



DECLARATION OF CONFORMITY

Applicable Council Directive 93/42/EEC (as amended by 2007/47/EC)

Conformity Assessment Procedures Annex V per Article 11.2

Classification Class IIa per Annex IX, Rule 5

Product Name Orthodontic Adhesive Products

GMDN Code 31750, 35870

Catalog Numbers See Attached List of Devices

Manufacturer Name and Address Lancer Orthodontics, Inc.
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This product is marked with the CE Marking and Notified Body Number (0086) according to the specified Council Directive.

Certificate Number CE 02013

Date CE Certificate First Issued 16 July, 1998

Date of Expiry 15 July, 2018

The undersigned hereby declares, on behalf of Lancer Orthodontics, Inc. of Vista, California USA, that the above-referenced product, to which this declaration relates, is in conformity with the provisions of Council Directive 93/42/EEC (as amended).

Regulatory Affairs Manager

July 13, 2017

Date



List of Devices Covered Class IIa Orthodontic Adhesives

Catalog Number	Product Description	GMDN Code
810-111	LIGHT ACTIVATED ADHESIVE	31750
810-211	PORCELAIN CONDITIONER	35870
810-313	ETCHING GEL-12g SYRINGE	35870
810-314	TIPS-ETCHING GEL 25/PK	35870
810-502	ADHESIVE-FORMULA 2 PUSH	31750
810-503	ADHESIVE-FORMULA 3 PATIE	31750
810-510	ADHESIVE-FORMULA 10 LIGH	31750
810-522	PASTE-FORMULA 1 14g JAR	31750
810-523	PASTE-FORMULA 2 3.5g SYR	31750
810-524	PASTE-FORMULA 3 .35g TIP	31750
810-525	PASTE-FORMULA 10 .35g TI	31750
810-526	RESIN-FORMULA 10 7cc 2/	35870
810-527	PRIMER-FORMULA SERIES 16	35870
810-528	ETCH-FORMULA SERIES LIQU	35870
810-529	ETCH-FORMULA SERIES GEL	35870
810-F11	FORMULA 11-LIGHT ACTIVAT	31750
810-F14	FORMULA 14-DUAL MIX BAND	31750
811-002	RELY A BOND NO MIX	31750
811-005	RELY A BOND PASTE-SYRING	31750
811-007	RELY A BOND PRIMER 16cc	35870
811-008	RELIANCE LIGHT BOND	31750
811-009	REL-LIGHT BOND SEALANT	35870
811-010	REL-LIGHT CURED COMPOSIT	35870
811-011	REL-BAND CEMENT	31750
811-012	ASSURE BONDING RESIN	35870
811-014	RELIANCE METAL PRIMER (1	35870
811-015	RELIANCE MARK II CR SYRI	31750
811-016	RELIANCE QUICK CURE PAST	31750
811-017	REL-ETCHING GEL ECONOMY	35870
811-051	PHASE II SYRINGE KIT	35870
811-074	PHASE II DUAL CURE PASTE	31750
811-102	REL-LIGHT BOND PASTE SCR	31750
811-103	LIGHT BOND SYRINGE NO FL	31750
811-104	LIGHT BOND MED PASTE IN	31750
811-108	REL-LIGHT BOND SEALANT	35870
811-110	REL-LIGHT BOND ECONOMY	35870
811-130	ULTRA BAND-LOK SYRINGE	31750
811-132	ULTRA BAND LOK BLUE SYRI	31750
811-150	MAXIMUM CURE SEALANT A	35870



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Catalog Number	Product Description	GMDN Code
811-151	MAXIMUM CURE SEALANT B	35870
811-152	MAXIMUM CURE FILLED SEAL	35870
811-153	MAXIMUM CURE FILLED SEAL	35870
811-154	MAXIMUM CURE SEALANT A	35870
811-155	MAXIMUM CURE SEALANT B	35870
811-160	RELIANCE 1ST AND FINAL P	31750
811-161	LIGHT BOND SYRINGE W/FLU	31750
811-162	LIGHT BOND MED VISCOSITY	31750
811-163	LIGHT BOND TIPS W/FLUORI	31750
811-170	LIGHT CURE RETAINER SYRI	31750
811-172	LIGHT CURE RETAINER TIPS	31750
811-173	FLOW TAIN W/TIPS (1.5g)	31750
811-177	REL-ENHANCE ADHESION	31750
811-178	REL-ENHANCE ADHESION	31750
811-190	REL-PLASTIC CONDITIONER	35870
811-191	REL-PORCELAIN CONDITONE	35870
811-192	<u>REL-PORCELAIN ETCH 9GM</u>	35870
811-200	INTACT GLASS IONOMER CEM	31750
811-210	INTACT GLASS IONOMER CEM	31750
811-400	RELY A BOND NO MIX CARTR	31750
811-401	RELY A BOND PASTE-CARTRI	31750
811-403	ULTRA BAND-LOK BLUE SYRI	31750
811-404	ULTRA BAND-LOK NATURAL S	31750
811-405	ASSURE ADHESIVE KIT SCRE	31750
D11-2030	GC FUJI LC CAPSULES STAR	31750
D11-2032	GC FUJI LC CAPSULES REFI	31750
D11-2037	FUJI ORTHO-SELF CURE CEM	31750
D11-2038	GC FUJI ORTHO BAND PASTE	31750
D11-2039	GC FUJI ORTHO BAND PASTE	31750
D11-4357	FUJI ORTHO-SELF CURE CEM	31750
D11-7850	FUJI ORTHO-LITE CURE INT	31750
D11-9005	FUJI ORTHO-LC GLASS CEME	31750
D11-9110	FUJI ORTHO LIQ ONLY 8 6M	31750
D11-9338	FUJI ORTHO CONDITIONER	35870

***end of list