



DECLARATION OF CONFORMITY

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

Conformity Assessment ProceduresAnnex V per Article 11.2

Classification.....Class IIa per Annex IX, Rule 5

Product Name.....Orthodontic Adhesive Products

GMDN Code31750

Catalog NumbersSee 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 (2797) according to the specified Council Directive.

Certificate NumberCE 02013

Date CE Certificate First Issued..... 16 July 1998

Date of Expiry 15 July 2023

The undersigned hereby declares, on behalf of Lancer Orthodontics, Inc. of Carlsbad, 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

12 February 2020

Date



List of Devices Covered Class IIa Orthodontic Adhesives

Catalog Number	Product Description	GMDN Code
811-002	RELY A BOND NO MIXSYRINGE KIT	
811-005RM	RELY A BOND PASTE-SYRINGE	
811-007	RELY A BOND PRIMER 16cc	
811-008	RELIANCE LIGHT BOUNDRESIN	
811-010	REL-LIGHT CURED COMPOSITE	
811-012	ASSURE BONDING RESIN	
811-017RM	REL-ETCHING GEL ECONOMY	
811-108	REL-LIGHT BOND SEALANT FLUORIDE RELEASE 3CC	
811-110	REL-LIGHT BOND ECONOMY SEALANT 7CC	
811-161	LIGHT BOND SYRINGE W/FLUORIDE (5G)	
811-162	LIGHT BOND MED VISCOSITY SYRINGE W/FLUORIDE (5G)	
811-163	LIGHT BOND TIPS W/FLUORIDE (5g)	
811-172	LIGHT CURE RETAINER TIPS-REFILL (5G)	
811-177	REL-ENHANCE ADHESION BOOSTER A 6CC	
811-178	REL-ENHANCE ADHESION BOOSTER B 6CC	
811-191	REL-PORCELAIN CONDITIONER 8CC	
811-192	REL-PORCELAIN ETCH 9GM	
811-400	RELY A BOND NO MIX CARTRIDGE KIT	
811-401	RELY A BOND PASTE-CARTRIDGE 34/PK	
811-403	ULTRA BAND-LOK BLUE SYRINGE (5g)	
811-405	ASSURE ADHESIVE KIT SCREW SYRINGE W/FLUORIDE	
810-111	LIGHT ACTIVATED ADHESIVE SYRINGE 5gm	
810-141	DUAL MIX BAND CEMENT TIPS 25/PK	
810-211	PORCELAIN CONDITIONER LANCER	
810-313	ETCHING GEL-12g SYRINGE W/TIPS 1PK	
810-314	TIPS-ETCHING GEL 25/PK	
810-502	ADHESIVE-FORMULA 2 PUSH SYRINGE KIT	
810-510	ADHESIVE-FORMULA 10 LIGHT CURE KIT	
810-522	PASTE-FORMULA 1 14g JAR	
810-523	PASTE-FORMULA 2 3.5g SYRINGE 4/PK	
810-525	PASTE-FORMULA 10 .35g TIP 57/PK	
810-526	RESIN-FORMULA 10 7cc 2/PK	
810-527	PRIMER-FORMULA SERIES 16cc	
810-528	ETCH-FORMULA SERIES LIQUID 18g	
810-529	ETCH-FORMULA SERIES GEL 24g 1/PK	
810-F11	FORMULA 11-LIGHT ACTIVATED ADHESIVE KIT	
810-F14	FORMULA 14-DUAL MIX BAND CEMENT KIT	
D11-2039	GC FUJI ORTHO BAND PASTE REFILL	
D11-7850	FUJI ORTHO-LITE CURE INTRO	



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Catalog Number	Product Description	GMDN Code
D11-9005	FUJI ORTHO-LC GLASS CEMENT STANDARD	
D11-9338	FUJI ORTHO CONDITIONER ONLY 25GM	
19004-02	INTACT MIXING PADS	
19022-01	INTACT BOTTLE	
811-200	INTACT CEMENT 30G BOTTLE	
811-210	INTACT CEMENT 200G BOTTLE	
60011-01	INTACT BOX 30g	
D11-2032	GC FUJI LC CAPSULES REFILL PACKAGE	
D11-2033	GC FUJI CAPSULE APPLIER II	
D11-2040	GC PASTE DISPENSER	
D11-9110	FUJI ORTHO LIQ ONLY 8 6M	
D11-9662	FUJI ORTHO PWD ONLY 40 6M	

***end of list