



DECLARATION OF CONFORMITY

Applicable Council Directive 93/42/EEC (as amended)

Conformity Assessment Procedures Annex V per Article 11-2

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

Product Name Orthodontic Lingual Attachments

GMDN Codes See Attached List of Devices

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

November 9, 2017
Date



List of Devices Covered Class IIa Orthodontic Lingual Attachments

| Catalog Number | Product Description | GMDN Code |
|----------------|------------------------------------|-----------|
| 400-002 | RAM CLEAT-ANT CUS BI | 40734 |
| 400-003 | RAM CLEAT-MOLAR | 40734 |
| 400-005 | LINGUAL BUTTON-FLAT CUSPID/MOLAR | 40734 |
| 400-006 | LINGUAL BUTTON-CURVED BICUSP/MOLAR | 40734 |
| 400-010 | LUGS-ANT,CUS,BIC FLAT | 40734 |
| 400-011 | LUGS-MOLAR | 40734 |
| 400-014 | EYELET DIRECT BOND 10/PK | 40734 |
| 400-015 | EYELETS - CURL 10/PK | 40734 |
| 400-016 | EYELETS - CHAIN | 40734 |
| 400-017 | DB OPEN BITE 10/PK | 40734 |
| 400-201 | DB CUSPID/MOLAR LING BUTTON 10/PK | 40734 |
| 400-202 | DB BICUSPID LINGUAL BUTTON 10/PK | 40734 |
| 400-203 | DB CUS/MOLAR RAM CLEAT 10/PK | 40734 |
| 400-204 | DB BICUSPID RAM CLEAT 10/PK | 40734 |
| 400-213 | MINI DB BUTTONS 20/PK | 40734 |
| 400-214 | TWIST LIGATING BUTTON 5/PK | 40734 |
| 425-001 | LINGUAL SHEATH W/WINDOW 036 | 40734 |
| 425-002 | LINGUAL SHEATH W/WIND/HK 036 UR/LL | 40734 |
| 425-003 | LINGUAL SHEATH W/WIND/HK 036 UL/LR | 40734 |
| 425-011 | LINGUAL SHEATH W/WIN/INDENT 036 | 40734 |
| 425-013 | LING SHEATH WIND/IND/HK 036 UR/LL | 40734 |
| 425-014 | LING SHEATH WIND/IND/HK 036 UL/LR | 40734 |
| 425-021 | LINGUAL SHEATH W/INDENT 036 | 40734 |

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