

**Ortho Club**

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**Registration Information**

Self Certified under Annex VII

**Conformity Assessment**

Device Classification Class I  
 Route to Compliance Annex VII

**Authorized Representative**

mdi Europa GmbH  
 Langenhagen Str. 71 30855 Langenhagen  
 Germany

**DECLARATION OF CONFORMITY**

**Class I Products**

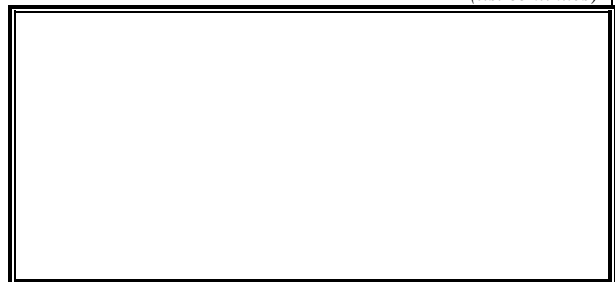
UMDNS Code	Product Family/Description	Part number Prefix (Part Number begins with...)				
13-370	<b>Orthodontic Retainers</b> Tooth Positioners	PFTP*				
13-380	<b>Dental Retractors</b> Check Retractors	BPR-*	CH*	CR*	EX-9*	M986-*
	Photo Retractors	M987-*	M993-*	M995-*	M996-*	M997-*
	Lip Retractors	M998-*	PCKE-*	TLC*		
16-189	<b>Dental Wax</b> Bite Wax	LR*	M984-*	M985-*		
	Brace Guard/Silicone	BWX*				
	Patient Wax	79*	SMB*	700*		
	Utility Wax	M200-*	M201-*	PWX*	WB*	
16-191	<b>Extraoral Headgear</b> Facemasks	UWX*	700-*			
	Highpull Headcaps	M545-*	M540-*	PFM*	RPFM*	
	Neckpads	HPL*	HPS*	SOF*		
	Safety Modules	CP*				
16-192	<b>Facebows</b> Stainless Steel Coated	M525-*	SRD*	SRB*		
	Stainless Steel Non-Coated	CCFB*	M500-*			
16-201	<b>Dental Polishing Strips</b> Diamond Disks	STFB*				
		DISC*	129*	120*	314*	180*
		183*	314*	699*	710*	790*
		915*	913*			
	Burs	5500*	9630*	916*	917*	927*
		1201*	1202*	1300*	R133*	R368*
	Lightning Strips	R379*	R909*			
		LSDS*	LSSS*	620-*	630-*	5VM*
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*			

(list continues)

\_\_\_\_\_  
Name/Title

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date



Ortho Club 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*	S310-*		
	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-*
		325-*				
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*
		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	07-*	SGP*	SGS*	SGH*	SP*
	Paragon Instruments	IPL1-*				
	Armada Instruments	IPL2-*				
	Excelsior Instruments	IPL-*				
	Pliers and Cutters	GH0*	MNH*	MOSQ*	ODG*	SEPP*
		VBND*	969*			
16-680	<b>Dental Impression Materials, Other</b>					
	Alginate Flavorings	ALFL*				
17-595	<b>Protectors, Teeth</b>					
	Lip Protectors	LPCL*	M410-*			
	Mouthguards	240-*	5800*	MGS-*		

We, Ortho Club 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 7th day of December, 2015, by Bridget Robertson  
 Bridget Robertson, Regulatory Compliance Administrator

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 98/79/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

\_\_\_\_\_  
 Name/Title

\_\_\_\_\_  
 Signature

\_\_\_\_\_  
 Date

