



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.
2726 Loker Avenue West
Carlsbad, California 92010
USA
European Representative Kristal S.r.l.
Via Claudio Cogorano 25
IT-57123 Livorno (LI)
Italy
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 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 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

***end of list