



Reliance Orthodontic Products, Inc.

Toll Free 1-800-323-4348 · Phone 630-773-4009 · Fax 630-250-7704
1540 West Thorndale Ave. · Itasca, IL · 60143 · U.S.A.

DECLARATION OF CONFORMITY Class I Self-Certified Products

Product Identification		
Product Name	Catalogue Number(s)	Rule
UV Disclosing Light	UVML	1
Microbrush	MB, MBSF	5
Faciforms	FFL, FFR	5
Stick N Place Instruments	SNP16	5
Disposable Benda Brushes	BB250, BT250, BB50	5
Brush Handle	BH	1
Sponge Pellets	SP	5
Mixing Well	1MXW, 1SEPW	1
Mixing Pad	1PADS	1
Spatula	S	1
Scoops	1SCOOP	1
Restore Polishing Paste	RESPP2	5
1 st and Final Pumice	FF	5
Access Cheek Retractor	CH1, CH2	5
Power Slot Light Guide	LEDPS	5
Mark II CR Syringe	CRII	1
A2 Aligner Attachment Molds	AO, AR, ABUT	5
CC Chain and Molds	CCO, CCP, DCCO, DCCP	5
Syringe Assist	FTWING	1
Tips	SMT, LLTIPS60, LLTIPS, TIPS5, 19TIPS10, 22TIPS10, 22TIPS50, A2TIP	5
Etchmaster	EMHA, EMHAR, EMGAS, EMTLL, EMTRS, EMTLS, EMTRL, EMTLS50, EMTRS50	5
Accessory Pack	PASACC	5
Applicators	WA	1

Manufacturer		
Name of Company	Address	Representative
Reliance Orthodontic Products, Inc	1540 West Thorndale Avenue Itasca, Il 60143	Paula Wendland, Regulatory Affairs Manager



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Australian Sponsor		
Name of Company	Address	Telephone/Email
Emergo Europe	Prinsessegracht 20 2514 AP The Hague, The Netherlands	+31.70.345.8570 – phone +31.71.346.7299

Conformity Assessment		
Device Classification	Route to Compliance	Standards Applied
Class I Rules 1 and 5	Annex VII of the Medical Devices Directive 93/42/EEC as amended by Medical Device Directive 2007/47/EEC	ISO13485 ISO14971 EN ISO 15223 EN 1041 ISO 1641 IEC 62366

Reliance Orthodontic Products, Inc. declares that the below mentioned products meet the provision of the Council Directive 93/42/EEC as amended by Medical Device Directive 2007/47/EEC for Medical Devices. All supporting documentation is retained at the premises of the manufacturer.

Company Representative: Paula Wendland

Title: Regulatory Affairs Manager

Signature:

Date:

4.25.18