental Matrix Band Wedge					
	NEET Separating Springs	M125-*	M126-*	M130*	NEET*	
	Elastomeric Separators	M926-*	M927-*	ROSP10*	SEP0*	500-*
		325-*				
16-664	Orthodontic Hand Instruments					
	Applicator Brushes	BND*	BDB*	BB2*	BT2*	
	Hand Instruments	BSEAT*	BSHH*	DEDEB*	EPT*	EXPKY*
		INTPR*	IRT-*	ISP-*	LIGDIR*	MBP*
		PLA*	THS*	TS-1*	TWEEZ*	TWIRL*
	Mixing Spatulas	S*	030*			
	Wax Marking Pencils	AMP0*				
	Mini Mold Products	MMAS*	MMB*	MMH*	MMM*	MMT*
		MMW*				
	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*	
16-680	Dental Impression Materials, Other					
	Alginate Flavorings	ALFL*				
17-595	Protectors, Teeth					
	Lip Protectors	LPCL*	M410-*			
	Mouthguards	5800*	MGS-*			
	Patient Care Kits	M340-*				

We, Orthodontic Design and Production (ODP) 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 23rd day of September, 2018 by



Eveline Carr, Regulatory Manager

This document expires 5 years from the above date.

We hereby appoint mdi Europa GmbH, Langenhagener Str. 79, 30855 Langenhagen in Germany to act as European Authorized Representative, as explicitly stated in Article 1, §2(g) of Directive 93/42/EC.

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