

FlexMedics

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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	Orthodontic Retainers					
	Tooth Positioners	PFTP*				
13-380	Dental Retractors					
	Check Retractors	BPR-*	CH*	CR*	EX-9*	M986-*
		M987-*	M993-*	M995-*	M996-*	M997-*
	Photo Retractors	M998-*	PCKE-*	TLC*		
	Lip Retractors	LR*	M984-*	M985-*		
Tongue Blocks	TBU-*					
16-189	Dental Wax					
	Bite Wax	BWX*				
	Brace Guard/Silicone	MK80*	SMB*	700*		
	Patient 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*				
	Safety Modules	M525-*	SRD*	SRB*		
16-192	Facebows					
	Stainless Steel Coated	CCFB*	M500-*			
	Stainless Steel Non-Coated	STFB*				
16-201	Dental Polishing Strips					
	Diamond Disks	DISC*	129*	120*	314*	180*
		183*	314*	699*	710*	790*
		915*	913*			
	Burs	5500*	9630*	916*	917*	927*
		1201*	1202*	1300*	R133*	R368*
		R379*	R909*			
Lightning Strips	LSDS*	LSSS*	620-*	630-*	5VM*	
16-223	Positioning Aids					
	Gauges/Placers	BRKTP*	BRPL*	KBTP*	SSBR*	ISP-05*
	Rulers	CCOF*	CCOT*	OP*	RULER*	
	Zand Gauges	ZDG*				
	Arch Evaluator Templates	AE*	AET*			
16-350	Impression Trays					
	Disposable Trays	DIT*	GIT*	S310-*		
	Stainless Steel	TRAY*				
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					

FlexMedics Declaration of Conformity, Class I, continued

UMDNS Code	Product Family/Description	Part number Prefix (Part Number begins with...)				
	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	Dental Impression Materials, Other					
	Alginate Flavorings	ALFL*				
17-595	Protectors, Teeth					
	Lip Protectors	LPCL*	M410-*			
	Mouthguards	240-*	5800*	MGS-*		

We, FlexMedics 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 1st day of December, 2017, by 
 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