



## 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 ..... Ceramic Orthodontic Brackets

GMDN Code ..... 58937

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.  
Via Grande 225  
Livorno 57123  
Italy  
Tel: +39 024453401  
Fax: +39 0248408305  
e-mail: info@kristalsrl.net

Notified Body ..... BSI  
Kitemark Court  
Davey Avenue, Knowlhill  
Milton Keynes, MK5 8PP  
United Kingdom

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

March 22, 2017

Date



## List of Devices Covered

### Class IIa Ceramic Orthodontic Brackets

Catalog Number	Product Description	GMDN Code
231-401	OPTYC MBT CEN +17T +4A 018 UR	58937
231-402	OPTYC MBT CEN +17T +4A 018 UL	58937
231-411	OPTYC MBT LAT +10T +8A 018 UR	58937
231-412	OPTYC MBT LAT +10T +8A 018 UL	58937
231-421	OPTYC MBT CUS HK 0T +8A 018 UR	58937
231-422	OPTYC MBT CUS HK 0T +8A 018 UL	58937
231-433	OPTYC MBT BIC -7T 0A 018 UP	58937
231-441	OPTYC MBT ANT -6T 0A 018 LO	58937
231-451	OPTYC MBT CUS HK 0T +3A 018 LR	58937
231-452	OPTYC MBT CUS HK 0T +3A 018 LL	58937
231-463	OPTYC MBT 1BIC -12T 0A 018 LO	58937
231-473	OPTYC MBT 2BIC -17T 0A 018 LO	58937
231-501	OPTYC MBT CEN +17T +4A 022 UR	58937
231-502	OPTYC MBT CEN +17T +4A 022 UL	58937
231-511	OPTYC MBT LAT +10T +8A 022 UR	58937
231-512	OPTYC MBT LAT +10T +8A 022 UL	58937
231-521	OPTYC MBT CUS HK 0T +8A 022 UR	58937
231-522	OPTYC MBT CUS HK 0T +8A 022 UL	58937
231-533	OPTYC MBT BIC -7T 0A 022 UP	58937
231-541	OPTYC MBT ANT -6T 0A 022 LO	58937
231-551	OPTYC MBT CUS HK 0T +3A 022 LR	58937
231-552	OPTYC MBT CUS HK 0T +3A 022 LL	58937
231-563	OPTYC MBT 1BIC -12T 0A 022 LO	58937
231-573	OPTYC MBT 2BIC -17T 0A 022 LO	58937
231-941	OPTYC MBT REDI-PK HKS .018	58937
231-942	OPTYC MBT REDI-PK HKS .022	58937
231-947	OPTYC MBT REDI-PK HK/CUS .018	58937
231-948	OPTYC MBT REDI-PK HK/CUS .022	58937
245-001	INTG EDG MWT CENT 0T 0A 018 UP	58937
245-002	INTG EDG NT LAT 0T 0A 018 UP	58937
245-003	INTG EDG MT CUS/BI 0T 0A 018 UP/LO	58937
245-004	INTG EDG NT ANT 0T 0A 018 LO	58937
245-101	INTG EDG MWT CENT 0T 0A 022 UP	58937
245-102	INTG EDG MT LAT 0T 0A 022 UP	58937
245-103	INTG EDG MT CUS/BI 0T 0A 022 UP/LO	58937
245-104	INTG EDG NT ANT 0T 0A 022 LO	58937
245-931	INTRG REDI PAK EDGEWISE.018	58937
245-932	INTRG REDI PAK EDGEWISE.022	58937
246-031	INTRG ROTH BIC HK -7T 0A 018 UP	58937
246-061	INTRG ROTH 1BIC HK -17T 0A 018 LOW	58937
246-071	INTRG ROTH 2BIC HK -22T 0A 018 LOW	58937
246-131	INTRG ROTH BIC HK -7T 0A 022 UP	58937
246-161	INTRG ROTH 1BIC HK -17T 0A 022 LO	58937
246-171	INTRG ROTH 2BIC HK -22T 0A 022 LOW	58937
246-173	INTRG ROTH 2BIC -22T 0A 022 LOW	58937
246-401	OPTYC ROTH CENT +12T +5A 018 UR	58937
246-402	OPTYC ROTH CENT +12T +5A 018 UL	58937
246-411	OPTYC ROTH LAT +8T +9A 018 UR	58937
246-412	OPTYC ROTH LAT +8T +9A 018 UL	58937
246-421	OPTYC ROTH CUS HK 0T +11A 018 UR	58937
246-422	OPTYC ROTH CUS HK 0T +11A 018 UL	58937
246-433	OPTYC ROTH BIC -7T 0A 018 UP	58937
246-441	OPTYC ROTH ANT 0T 0A 018 LOW	58937



## List of Devices Covered

### Class IIa Ceramic Orthodontic Brackets

Catalog Number	Product Description	GMDN Code
246-451	OPTYC ROTH CUS HK -11T 5A 018 LR	58937
246-452	OPTYC ROTH CUS HK -11T 5A 018 LL	58937
246-463	OPTYC ROTH 1BIC -17T 0A 018 LOW	58937
246-473	OPTYC ROTH 2BIC -22T 0A 018 LOW	58937
246-501	OPTYC ROTH CENT +12T +5A 022 UR	58937
246-502	OPTYC ROTH CENT +12T +5A 022 UL	58937
246-511	OPTYC ROTH LAT +8T +9A 022 UR	58937
246-512	OPTYC ROTH LAT +8T +9A 022 UL	58937
246-521	OPTYC ROTH CUS HK 0T +11A 022 UR	58937
246-522	OPTYC ROTH CUS HK 0T +11A 022 UL	58937
246-533	OPTYC ROTH BIC -7T 0A 022 UP	58937
246-541	OPTYC ROTH ANT 0T 0A 022 LOW	58937
246-551	OPTYC ROTH CUS HK -11T 5A 022 LR	58937
246-552	OPTYC ROTH CUS HK -11T 5A 022 LL	58937
246-563	OPTYC ROTH 1BIC -17T 0A 022 LOW	58937
246-573	OPTYC ROTH 2BIC -22T 0A 022 LOW	58937
246-941	OPTYC ROTH REDI-PK HKS .018	58937
246-942	OPTYC ROTH REDI-PK HKS .022	58937
246-945	OPTYC ROTH REDI-PK HK/CUS .018	58937
246-946	OPTYC ROTH REDI-PK HK/CUS .022	58937
253-001	INTRG METAL SLOT ROTH CEN +12T 5A .018 UR	58937
253-002	INTRG METAL SLOT ROTH CEN +12T 5A .018 UL	58937
253-011	INTRG METAL SLOT ROTH LAT +8T -9A .018 UR	58937
253-012	INTRG METAL SLOT ROTH LAT +8T -9A .018 UL	58937
253-021	INTRG METAL SLOT ROTH CUS HK 0T +11A .018 UR	58937
253-022	INTRG METAL SLOT ROTH CUS HK 0T +11A .018 UL	58937
253-023	INTRG METAL SLOT ROTH CUS 0T +11A .018 UR	58937
253-024	INTRG METAL SLOT ROTH CUS 0T +11A .018 UL	58937
253-031	INTRG METAL SLOT ROTH BIC HK -7T 0A .018 UNIV	58937
253-033	INTRG METAL SLOT ROTH BIC -7T 0A .018 UNIV	58937
253-041	INTRG METAL SLOT ROTH ANT 0T 0A .018 LOWER	58937
253-051	INTRG METAL SLOT ROTH CUS HK -11T +5A .018 LR	58937
253-052	INTRG METAL SLOT ROTH CUS HK -11T +5A .018 LL	58937
253-053	INTRG METAL SLOT ROTH CUS -11T +5A .018 LR	58937
253-054	INTRG METAL SLOT ROTH CUS -11T +5A .018 LL	58937
253-061	INTRG METAL SLOT ROTH 1BIC HK -17T 0A .018 UNI	58937
253-063	INTRG METAL SLOT ROTH 1BIC -17T 0A .018 UNI	58937
253-071	INTRG METAL SLOT ROTH 2BIC HK -22T 0A .018 UNI	58937
253-073	INTRG METAL SLOT ROTH 2BIC -22T 0A .018 UNI	58937
253-101	INTRG METAL SLOT ROTH CEN +12T 5A .022 UR	58937
253-102	INTRG METAL SLOT ROTH CEN +12T 5A .022 UL	58937
253-111	INTRG METAL SLOT ROTH LAT +8T -9A .022 UR	58937
253-112	INTRG METAL SLOT ROTH LAT +8T -9A .022 UL	58937
253-121	INTRG METAL SLOT ROTH CUS HK 0T +11A .022 UR	58937
253-122	INTRG METAL SLOT ROTH CUS HK 0T +11A .022 UL	58937
253-123	INTRG METAL SLOT ROTH CUS 0T +11A .022 UR	58937
253-124	INTRG METAL SLOT ROTH CUS 0T +11A .022 UL	58937
253-131	INTRG METAL SLOT ROTH BIC HK -7T 0A .022 UNIV	58937
253-133	INTRG METAL SLOT ROTH BIC -7T 0A .022 UNIV	58937
253-141	INTRG METAL SLOT ROTH ANT 0T 0A .022 LOWER	58937
253-151	INTRG METAL SLOT ROTH CUS HK -11T +5A .022 LR	58937
253-152	INTRG METAL SLOT ROTH CUS HK -11T +5A .022 LL	58937
253-153	INTRG METAL SLOT ROTH CUS -11T +5A .022 LR	58937
253-154	INTRG METAL SLOT ROTH CUS -11T +5A .022 LL	58937



## List of Devices Covered

### Class IIa Ceramic Orthodontic Brackets

Catalog Number	Product Description	GMDN Code
253-161	INTRG METAL SLOT ROTH1BIC HK -17T 0A .022 UNI	58937
253-163	INTRG METAL SLOT ROTH1BIC -17T 0A .022 UNI	58937
253-171	INTRG METAL SLOT ROTH2BIC HK -22T 0A .022 UNI	58937
253-173	INTRG METAL SLOT ROTH2BIC -22T 0A .022 UNI	58937
253-931	INTRG METAL SLOT REDIPAK ROTH HK.018	58937
253-932	INTRG METAL SLOT REDIPAK ROTH HK.022	58937
253-933	INTRG METAL SLOT REDIPAK ROTH.018	58937
253-934	INTRG METAL SLOT REDIPAK ROTH.022	58937
253-935	INTRG METAL SLOT REDI-PK ROTH HK/CUS 018	58937
255-001	INTRG M/SLOT RICKETTS CEN +22T -5A .018 UR	58937
255-002	INTRG M/SLOT RICKETTS CEN +22T -5A .018 UL	58937
255-011	INTRG M/SLOT RICKETTS LAT +14T -8A .018 UR	58937
255-012	INTRG M/SLOT RICKETTS LAT +14T -8A .018 UL	58937
255-021	INTRG M/SLOT RICKETTS CUS HK +7T -5A .018 UR	58937
255-022	INTRG M/SLOT RICKETTS CUS HK +7T -5A .018 UL	58937
255-023	INTRG M/SLOT RICKETTS CUS +7T -5A .018 UR	58937
255-024	INTRG M/SLOT RICKETTS CUS +7T -5A .018 UL	58937
255-031	INTRG M/SLOT RICKETTS BIC HK -7T 0A .018 UP UNIV	58937
255-033	INTRG M/SLOT RICKETTS BIC 0T 0A .018 UP UNIV	58937
255-041	INTRG M/SLOT RICKETTS ANT 0T 0A .018 LOWER	58937
255-051	INTRG M/SLOT RICKETTS CUS HK +7T -5A .018 LR	58937
255-052	INTRG M/SLOT RICKETTS CUS HK +7T -5A .018 LL	58937
255-053	INTRG M/SLOT RICKETTS CUS +7T -5A .018 LR	58937
255-054	INTRG M/SLOT RICKETTS CUS +7T -5A .018 LL	58937
255-061	INTRG M/SLOT RICKETTS 1BIC HK 018-11T 0A LO UNIV	58937
255-071	INTRG M/SLOT RICKETTS 2BIC HK 018-17T 0A LO UNIV	58937
255-931	INTRG METAL SLOT REDIPAK RICKETTS HK/CUS 018	58937
255-933	INTRG METAL SLOT REDIPAK RICKETTS.018	58937
257-001	CERAMIC TWEED CENT 0T 0A.018 UP	58937
257-004	CERAMIC TWEED LO ANT 0T0A .018 LO	58937
257-101	CERAMIC TWEED CENT 0T 0A.022 UP	58937
257-102	CERAMIC TWEED LAT 0T 0A.022 UP	58937
257-103	CERAMIC TWEED CUS/BIC OTOA .022 UP/LO	58937
257-903	INTRG REDI PAK TWEED .018	58937
257-905	INTRG REDI PAK TWEED .022	58937
259-001	INTRG METAL SLOT MBT CEN +17T +4A .018 UR	58937
259-002	INTRG METAL SLOT MBT CEN +17T +4A .018 UL	58937
259-011	INTRG METAL SLOT MBT LAT +10T -8A .018 UR	58937
259-012	INTRG METAL SLOT MBT LAT +10T -8A .018 UL	58937
259-021	INTRG METAL SLOT MBT CUS HK 0T +8A .018 UR	58937
259-022	INTRG METAL SLOT MBT CUS HK 0T +8A .018 UL	58937
259-031	INTRG METAL SLOT MBT BIC HK -7T 0A .018 UPPER	58937
259-041	INTRG METAL SLOT MBT ANT -6T 0A .018 LOWER	58937
259-051	INTRG METAL SLOT MBT CUS HK 0T +3A .018 LR	58937
259-052	INTRG METAL SLOT MBT CUS HK 0T +3A .018 LL	58937
259-061	INTRG METAL SLOT MBT 1BI HK -12T +2A .018 LOWER	58937
259-071	INTRG METAL SLOT MBT 2BI HK -17T +2A .018 LOWER	58937
259-101	INTRG METAL SLOT MBT CEN +17T +4A .022 UR	58937
259-102	INTRG METAL SLOT MBT CEN +17T +4A .022 UL	58937
259-111	INTRG METAL SLOT MBT LAT +10T -8A .022 UR	58937
259-112	INTRG METAL SLOT MBT LAT +10T -8A .022 UL	58937
259-121	INTRG METAL SLOT MBT CUS HK 0T +8A .022 UR	58937
259-122	INTRG METAL SLOT MBT CUS HK 0T +8A .022 UL	58937
259-123	INTRG METAL SLOT MBT CUS 0T +8A .022 UR	58937



## List of Devices Covered

### Class IIa Ceramic Orthodontic Brackets

Catalog Number	Product Description	GMDN Code
259-124	INTRG METAL SLOT MBT CUS 0T +8A .022 UL	58937
259-131	INTRG METAL SLOT MBT BIC HK -7T 0A .022 UPPER	58937
259-133	INTRG METAL SLOT MBT BIC -7T 0A .022 UP UNIV	58937
259-141	INTRG METAL SLOT MBT ANT -6T 0A .022 LOWER	58937
259-151	INTRG METAL SLOT MBT CUS HK 0T +3A .022 LR	58937
259-152	INTRG METAL SLOT MBT CUS HK 0T +3A .022 LL	58937
259-153	INTRG METAL SLOT MBT CUS 0T +3A .022 LR	58937
259-154	INTRG METAL SLOT MBT CUS 0T +3A .022 LL	58937
259-161	INTRG METAL SLOT MBT 1BI HK -12T +2A .022 LOWER	58937
259-163	INTRG METAL SLOT MBT 1BI -12T +2A .022 LOWER	58937
259-171	INTRG METAL SLOT MBT 2BI HK -17T +2A .022 LOWER	58937
259-173	INTRG METAL SLOT MBT 2BI -17T +2A .022 LOWER	58937
259-931	INTRG METAL SLOT REDIPAK MBT HK.018	58937
259-932	INTRG METAL SLOT REDIPAK MBT HK.022	58937
259-933	INTRG METAL SLOT REDIPAK MBT.018	58937
259-934	INTRG METAL SLOT REDIPAK MBT.022	58937
259-936	INTRG METAL SLOT REDI-PK MBT HK/CUS 022	58937
25M-12L	VELOCITY WHISPER MBT CEN +17T +4A .022 UL	58937
25M-12R	VELOCITY WHISPER MBT CEN +17T +4A .022 UR	58937
25M-18L	VELOCITY WHISPER MBT CEN +17T +4A .018 UL	58937
25M-18R	VELOCITY WHISPER MBT CEN +17T +4A .018 UR	58937
25M-22L	VELOCITY WHISPER MBT LAT +10T +8A .022 UL	58937
25M-22R	VELOCITY WHISPER MBT LAT +10T +8A .022 UR	58937
25M-28L	VELOCITY WHISPER MBT LAT +10T +8A .018 UL	58937
25M-28R	VELOCITY WHISPER MBT LAT +10T +8A .018 UR	58937
25M-32L	VELOCITY WHISPER MBT CUS HK -7T +8A .022 UL	58937
25M-32L0	VELOCITY WHISPER MBT CUS HK 0T +8A .022 UL	58937
25M-32R	VELOCITY WHISPER MBT CUS HK -7T +8A .022 UR	58937
25M-32R0	VELOCITY WHISPER MBT CUS HK 0T +8A .022 UR	58937
25M-38L	VELOCITY WHISPER MBT CUS HK -7T +8A .018 UL	58937
25M-38L0	VELOCITY WHISPER MBT CUS HK 0T +8A .018 UL	58937
25M-38R	VELOCITY WHISPER MBT CUS HK -7T +8A .018 UR	58937
25M-38R0	VELOCITY WHISPER MBT CUS HK 0T +8A .018 UR	58937
25M-42L	VELOCITY WHISPER MBT BIC HK -7T 0A .022 UL	58937
25M-42R	VELOCITY WHISPER MBT BIC HK -7T 0A .022 UR	58937
25M-42U	VELOCITY WHISPER MBT BIC -7T 0A .022	58937
25M-48L	VELOCITY WHISPER MBT BIC HK -7T 0A .018 UL	58937
25M-48R	VELOCITY WHISPER MBT BIC HK -7T 0A .018 UR	58937
25M-48U	VELOCITY WHISPER MBT BIC -7T 0A .018	58937
25M-52U	VELOCITY WHISPER MBT ANT -6T 0A .022	58937
25M-58U	VELOCITY WHISPER MBT ANT -6T 0A .018	58937
25M-62L	VELOCITY WHISPER MBT CUS HK -6T +3A .022 LL	58937
25M-62L0	VELOCITY WHISPER MBT CUS HK 0T +3A .022 LL	58937
25M-62R	VELOCITY WHISPER MBT CUS HK -6T +3A .022 LR	58937
25M-62R0	VELOCITY WHISPER MBT CUS HK 0T +3A .022 LR	58937
25M-68L	VELOCITY WHISPER MBT CUS HK -6T +3A .018 LL	58937
25M-68L0	VELOCITY WHISPER MBT CUS HK 0T +3A .018 LL	58937
25M-68R	VELOCITY WHISPER MBT CUS HK -6T +3A .018 LR	58937
25M-68R0	VELOCITY WHISPER MBT CUS HK 0T +3A .018 LR	58937
25M-72L	VELOCITY WHISPER MBT 1BIC HK -12T 0A .022 LL	58937
25M-72R	VELOCITY WHISPER MBT 1BIC HK -12T 0A .022 LR	58937
25M-72U	VELOCITY WHISPER MBT 1BIC -12T 0A .022	58937
25M-78L	VELOCITY WHISPER MBT 1BIC HK -12T 0A .018 LL	58937
25M-78R	VELOCITY WHISPER MBT 1BIC HK -12T 0A .018 LR	58937





## List of Devices Covered

### Class IIa Ceramic Orthodontic Brackets

Catalog Number	Product Description	GMDN Code
25M-78U	VELOCITY WHISPER MBT 1BIC -12T 0A .018	58937
25M-82L	VELOCITY WHISPER MBT 2BIC HK -17T 0A .022 LL	58937
25M-82R	VELOCITY WHISPER MBT 2BIC HK -17T 0A .022 LR	58937
25M-82U	VELOCITY WHISPER MBT 2BIC -17T 0A .022	58937
25M-88L	VELOCITY WHISPER MBT 2BIC HK -17T 0A .018 LL	58937
25M-88R	VELOCITY WHISPER MBT 2BIC HK -17T 0A .018 LR	58937
25M-88U	VELOCITY WHISPER MBT 2BIC -17T 0A .018	58937
25MK-3-18	VELOCITY WHISPER MBT HK3 .018	58937
25MK-3-180	VELOCITY WHISPER MBT HK3 .018 CUS 0T	58937
25MK-3-1806	VELOCITY WHISPER MBT HK3 .018 6X6 CUS 0T	58937
25MK-3-186	VELOCITY WHISPER MBT HK3 .018 6X6	58937
25MK-3-22	VELOCITY WHISPER MBT HK3 .022	58937
25MK-3-220	VELOCITY WHISPER MBT HK3 .022 CUS 0T	58937
25MK-3-2206	VELOCITY WHISPER MBT HK3 .022 6X6 CUS 0T	58937
25MK-3-226	VELOCITY WHISPER MBT HK3 .022 6X6	58937
25MK-345-18	VELOCITY WHISPER MBT HK345 .018	58937
25MK-345-180	VELOCITY WHISPER MBT HK345 .018 CUSP 0T	58937
25MK-345-1806	VELOCITY WHISPER MBT HK345 .018 6X6 CUSP 0T	58937
25MK-345-186	VELOCITY WHISPER MBT HK345 .018 6X6	58937
25MK-345-22	VELOCITY WHISPER MBT HK345 .022	58937
25MK-345-220	VELOCITY WHISPER MBT HK345 .022 CUS 0T	58937
25MK-345-2206	VELOCITY WHISPER MBT HK345 .022 6X6 CUS 0T	58937
25MK-345-226	VELOCITY WHISPER MBT HK345 .022 6X6	58937
25R-12L	VELOCITY WHISPER ROTH CEN +12T +5A .022 UL	58937
25R-12R	VELOCITY WHISPER ROTH CEN +12T +5A .022 UR	58937
25R-18L	VELOCITY WHISPER ROTH CEN +12T +5A .018 UL	58937
25R-18R	VELOCITY WHISPER ROTH CEN +12T +5A .018 UR	58937
25R-22L	VELOCITY WHISPER ROTH LAT +8T +9A .022 UL	58937
25R-22R	VELOCITY WHISPER ROTH LAT +8T +9A .022 UR	58937
25R-28L	VELOCITY WHISPER ROTH LAT +8T +9A .018 UL	58937
25R-28R	VELOCITY WHISPER ROTH LAT +8T +9A .018 UR	58937
25R-32L	VELOCITY WHISPER ROTH CUS HK 0T +11A .022 UL	58937
25R-32R	VELOCITY WHISPER ROTH CUS HK 0T +11A .022 UR	58937
25R-38L	VELOCITY WHISPER ROTH CUS HK 0T +11A .018 UL	58937
25R-38R	VELOCITY WHISPER ROTH CUS HK 0T +11A .018 UR	58937
25R-42L	VELOCITY WHISPER ROTH BIC HK -7T 0A .022 UL	58937
25R-42R	VELOCITY WHISPER ROTH BIC HK -7T 0A .022 UR	58937
25R-42U	VELOCITY WHISPER ROTH BIC -7T 0A .022	58937
25R-48L	VELOCITY WHISPER ROTH BIC HK -7T 0A .018 UL	58937
25R-48R	VELOCITY WHISPER ROTH BIC HK -7T 0A .018 UR	58937
25R-48U	VELOCITY WHISPER ROTH BIC -7T 0A .018	58937
25R-52U	VELOCITY WHISPER ROTH ANT 0T 0A .022	58937
25R-58U	VELOCITY WHISPER ROTH ANT 0T 0A .018	58937
25R-62L	VELOCITY WHISPER ROTH CUS HK -11T +5A .022 LL	58937
25R-62R	VELOCITY WHISPER ROTH CUS HK -11T +5A .022 LR	58937
25R-68L	VELOCITY WHISPER ROTH CUS HK -11T +5A .018 LL	58937
25R-68R	VELOCITY WHISPER ROTH CUS HK -11T +5A .018 LR	58937
25R-72L	VELOCITY WHISPER ROTH 1BIC HK -17T 0A .022 LL	58937
25R-72R	VELOCITY WHISPER ROTH 1BIC HK -17T 0A .022 LR	58937
25R-72U	VELOCITY WHISPER ROTH 1BIC -17T 0A .022	58937
25R-78L	VELOCITY WHISPER ROTH 1BIC HK -17T 0A .018 LL	58937
25R-78R	VELOCITY WHISPER ROTH 1BIC HK -17T 0A .018 LR	58937
25R-78U	VELOCITY WHISPER ROTH 1BIC -17T 0A .018	58937
25R-82L	VELOCITY WHISPER ROTH 2BIC HK -22T 0A .022 LL	58937



## List of Devices Covered Class IIa Ceramic Orthodontic Brackets

Catalog Number	Product Description	GMDN Code
25R-82R	VELOCITY WHISPER ROTH 2BIC HK -22T 0A .022 LR	58937
25R-82U	VELOCITY WHISPER ROTH 2BIC -22T 0A .022	58937
25R-88L	VELOCITY WHISPER ROTH 2BIC HK -22T 0A .018 LL	58937
25R-88R	VELOCITY WHISPER ROTH 2BIC HK -22T 0A .018 LR	58937
25R-88U	VELOCITY WHISPER ROTH 2BIC -22T 0A .018	58937
25RK-3-18	VELOCITY WHISPER ROTH HK 3 .018	58937
25RK-3-186	VELOCITY WHISPER ROTH HK 3 .018 6X6	58937
25RK-3-22	VELOCITY WHISPER ROTH HK 3 .022	58937
25RK-3-226	VELOCITY WHISPER ROTH HK 3 .022 6X6	58937
25RK-345-18	VELOCITY WHISPER ROTH HK 345 .018	58937
25RK-345-186	VELOCITY WHISPER ROTH HK 345 .018 6X6	58937
25RK-345-22	VELOCITY WHISPER ROTH HK 345 .022	58937
25RK-345-226	VELOCITY WHISPER ROTH HK 345 .022 6X6	58937
299-050	RICKETTS CERAMIC REDI-PKH/CUS 0185X030	58937
299-070	MBT CERAMIC W/METAL SLOTREDI-PK HK 022	58937

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