

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

Catalog Numbers See Attached List of Devices

Manufacturer Name and Address Lancer Orthodontics, Inc.
Vista Technology Center
1493 Poinsettia Avenue, Suite 143
Vista, California 92081 USA

European Representative Kristal S.r.l.
Livorno (LI) Via Claudio
Cogorano 25 CAP 75123
Stradario 03530
Tel: +39 024453401
Fax: +39 0248408305
e-mail: info@kristalsrl.net

Notified Body BSI
Say Building
John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands

This product is marked with the CE Marking and Notified Body Number (2797) according to the specified Council Directive.

Certificate Number CE 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 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

28 March, 2019

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 | |



List of Devices Covered Class IIa Orthodontic Adhesives

| 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