



## EC 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 Buccal Tubes

GMDN Code .....31759

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 Buccal Tubes

Catalog Number	Product Description	GMDN Code
310-005	NF SGL BT MOLAR -14T +8D0 018 UR	31759
310-006	NF SGL BT MOLAR -14T +8D0 018 UL	31759
310-101	NF SGL BT 0T +8DO 022 UR	31759
310-102	NF SGL BT 0T +8DO 022 UL	31759
310-105	NF SGL BT MOLAR -14T +8D0 022 UR	31759
310-106	NF SGL BT MOLAR -14T +8D0 022 UL	31759
311-005	NF SGL BT MOLAR -25T +5D0 018 LR	31759
311-006	NF SGL BT MOLAR -25T +5D0 018 LL	31759
311-105	NF SGL BT MOLAR -25T +5D0 022 LR	31759
311-106	NF SGL BT MOLAR -25T +5D0 022 LL	31759
322-001	BT COMB W/HK 0T 0DO 018/045 UR	31759
322-002	BT COMB W/HK 0T 0DO 018/045 UL	31759
322-023	BT COMB W/HK -10T 8DO 018/045 UR	31759
322-024	BT COMB W/HK -10T 8DO 018/045 UL	31759
322-101	BT COMB W/HK 0T 0DO 022/045 UR	31759
322-102	BT COMB W/HK 0T 0DO 022/045 UL	31759
322-103	BT COMB W/HK 0T 8DO 022/045 UR	31759
322-104	BT COMB W/HK 0T 8DO 022/045 UL	31759
322-105	BT COMB 0T 0DO 022/051	31759
322-123	BT COMB W/HK -10T 8DO 022/045 UR	31759
322-124	BT COMB W/HK -10T 8DO 022/045 UL	31759
324-001	BT SGL W/HK 0T 0DO 018 UR/LL	31759
324-002	BT SGL W/HK 0T 0DO 018 UL/LR	31759
324-031	BT SGL W/HK -25T 0DO 018 LR	31759
324-032	BT SGL W/HK -25T 0DO 018 LL	31759
324-101	BT SGL W/HK 0T 0DO 022 UR/LL	31759
324-102	BT SGL W/HK 0T 0DO 022 UL/LR	31759
324-131	BT SGL W/HK -25T 0DO 022 LR	31759
324-132	BT SGL W/HK -25T 0DO 022 LL	31759
324-211	BT SGL W/HK -10T 8DO 018 UR	31759
324-212	BT SGL W/HK -10T 8DO 018 UL	31759
324-231	BT SGL W/HK -25T 8DO 018 LR	31759
324-232	BT SGL W/HK -25T 8DO 018 LL	31759
324-233	BT SGL NC HK STD 018 HK 0T 0DO UR/LL	31759
324-234	BT SGL NC HK STD 018 HK 0T 0DO UL/LR	31759
324-235	BT SGL NC HK ROTH 018 HK -10T 8DO UR	31759
324-236	BT SGL NC HK ROTH 018 HK -10T 8DO UL	31759
324-237	BT SGL NC HK MBT 018 HK -14T 10DO UR	31759
324-238	BT SGL NC HK MBT 018 HK -14T 10DO UL	31759
324-239	BT SGL NC HK MBT 018 HK -20T 0DO LR	31759
324-240	BT SGL NC HK MBT 018 HK -20T 0DO LL	31759
324-241	BT SGL NC HK ROTH 018 HK -25T 5DO LR	31759
324-242	BT SGL NC HK ROTH 018 HK -25T 5DO LL	31759
324-301	BT SGL W/HK 0T 8DO 022 UR LL	31759
324-302	BT SGL W/HK 0T 8DO 022 UL LR	31759
324-311	BT SGL W/HK -10T 8DO 022 UR	31759
324-312	BT SGL W/HK -10T 8DO 022 UL	31759
324-331	BT SGL W/HK -25T 8DO 022 LR	31759
324-332	BT SGL W/HK -25T 8DO 022 LL	31759
324-333	BT SGL NC HK STD 022 HK 0T 0DO UR/LL	31759
324-334	BT SGL NC HK STD 022 HK 0T 0DO UL/LR	31759
324-335	BT SGL NC HK ROTH 022 HK -10T 8DO UR	31759
324-336	BT SGL NC HK ROTH 022 HK -10T 8DO UL	31759
324-337	BT SGL NC HK MBT 022 HK -14T 10DO UR	31759



## List of Devices Covered Class IIa Orthodontic Buccal Tubes

Catalog Number	Product Description	GMDN Code
324-338	BT SGL NC HK MBT 022 HK -14T 10DO UL	31759
324-339	BT SGL NC HK MBT 022 HK -20T 0DO LR	31759
324-340	BT SGL NC HK MBT 022 HK -20T 0DO LL	31759
324-341	BT SGL NC HK ROTH 022 HK -25T 5DO LR	31759
324-342	BT SGL NC HK ROTH 022 HK -25T 5DO LL	31759
324-841	BT MBT SGL W/HK -14T 8DO 018 UR	31759
324-842	BT MBT SGL W/HK -14T 8DO 018 UL	31759
324-861	BT MBT SGL W/HK -20T 8DO 018 LR	31759
324-862	BT MBT SGL W/HK -20T 8DO 018 LL	31759
324-941	BT MBT SGL W/HK -14T 8DO 022 UR	31759
324-942	BT MBT SGL W/HK -14T 8DO 022 UL	31759
324-961	BT MBT SGL W/HK -20T 8DO 022 LR	31759
324-962	BT MBT SGL W/HK -20T 8DO 022 LL	31759
326-801	BT COMB CV HK 0T 8DO 018/045 UR	31759
326-825	BT CNV/COMB HK -10T 0DO 018/045 UR	31759
326-826	BT CNV/COMB HK -10T 0DO 018/045 UL	31759
326-829A	BT COMB CV HK GING -10T 10DO 018/045 UR	31759
326-830A	BT COMB CV HK GING-10T 10DO 018/045 UL	31759
326-851	BT CNV/COMB HK -10T 8DO 018/045 UR	31759
326-851DL	DB COMB CONV HK -10T +8DO 045.018 UR	31759
326-852	BT CNV/COMB HK -10T 8DO 018/045 UL	31759
326-852DL	DB COMB CONV HK -10T +8DO 045.018 UL	31759
326-853	BT CNV/COMB HK -14T 8DO 018/045 UR	31759
326-854	BT CNV/COMB HK -14T 8DO 018/045 UL	31759
326-855	BT CNV/COMB HK 0T 0DO 018/045 UR/LL	31759
326-856	BT CNV/COMB HK 0T 0DO 018/045 UL/LR	31759
326-857	BT CNV/COMB HK -10T 8DO018/045 GING UR	31759
326-858	BT CNV/COMB HK -10T 8DO018/045 GING UL	31759
326-859	BT CNV/COMB HK -14T 8DO018/045 GING UR	31759
326-860	BT CNV/COMB HK -14T 8DO018/045 GING UL	31759
326-911	BT COMB CV HK 0T 8DO 022/051 UR	31759
326-912	BT COMB CV HK 0T 8DO 022/051 UL	31759
326-915	BT CNV/COMB HK 0T0DO 022/051 UR "SP"	31759
326-921A	BT COMB CV HK-10T 10DO 022/045 UR	31759
326-922A	BT COMB CV HK-10T 10DO022/045 UL	31759
326-925	BT CNV/COMB HK -10T 10DO 022/045 UR	31759
326-926	BT CNV/COMB HK -10T 10DO 022/045 UL	31759
326-931	BT COMB CV HK -10T 8DO 022/051 UR	31759
326-932	BT COMB CV HK -10T 8DO 022/051 UL	31759
326-935	BT CNV/COMB HK -10T 10DO 022/051 UR	31759
326-936	BT CNV/COMB HK -10T 10DO 022/051 UL	31759
326-951	BT CNV/COMB HK -10T 8DO 022/045 UR	31759
326-951DL	DB COMB CONV HK -10T +8DO 045.022 UR	31759
326-952	BT CNV/COMB HK -10T 8DO 022/045 UL	31759
326-952DL	DB COMB CONV HK -10T +8DO 045.022 UL	31759
326-953	BT CNV/COMB HK -14T 8DO 022/045 UR	31759
326-953DL	DB COMB CONV HK -14T +8DO 045.022 UR	31759
326-954	BT CNV/COMB HK -14T 8DO 022/045 UL	31759
326-954DL	DB COMB CONV HK -14T +8DO 045.022 UL	31759
326-955	BT CNV/COMB HK 0T 0DO 022/045 UR/LL	31759
326-955DL	DB COMB CONV HK 0T 0DO 045.022 UR/LL	31759
326-956	BT CNV/COMB HK 0T 0DO 022/045 UL/LR	31759
326-956DL	DB COMB CONV HK 0T 0DO 045.022 UL/LR	31759
326-957	BT CNV/COMB HK -10T 8DO022/045 GING UR	31759
326-957DL	DB COMB CONV HK GING -10T +8DO 045.022 UR	31759



## List of Devices Covered Class IIa Orthodontic Buccal Tubes

Catalog Number	Product Description	GMDN Code
326-958	BT CNV/COMB HK -10T 8DO022/045 GING UL	31759
326-958DL	DB COMB CONV HK GING -10T +8DO 045.022 UL	31759
326-959	BT CNV/COMB HK -14T 8DO 022/045 GING UR	31759
326-960	BT CNV/COMB HK -14T 8DO 022/045 GING UL	31759
336-801	BT CONV SGL W/HK 0T 0DO 018 LR/UL	31759
336-801DL	DB CONV SGL HK 0T 0DO.018 LR/UL	31759
336-802	BT CONV SGL W/HK 0T 0DO 018 LL/UR	31759
336-802DL	DB CONV SGL HK 0T 0DO.018 LL/UR	31759
336-805	DB CONV SGL HK -10T 8DO018 UR	31759
336-805DL	DB ROTH CONV SGL HK -10T+8DO.018 UR	31759
336-806	DB CONV SGL HK -10T 8DO018 UL	31759
336-806DL	DB ROTH CONV SGL HK -10T+8DO.018 UL	31759
336-807	DB CONV SGL HK -25T 0DO018 LR	31759
336-808	DB CONV SGL HK -25T 0DO018 LL	31759
336-811	BT CNV SG HK F/CAP-25T 0DO 018 LR	31759
336-812	BT CNV SG HK F/CAP-25T 0DO 018 LL	31759
336-813	BT CNV SG HK F/CAP-25T 5DO 018 LR	31759
336-813DL	DB ROTH CONV SGL HK -25T+5DO.018 LR	31759
336-814	BT CNV SG HK F/CAP-25T 5DO 018 LL	31759
336-814A	BT CNV SG HK F/CAP-25T 5DO 018 LL	31759
336-814DL	DB ROTH CONV SGL HK -25T+5DO.018 LL	31759
336-821	BT CONV SGL W/HK -10T 8DO 018 UR	31759
336-821DL	DB ROTH CONV SGL HK -10T+8DO.018 UR	31759
336-822	BT CONV SGL W/HK -10T 8DO 018 UL	31759
336-822DL	DB ROTH CONV SGL HK -10T+8DO.018 UL	31759
336-841	BT MBT CONV SGL HK -14T 8DO 018 UR	31759
336-843DL	DB MBT CONV SGL HK -14T+8DO.018 UR	31759
336-844DL	DB MBT CONV SGL HK -14T+8DO.018 UL	31759
336-861	BT MBT CONV SGL HK F/CAP -20T 5DO 018 LR	31759
336-862	BT MBT CONV SGL HK F/CAP -20T 5DO 018 LL	31759
336-863DL	DB MBT CONV SGL HK -20T+5DO.018 LR	31759
336-864DL	DB MBT CONV SGL HK -20T+5DO.018 LL	31759
336-901	BT CONV SGL W/HK 0T 0DO 022 LR/UL	31759
336-901DL	DB CONV SGL HK 0T 0DO.022 LR/UL	31759
336-902	BT CONV SGL W/HK 0T 0DO 022 LL/UR	31759
336-902DL	DB CONV SGL HK 0T 0DO.022 LL/UR	31759
336-903	BT CONV SGL W/HK 0T 8DO 022 LR/UL	31759
336-904	BT CONV SGL W/HK 0T 8DO 022 LL/UR	31759
336-905	DB CONV SGL HK -10T 8DO022 UR	31759
336-905DL	DB ROTH CONV SGL HK -10T+8DO.022 UR	31759
336-906	DB CONV SGL HK -10T 8DO022 UL	31759
336-906DL	DB ROTH CONV SGL HK -10T+8DO.022 UL	31759
336-911	BT CONV SGL W/HK -25T 0DO 022 LR	31759
336-912	BT CONV SGL W/HK -25T 0DO 022 LL	31759
336-913	BT CNV SG HK F/CAP-25T 5DO 022 LR	31759
336-913A	BT CNV SG HK F/CAP-25T 5D/O 022 LR	31759
336-913DL	DB ROTH CONV SGL HK -25T+5DO.022 LR	31759
336-914	BT CNV SG HK F/CAP-25T 5DO 022 LL	31759
336-914A	BT CNV SG HK F/CAP-25T 5D/O 022 LL	31759
336-914DL	DB ROTH CONV SGL HK -25T+5DO.022 LL	31759
336-915	SFP BT SGL CONV HK -20T0DO 022 LR	31759
336-916	SFP BT SGL CONV HK -20T0DO 022 LL	31759
336-921	BT CONV SGL W/HK -10T 8DO 022 UR	31759
336-921DL	DB ROTH CONV SGL HK -10T+8DO.022 UR	31759
336-922	BT CONV SGL W/HK -10T 8DO 022 UL	31759



## List of Devices Covered Class IIa Orthodontic Buccal Tubes

Catalog Number	Product Description	GMDN Code
336-922DL	DB ROTH CONV SGL HK -10T+8DO.022 UL	31759
336-941	BT MBT CONV SGL HK -14T 8DO 022 UR	31759
336-942	BT MBT CONV SGL HK -14T 8DO 022 UL	31759
336-943	DB MBT CONV SGL HK -14T8DO 022 UR	31759
336-943DL	DB MBT CONV SGL HK -14T+8DO.022 UR	31759
336-944DL	DB MBT CONV SGL HK -14T+8DO.022 UL	31759
336-961	BT MBT CONV SGL HK F/CAP -20T 5DO 022 LR	31759
336-962	BT MBT CONV SGL HK F/CAP -20T 5DO 022 LL	31759
336-963DL	DB MBT CONV SGL HK -20T+5DO.022 LR	31759
336-964DL	DB MBT CONV SGL HK -20T+5DO.022 LL	31759
339-813	BT CONV BUMPER GING HK-25T 5DO 018 LR	31759
339-813DL	BT CONV GING HK-25T 5DO 018 LR	31759
339-814	BT CONV BUMPER GING HK-25T 5DO 018 LL	31759
339-814DL	DT CONV GING HK -25T 5DO 018 LL	31759
339-913	BT CONV BUMPER GING HK-25T 5DO 022 LR	31759
339-913DL	BT CONV GING HK -25T 5DO 022 LR	31759
339-914	BT CONV BUMPER GING HK-25T 5DO 022 LL	31759
339-914DL	DB CONV GING HK -25T 5DO 022 LL	31759
340-011A	BT RKTS TRP HK 0T 0DO 018/045 UR	31759
340-012A	BT RKTS TRP HK 0T 0DO 018/045 UL	31759
340-012DL	DB RKTS TRP HK 0T 0DO 045.018 UL	31759
340-013A	BT RKTS TRP 0T 0DO 018/045 UR/UL	31759
340-013DL	DB RKTS TRP 0T 0DO 045.018 UR/UL	31759
340-111A	BT RKTS TRP HK 0T 0DO 022/045 UR	31759
340-111DL	DB RKTS TRP HK 0T 0DO 045.022 UR	31759
340-112A	BT RKTS TRP HK 0T 0DO 022/045 UL	31759
340-802	BT CONV TRP 0T 8DO 018/045 UL	31759
340-821	BT CONV TRP -10T 8DO 018/045 UR	31759
340-821A	BT CONV TRP -10T 10D/O 018/045 UR	31759
340-822	BT CONV TRP -10T 8DO 018/045 UL	31759
340-822A	BT CONV TRP -10T 10D/O 018/O45 UL	31759
340-823	BT CONV TRP -10T 15DO 018/045 UR	31759
340-824	BT CONV TRP -10T 15DO 018/045 UL	31759
340-841	BT MBT CONV TRP -14T 8DO 018/045 UR	31759
340-842	BT MBT CONV TRP -14T 8DO 018/045 UL	31759
340-901	BT CONV TRP 0T 8DO 022/045 UR	31759
340-902	BT CONV TRP 0T 8DO 022/045 UL	31759
340-921	BT CONV TRP -10T 8DO 022/045 UR	31759
340-921A	BT CONV TRP -10T 10D/O 022/045 UR	31759
340-921DL	DB ROTH CONV TRP -10T+8DO.022 UR	31759
340-922	BT CONV TRP -10T 8DO 022/045 UL	31759
340-922A	BT CONV TRP -10T 10D/O 022/045 UL	31759
340-922DL	DB ROTH CONV TRP -10T+8DO.022 UL	31759
340-923	BT CONV TRP -10T 15DO 022/045 UR	31759
340-924	BT CONV TRP -10T 15DO 022/045 UL	31759
340-941	BT MBT CONV TRP -14T 8DO 022/045 UR	31759
340-941DL	DB MBT CONV TRP -14T+8DO.022 UR	31759
340-942	BT MBT CONV TRP -14T 8DO 022/045 UL	31759
340-942DL	DB MBT CONV TRP -14T+8DO.022 UL	31759
342-011A	BT RICKETTS DBL BALL HK 0T 0DO 018 L/R	31759
342-011DL	DB RKTS DBL HK 0T 0DO.018 L/R	31759
342-011DS	DB RKTS DBL HK 0T 0DO.018 L/R	31759
342-803	BT CONV DBL 0T 8DO 018 UL/LR	31759
342-804	BT CONV DBL 0T 8DO 018 UR/LL	31759
342-811	BT CONV DBL -25T 0DO 018 LR	31759



## List of Devices Covered Class IIa Orthodontic Buccal Tubes

Catalog Number	Product Description	GMDN Code
342-812	BT CONV DBL -25T 0DO 018 LL	31759
342-813	BT CONV DBL -25T 8DO 018 LR	31759
342-813DL	DB ROTH CONV DBL -25T 8DO.018 LR	31759
342-814	BT CONV DBL -25T 8DO 018 LL	31759
342-814A	BT CONV DBL -25T 5D/O 018 LL	31759
342-821	BT CONV DBL -10T 8DO 018 UR	31759
342-821DL	DB ROTH CONV DBL-10T 8DO.018 UR	31759
342-822	BT CONV DBL -10T 8DO 018 UL	31759
342-822DL	DB ROTH CONV DBL-10T 8DO.018 UL	31759
342-861	BT MBT CONV DBL -20T 8DO 018 LR	31759
342-862	BT MBT CONV DBL -20T 8DO 018 LL	31759
342-903	BT CONV DBL 0T 8DO 022 LR	31759
342-903DL	DB CONV DBL 0T 8DO.022 UL/LR	31759
342-904	BT CONV DBL 0T 8DO 022 LL	31759
342-904DL	DB CONV DBL 0T 8DO.022 UR/LL	31759
342-911	BT CONV DBL -25T 0DO 022 LR	31759
342-912	BT CONV DBL -25T 0DO 022 LL	31759
342-913	BT CONV DBL -25T 8DO 022 LR	31759
342-913DL	DB ROTH CONV DBL -25T 8DO.022 LR	31759
342-914	BT CONV DBL -25T 8DO 022 LL	31759
342-914DL	DB ROTH CONV DBL -25T 8DO.022 LL	31759
342-921	BT CONV DBL -10T 8DO 022 UR	31759
342-921DL	DB ROTH CONV DBL-10T 8DO.022 UR	31759
342-922	BT CONV DBL -10T 8DO 022 UL	31759
342-922DL	DB ROTH CONV DBL-10T 8DO.022 UL	31759
342-961	BT MBT CONV DBL -20T 8DO 022 LR	31759
342-961DL	DB ROTH CONV DBL -20T 8DO.022 LR	31759
342-962	BT MBT CONV DBL -20T 8DO 022 LL	31759
342-962DL	DB ROTH CONV DBL -20T 8DO.022 LL	31759
346-605DL	DB RKTS DBL HK 5mm 0T 0DO.018 LR	31759
346-606DL	DB RKTS DBL HK 5mm 0T 0DO.018 LL	31759
351-001	DB BT SGL 3mm 0T 0DO 018 UP/LO	31759
351-003	DB BT SGL 3mm HK 0T 0DO 018 UR/LL	31759
351-004	DB BT SGL 3mm HK 0T 0DO 018 UL/LR	31759
351-031	DB BT SGL 3mm -10T 8DO 018 UR	31759
351-032	DB BT SGL 3mm -10T 8DO 018 UL	31759
351-033	DB BT SGL 3mm HK -10T 8DO 018 UR	31759
351-034	DB BT SGL 3mm HK -10T 8DO 018 UL	31759
351-043	DB BT SGL 3mm HK -25T 0DO 018 LR	31759
351-044	DB BT SGL 3mm HK -25T 0DO 018 LL	31759
351-051	DB BT SGL 3mm -25T 8DO 018 LR	31759
351-052	DB BT SGL 3mm -25T 8DO 018 LL	31759
351-053	DB BT SGL 3mm HK -25T 8DO 018 LR	31759
351-054	DB BT SGL 3mm HK -25T 8DO 018 LL	31759
351-101	DB BT SGL 3mm 0T 0DO 022 UP/LO	31759
351-103	DB BT SGL 3mm HK 0T 0DO 022 UR/LL	31759
351-104	DB BT SGL 3mm HK 0T 0DO 022 UL/LR	31759
351-111	DB BT SGL 3mm 0T 8DO 022 UR/LL	31759
351-112	DB BT SGL 3mm 0T 8DO 022 UL/LR	31759
351-113	DB BT SGL 3mm HK 0T 8DO 022 UR/LL	31759
351-114	DB BT SGL 3mm HK 0T 8DO 022 UL/LR	31759
351-131	DB BT SGL 3mm -10T 8DO 022 UR	31759
351-132	DB BT SGL 3mm -10T 8DO 022 UL	31759
351-133	DB BT SGL 3mm HK -10T 8DO 022 UR	31759
351-134	DB BT SGL 3mm HK -10T 8DO 022 UL	31759



## List of Devices Covered Class IIa Orthodontic Buccal Tubes

Catalog Number	Product Description	GMDN Code
351-143	DB BT SGL 3mm HK -25T 0DO 022 LR	31759
351-144	DB BT SGL 3mm HK -25T 0DO 022 LL	31759
351-151	DB BT SGL 3mm -25T 8DO 022 LR	31759
351-152	DB BT SGL 3mm -25T 8DO 022 LL	31759
351-153	DB BT SGL 3mm HK -25T 8DO 022 LR	31759
351-154	DB BT SGL 3mm HK -25T 8DO 022 LL	31759
351-603	DB BT SGL W/HK 0T 0DO 018 UR/LL	31759
351-604	DB BT SGL W/HK 0T 0DO 018 UL/LR	31759
351-613	DB BT SGL W/HK 0T 8DO 018 UR/LL	31759
351-614	DB BT SGL W/HK 0T 8DO 018 UL/LR	31759
351-633	DB BT SGL W/HK -10T 8DO 018 UR	31759
351-634	DB BT SGL W/HK -10T 8DO 018 UL	31759
351-635	PRAXIS BT SGL NC HK MBT -14T 10DO .018 UR6	31759
351-636	PRAXIS BT SGL NC HK MBT -14T 10DO .018 UL6	31759
351-637	PRAXIS BT SGL NC HK MBT -14T 10DO .018 UR7	31759
351-638	PRAXIS BT SGL NC HK MBT -14T 10DO .018 UL7	31759
351-639	PRAXIS BT SGL NC HK MBT -20T 0DO .018 LR6	31759
351-640	PRAXIS BT SGL NC HK MBT -20T 0DO .018 LL6	31759
351-641	PRAXIS BT SGL NC HK MBT -20T 0DO .018 LR7	31759
351-642	PRAXIS BT SGL NC HK MBT -20T 0DO .018 LL7	31759
351-653	DB BT SGL W/HK -25T 8DO 018 LR	31759
351-654	DB BT SGL W/HK -25T 8DO 018 LL	31759
351-655	MINI BT SGL NC 0T 0DO UR/LL .018	31759
351-656	MINI BT SGL NC 0T 0DO UL/LR .018	31759
351-657	MINI BT SGL NC -14T 0DO UR/LL .018	31759
351-658	MINI BT SGL NC -14T 0DO UL/LR .018	31759
351-703	DB BT SGL W/HK 0T 0DO 022 UR/LL	31759
351-704	DB BT SGL W/HK 0T 0DO 022 UL/LR	31759
351-713	DB BT SGL W/HK 0T 8DO 022 UR/LL	31759
351-714	DB BT SGL W/HK 0T 8DO 022 UL/LR	31759
351-733	DB BT SGL W/HK -10T 8DO 022 UR	31759
351-734	DB BT SGL W/HK -10T 8DO 022 UL	31759
351-735	PRAXIS BT SGL NC HK MBT -14T 10DO .022 UR6	31759
351-736	PRAXIS BT SGL NC HK MBT -14T 10DO .022 UL6	31759
351-737	PRAXIS BT SGL NC HK MBT -14T 10DO .022 UR7	31759
351-738	PRAXIS BT SGL NC HK MBT -14T 10DO .022 UL7	31759
351-739	PRAXIS BT SGL NC HK MBT -20T 0DO .022 LR6	31759
351-740	PRAXIS BT SGL NC HK MBT -20T 0DO .022 LL6	31759
351-741	PRAXIS BT SGL NC HK MBT -20T 0DO .022 LR7	31759
351-742	PRAXIS BT SGL NC HK MBT -20T 0DO .022 LL7	31759
351-743	ROTH BT SGL HK -10T 8DO.022 UR6	31759
351-744	ROTH BT SGL HK -10T 8DO 022 UL6	31759
351-745	ROTH BT SGL HK -10T 8DO 022 UR7	31759
351-746	ROTH BT SGL HK -10T 8DO 022 UL7	31759
351-747	ROTH BT SGL HK -25T 5DO 022 LR6	31759
351-748	ROTH BT SGL HK -25T 5DO 022 LL6	31759
351-749	ROTH BT SGL HK -25T 5DO 022 LR7	31759
351-750	ROTH BT SGL HK -25T 5DO 022 LL7	31759
351-753	DB BT SGL W/HK -25T 8DO 022 LR	31759
351-754	DB BT SGL W/HK -25T 8DO 022 LL	31759
351-755	MINI BT SGL NC 0T 0DO UR/LL .022	31759
351-756	MINI BT SGL NC 0T 0DO UL/LR .022	31759
351-757	MINI BT SGL NC -14T 0DO UR/LL .022	31759
351-758	MINI BT SGL NC -14T 0DO UL/LR .022	31759
351-841	DB BT MBT SGL W/HK -14T 8DO 018 UR	31759



## List of Devices Covered Class IIa Orthodontic Buccal Tubes

Catalog Number	Product Description	GMDN Code
351-842	DB BT MBT SGL W/HK -14T 8DO 018 UL	31759
351-861	DB BT MBT SGL W/HK -20T 8DO 018 LR	31759
351-862	DB BT MBT SGL W/HK -20T 8DO 018 LL	31759
351-941	DB BT MBT SGL W/HK -14T 8DO 022 UR	31759
351-942	DB BT MBT SGL W/HK -14T 8DO 022 UL	31759
351-961	DB BT MBT SGL W/HK -20T 8DO 022 LR	31759
351-962	DB BT MBT SGL W/HK -20T 8DO 022 LL	31759
352-003	LTWIRE BT SGL W/HK 0DO 036 UR/LL	31759
352-004	LTWIRE BT SGL W/HK 0DO 036 UL/LR	31759
354-033	LTWIRE BT SGL W/HK 036 UR/LL	31759
354-034	LTWIRE BT SGL W/HK 036 UL/LR	31759
356-405	CAT BT COMB HK -10T 8DO 018 UR	31759
356-406	CAT BT COMB HK -10T 8DO 018 UL	31759
356-413	CAT BT COMB HK -25T 8DO 018 LR	31759
356-414	CAT BT COMB HK -25T 8DO 018 LL	31759
356-505	CAT BT COMB HK -10T 8DO 022 UR	31759
356-505DL	DB BT COMB HK -10T 8DO 022 UR	31759
356-506	CAT BT COMB HK -10T 8DO 022 UL	31759
356-506DL	DB BT COMB HK -10T 8DO 022 UL	31759
356-513	CAT BT COMB HK -25T 8DO 022 LR	31759
356-513DL	DB BT COMB HK -25T 8DO 022 LR	31759
356-514	CAT BT COMB HK -25T 8DO 022 LL	31759
356-514DL	DB BT COMB HK -25T 8DO 022 LL	31759
356-601	CAT BT TRP HK -10T 8DO 018/45 UR	31759
356-602	CAT BT TRP HK -10T 8DO 018/45 UL	31759
356-855	CAT DB BT COMB CNV HK-10T8DO 018 UR	31759
356-863	CAT DB BT COMB CNV HK-25T 8DO 018 LR	31759
356-864	CAT DB BT COMB CNV HK-25T 8DO 018 LL	31759
3DL2-DC01	BT DBL CV 3.6mm DL -14T 10DO .022 UR	31759
3DL2-DC02	BT DBL CV 3.6mm DL -14T 10DO .022 UL	31759
3DL2-DC05	BT DBL CV 3.6mm DL -10T 8DO .022 UR	31759
3DL2-DC06	BT DBL CV 3.6mm DL -10T 8DO .022 UL	31759
3DL2-DC07	BT DBL CV 3.6mm DL -25T 5DO .022 LR	31759
3DL2-DC08	BT DBL CV 3.6mm DL -25T 5DO .022 LL	31759
3DL2-SN01	BT SGL NC 4.3mm DL -14T 10DO .022 UR	31759
3DL2-SN02	BT SGL NC 4.3mm DL -14T 10DO .022 UL	31759
3DL2-SN03	BT SGL NC 4.3mm DL -20T 0DO .022 LR	31759
3DL2-SN04	BT SGL NC 4.3mm DL -20T 0DO .022 LL	31759
3DL2-SN05	BT SGL NC 4.3mm DL -10T 8DO .022 UR	31759
3DL2-SN06	BT SGL NC 4.3mm DL -10T 8DO .022 UL	31759
3DL2-SN07	BT SGL NC 4.3mm DL -25T 5DO .022 LR	31759
3DL2-SN08	BT SGL NC 4.3mm DL -25T 5DO .022 LL	31759
3DL8-DC01	BT DBL CV 3.6mm DL -14T 10DO .018 UR	31759
3DL8-DC02	BT DBL CV 3.6mm DL -14T 10DO .018 UL	31759
3DL8-DC05	BT DBL CV 3.6mm DL -10T 8DO .018 UR	31759
3DL8-DC06	BT DBL CV 3.6mm DL -10T 8DO .018 UL	31759
3DL8-DC07	BT DBL CV 3.6mm DL -25T 5DO .018 LR	31759
3DL8-DC08	BT DBL CV 3.6mm DL -25T 5DO .018 LL	31759
3DL8-SN01	BT SGL NC 4.3mm DL -14T 10DO .018 UR	31759
3DL8-SN02	BT SGL NC 4.3mm DL -14T 10DO .018 UL	31759
3DL8-SN03	BT SGL NC 4.3mm DL -20T 0DO .018 LR	31759
3DL8-SN04	BT SGL NC 4.3mm DL -20T 0DO .018 LL	31759
3DL8-SN05	BT SGL NC 4.3mm DL -10T 8DO .018 UR	31759
3DL8-SN06	BT SGL NC 4.3mm DL -10T 8DO .018 UL	31759
3DL8-SN07	BT SGL NC 4.3mm DL -25T 5DO .018 LR	31759





## List of Devices Covered Class IIa Orthodontic Buccal Tubes

Catalog Number	Product Description	GMDN Code
3DL8-SN08	BT SGL NC 4.3mm DL -25T 5DO .018 LL	31759
3DS2-SN01	BT SGL NC 4.3mm DS -14T 10DO .022 UR	31759
3DS2-SN02	BT SGL NC 4.3mm DS -14T 10DO .022 UL	31759
3DS2-SN03	BT SGL NC 4.3mm DS -20T 0DO .022 LR	31759
3DS2-SN04	BT SGL NC 4.3mm DS -20T 0DO .022 LL	31759
3DS2-SN05	BT SGL NC 4.3mm DS -10T 8DO .022 UR	31759
3DS2-SN06	BT SGL NC 4.3mm DS -10T 8DO .022 UL	31759
3DS2-SN07	BT SGL NC 4.3mm DS -25T 5DO .022 LR	31759
3DS2-SN08	BT SGL NC 4.3mm DS -25T 5DO .022 LL	31759
3DS8-SN01	BT SGL NC 4.3mm DS -14T 10DO .018 UR	31759
3DS8-SN02	BT SGL NC 4.3mm DS -14T 10DO .018 UL	31759
3DS8-SN03	BT SGL NC 4.3mm DS -20T 0DO .018 LR	31759
3DS8-SN04	BT SGL NC 4.3mm DS -20T 0DO .018 LL	31759
3DS8-SN05	BT SGL NC 4.3mm DS -10T 8DO .018 UR	31759
3DS8-SN06	BT SGL NC 4.3mm DS -10T 8DO .018 UL	31759
3DS8-SN07	BT SGL NC 4.3mm DS -25T 5DO .018 LR	31759
3DS8-SN08	BT SGL NC 4.3mm DS -25T 5DO .018 LL	31759
3W2-DC01	BT DBL CV 3.6mm WD -14T 10DO .022 UR	31759
3W2-DC02	BT DBL CV 3.6mm WD -14T 10DO .022 UL	31759
3W2-DC05	BT DBL CV 3.6mm WD -10T 8DO .022 UR	31759
3W2-DC06	BT DBL CV 3.6mm WD -10T 8DO .022 UL	31759
3W2-DC07	BT DBL CV 3.6mm WD -25T5DO .022 LR	31759
3W2-DC08	BT DBL CV 3.6mm WD -25T5DO .022 LL	31759
3W2-SN01	BT SGL NC 4.3mm WD -14T 10DO .022 UR	31759
3W2-SN02	BT SGL NC 4.3mm WD -14T 10DO .022 UL	31759
3W2-SN03	BT SGL NC 4.3mm WD -20T 0DO .022 LR	31759
3W2-SN04	BT SGL NC 4.3mm WD -20T 0DO .022 LL	31759
3W2-SN05	BT SGL NC 4.3mm WD -10T 8DO .022 UR	31759
3W2-SN06	BT SGL NC 4.3mm WD -10T 8DO .022 UL	31759
3W2-SN07	BT SGL NC 4.3mm WD -25T 5DO .022 LR	31759
3W2-SN08	BT SGL NC 4.3mm WD -25T 5DO .022 LL	31759
3W2-TC01	BT TPL CV 3.5mm HGO .045 WD -14T 10DO .022 UR	31759
3W2-TC02	BT TPL CV 3.5mm HGO .045 WD -14T 10DO .022 UL	31759
3W2-TC05	BT TPL CV 3.5mm HGO .045 WD -10T 8DO .022 UR	31759
3W2-TC06	BT TPL CV 3.5mm HGO .045 WD -10T 8DO .022 UL	31759
3W2-TC11	BT TPL CV 3.5mm HGO .051 WD -14T 10DO .022 UR	31759
3W2-TC12	BT TPL CV 3.5mm HGO .051 WD -14T 10DO .022 UL	31759
3W2-TC15	BT TPL CV 3.5mm HGO .051 WD -10T 8DO .022 UR	31759
3W2-TC16	BT TPL CV 3.5mm HGO .051 WD -10T 8DO .022 UL	31759
3W8-DC01	BT DBL CV 3.6mm WD -14T 10DO .018 UR	31759
3W8-DC02	BT DBL CV 3.6mm WD -14T 10DO .018 UL	31759
3W8-DC05	BT DBL CV 3.6mm WD -10T 8DO .018 UR	31759
3W8-DC06	BT DBL CV 3.6mm WD -10T 8DO .018 UL	31759
3W8-DC07	BT DBL CV 3.6mm WD -25T5DO .018 LR	31759
3W8-DC08	BT DBL CV 3.6mm WD -25T5DO .018 LL	31759
3W8-SN01	BT SGL NC 4.3mm WD -14T 10DO .018 UR	31759
3W8-SN02	BT SGL NC 4.3mm WD -14T 10DO .018 UL	31759
3W8-SN03	BT SGL NC 4.3mm WD -20T 0DO .018 LR	31759
3W8-SN04	BT SGL NC 4.3mm WD -20T 0DO .018 LL	31759
3W8-SN05	BT SGL NC 4.3mm WD -10T 8DO .018 UR	31759
3W8-SN06	BT SGL NC 4.3mm WD -10T 8DO .018 UL	31759
3W8-SN07	BT SGL NC 4.3mm WD -25T 5DO .018 LR	31759
3W8-SN08	BT SGL NC 4.3mm WD -25T 5DO .018 LL	31759
3W8-TC01	BT TPL CV 3.5mm HGO .045 WD -14T 10DO .018 UR	31759
3W8-TC02	BT TPL CV 3.5mm HGO .045 WD -14T 10DO .018 UL	31759



## List of Devices Covered Class IIa Orthodontic Buccal Tubes

Catalog Number	Product Description	GMDN Code
3W8-TC05	BT TPL CV 3.5mm HGO .045 WD -10T 8DO .018 UR	31759
3W8-TC06	BT TPL CV 3.5mm HGO .045 WD -10T 8DO .018 UL	31759
3W8-TC11	BT TPL CV 3.5mm HGO .051 WD -14T 10DO .018 UR	31759
3W8-TC12	BT TPL CV 3.5mm HGO .051 WD -14T 10DO .018 UL	31759
3W8-TC15	BT TPL CV 3.5mm HGO .051 WD -10T 8DO .018 UR	31759
3W8-TC16	BT TPL CV 3.5mm HGO .051 WD -10T 8DO .018 UL	31759
INSBBP1-221	LP SG N/CONV BOND 4.3mm -20T 0DO .022 LR	31759
INSBBP1-222	LP SG N/CONV BOND 4.3mm -20T 0DO .022 LL	31759
INSBBP1-821	LP SG N/CONV BOND 4.3mm -20T 0DO .018 LR	31759
INSBBP1-822	LP SG N/CONV BOND 4.3mm -20T 0DO .018 LL	31759
INSBBP3-221	LP SG N/CONV BOND 4.3mm -10T 8DO .022 UR	31759
INSBBP3-222	LP SG N/CONV BOND 4.3mm -10T 8DO .022 UL	31759
INSBBP3-821	LP SG N/CONV BOND 4.3mm -10T 8DO .018 UR	31759
INSBBP3-822	LP SG N/CONV BOND 4.3mm -10T 8DO .018 UL	31759
INSBBP5-221	LP SG N/CONV BOND 4.3mm -25T 5DO .022 LR	31759
INSBBP5-222	LP SG N/CONV BOND 4.3mm -25T 5DO .022 LL	31759
INSBBP5-821	LP SG N/CONV BOND 4.3mm -25T 5DO .018 LR	31759
INSBBP5-822	LP SG N/CONV BOND 4.3mm -25T 5DO .018 LL	31759
INSBBP7-221	LP SG N/CONV BOND 4.3mm -14T 10DO .022 UR	31759
INSBBP7-222	LP SG N/CONV BOND 4.3mm -14T 10DO .022 UL	31759
INSBBP7-821	LP SG N/CONV BOND 4.3mm -14T 10DO .018 UR	31759
INSBBP7-822	LP SG N/CONV BOND 4.3mm -14T 10DO .018 UL	31759
INSBBSP1-221	LP SG N/CON BOND SM 4.3mm -20T 0DO .022 LR	31759
INSBBSP1-222	LP SG N/CON BOND SM 4.3mm -20T 0DO .022 LL	31759
INSBBSP1-821	LP SG N/CON BOND SM 4.3mm -20T 0DO .018 LR	31759
INSBBSP1-822	LP SG N/CON BOND SM 4.3mm -20T 0DO .018 LL	31759
INSBBSP3-221	LP SG N/CON BOND SM 4.3mm -10T 8DO .022 UR	31759
INSBBSP3-222	LP SG N/CON BOND SM 4.3mm -10T 8DO .022 UL	31759
INSBBSP3-821	LP SG N/CON BOND SM 4.3mm -10T 8DO .018 UR	31759
INSBBSP3-822	LP SG N/CON BOND SM 4.3mm -10T 8DO .018 UL	31759
INSBBSP5-221	LP SG N/CON BOND SM 4.3mm -25T 5DO .022 LR	31759
INSBBSP5-222	LP SG N/CON BOND SM 4.3mm -25T 5DO .022 LL	31759
INSBBSP5-821	LP SG N/CON BOND SM 4.3mm -25T 5DO .018 LR	31759
INSBBSP5-822	LP SG N/CON BOND SM 4.3mm -25T 5DO .018 LL	31759
INSBBSP7-221	LP SG N/CON BOND SM 4.3mm -14T 10DO .022 UR	31759
INSBBSP7-222	LP SG N/CON BOND SM 4.3mm -14T 10DO .022 UL	31759
INSBBSP7-821	LP SG N/CON BOND SM 4.3mm -14T 10DO .018 UR	31759
INSBBSP7-822	LP SG N/CON BOND SM 4.3mm -14T 10DO .018 UL	31759
INSBW2-221	LP SG N/CONV WELD 4.3mm -20T 0DO .022 LR	31759
INSBW2-222	LP SG N/CONV WELD 4.3mm -20T 0DO .022 LL	31759
INSBW2-821	LP SG N/CONV WELD 4.3mm -20T 0DO .018 LR	31759
INSBW2-822	LP SG N/CONV WELD 4.3mm -20T 0DO .018 LL	31759
INSBW4-221	LP SG N/CONV WELD 4.3mm -10T 8DO .022 UR	31759
INSBW4-222	LP SG N/CONV WELD 4.3mm -10T 8DO .022 UL	31759
INSBW4-821	LP SG N/CONV WELD 4.3mm -10T 8DO .018 UR	31759
INSBW4-822	LP SG N/CONV WELD 4.3mm -10T 8DO .018 UL	31759
INSBW6-221	LP SG N/CONV WELD 4.3mm -25T 5DO .022 LR	31759
INSBW6-222	LP SG N/CONV WELD 4.3mm -25T 5DO .022 LL	31759
INSBW6-821	LP SG N/CONV WELD 4.3mm -25T 5DO .018 LR	31759
INSBW6-822	LP SG N/CONV WELD 4.3mm -25T 5DO .018 LL	31759
INSBW8-221	LP SG N/CONV WELD 4.3mm -14T 10DO .022 UR	31759
INSBW8-222	LP SG N/CONV WELD 4.3mm -14T 10DO .022 UL	31759
INSBW8-821	LP SG N/CONV WELD 4.3mm -14T 10DO .018 UR	31759
INSBW8-822	LP SG N/CONV WELD 4.3mm -14T 10DO .018 UL	31759
CDBL-211	BT DOUBLE CONV DB LONG ROTH .022 LL	31759



## List of Devices Covered Class IIa Orthodontic Buccal Tubes

Catalog Number	Product Description	GMDN Code
CDBBL-212	BT DOUBLE CONV DB LONG ROTH .022 LR	31759
CDBBL-221	BT DOUBLE CONV DB LONG ROTH .022 UL	31759
CDBBL-222	BT DOUBLE CONV DB LONG ROTH .022 UR	31759
CDBBL-223	BT DOUBLE CONV DB LONG MBT .022 UL	31759
CDBBL-224	BT DOUBLE CONV DB LONG MBT .022 UR	31759
CDBBL-811	BT DOUBLE CONV DB LONG ROTH .018 LL	31759
CDBBL-812	BT DOUBLE CONV DB LONG ROTH .018 LR	31759
CDBBL-821	BT DOUBLE CONV DB LONG ROTH .018 UL	31759
CDBBL-822	BT DOUBLE CONV DB LONG ROTH .018 UR	31759
CDBBL-823	BT DOUBLE CONV DB LONG MBT .018 UL	31759
CDBBL-824	BT DOUBLE CONV DB LONG MBT .018 UR	31759
CDBBS-211	BT DOUBLE CONV DB SHORT ROTH .022 LL	31759
CDBBS-212	BT DOUBLE CONV DB SHORT ROTH .022 LR	31759
CDBBS-221	BT DOUBLE CONV DB SHORT ROTH .022 UL	31759
CDBBS-222	BT DOUBLE CONV DB SHORT ROTH .022 UR	31759
CDBBS-223	BT DOUBLE CONV DB SHORT MBT .022 UL	31759
CDBBS-224	BT DOUBLE CONV DB SHORT MBT .022 UR	31759
CDBBS-811	BT DOUBLE CONV DB SHORT ROTH .018 LL	31759
CDBBS-812	BT DOUBLE CONV DB SHORT ROTH .018 LR	31759
CDBBS-821	BT DOUBLE CONV DB SHORT ROTH .018 UL	31759
CDBBS-822	BT DOUBLE CONV DB SHORT ROTH .018 UR	31759
CDBBS-823	BT DOUBLE CONV DB SHORT MBT .018 UL	31759
CDBBS-824	BT DOUBLE CONV DB SHORT MBT .018 UR	31759
CDBWF-211	BT DOUBLE CONV WELD ROTH .022 LL	31759
CDBWF-212	BT DOUBLE CONV WELD ROTH .022 LR	31759
CDBWF-221	BT DOUBLE CONV WELD ROTH .022 UL	31759
CDBWF-222	BT DOUBLE CONV WELD ROTH .022 UR	31759
CDBWF-223	BT DOUBLE CONV WELD MBT .022 UL	31759
CDBWF-224	BT DOUBLE CONV WELD MBT .022 UR	31759
CDBWF-811	BT DOUBLE CONV WELD ROTH .018 LL	31759
CDBWF-812	BT DOUBLE CONV WELD ROTH .018 LR	31759
CDBWF-821	BT DOUBLE CONV WELD ROTH .018 UL	31759
CDBWF-822	BT DOUBLE CONV WELD ROTH .018 UR	31759
CDBWF-823	BT DOUBLE CONV WELD MBT .018 UL	31759
CDBWF-824	BT DOUBLE CONV WELD MBT .018 UR	31759
CTBWF-2214	BT TRIPLE CONV WELD ROTH .022/.045 HGO UL	31759
CTBWF-2215	BT TRIPLE CONV WELD ROTH .022/.051 HGO UL	31759
CTBWF-2224	BT TRIPLE CONV WELD ROTH .022/.045 HGO UR	31759
CTBWF-2225	BT TRIPLE CONV WELD ROTH .022/.051 HGO UR	31759
CTBWF-2234	BT TRIPLE CONV WELD MBT .022/.045 HGO UL	31759
CTBWF-2235	BT TRIPLE CONV WELD MBT .022/.051 HGO UL	31759
CTBWF-2244	BT TRIPLE CONV WELD MBT .022/.045 HGO UR	31759
CTBWF-2245	BT TRIPLE CONV WELD MBT .022/.051 HGO UR	31759
CTBWF-8214	BT TRIPLE CONV WELD ROTH .018/.045 HGO UL	31759
CTBWF-8215	BT TRIPLE CONV WELD ROTH .018/.051 HGO UL	31759
CTBWF-8224	BT TRIPLE CONV WELD ROTH .018/.045 HGO UR	31759
CTBWF-8225	BT TRIPLE CONV WELD ROTH .018/.051 HGO UR	31759
CTBWF-8234	BT TRIPLE CONV WELD MBT .018/.045 HGO UL	31759
CTBWF-8235	BT TRIPLE CONV WELD MBT .018/.051 HGO UL	31759
CTBWF-8244	BT TRIPLE CONV WELD MBT .018/.045 HGO UR	31759
CTBWF-8245	BT TRIPLE CONV WELD MBT .018/.051 HGO UR	31759
NS2BBP-201	IP SG N/C BOND 3mm 0T 0DO .022 UL/UR	31759
NS2BBP-202	IP SG N/C BOND 3mm 0T 0DO .022 UR/LL	31759
NS2BBP-203	IP SG N/C BOND 3mm -14T0DO .022 UL/LR	31759
NS2BBP-204	IP SG N/C BOND 3mm -14T0DO .022 UR/LL	31759



## List of Devices Covered Class IIa Orthodontic Buccal Tubes

Catalog Number	Product Description	GMDN Code
NS2BBP-211	IP SG N/C BOND 3mm -25T0DO .022 LL	31759
NS2BBP-212	IP SG N/C BOND 3mm -25T0DO .022 LR	31759
NS2BBP-213	IP SG N/C BOND 3mm -20T0DO .022 LL	31759
NS2BBP-214	IP SG N/C BOND 3mm -20T0DO .022 LR	31759
NS2BBP-221	IP SG N/C BOND 3mm -10T0DO .022 UL	31759
NS2BBP-222	IP SG N/C BOND 3mm -10T0DO .022 UR	31759
NS2BBP-801	IP SG N/C BOND 3mm 0T 0DO .018 UL/UR	31759
NS2BBP-802	IP SG N/C BOND 3mm 0T 0DO .018 UR/LL	31759
NS2BBP-803	IP SG N/C BOND 3mm -14T0DO .018 UL/LR	31759
NS2BBP-804	IP SG N/C BOND 3mm -14T0DO .018 UR/LL	31759
NS2BBP-811	IP SG N/C BOND 3mm -25T0DO .018 LL	31759
NS2BBP-812	IP SG N/C BOND 3mm -25T0DO .018 LR	31759
NS2BBP-813	IP SG N/C BOND 3mm -20T0DO .018 LL	31759
NS2BBP-814	IP SG N/C BOND 3mm -20T0DO .018 LR	31759
NS2BBP-821	IP SG N/C BOND 3mm -10T0DO .018 UL	31759
NS2BBP-822	IP SG N/C BOND 3mm -10T0DO .018 UR	31759
INSBBP-201	LP SG N/CONV BOND 4.3mm 0T 0DO .022 UR/LL	31759
INSBBP-202	LP SG N/CONV BOND 4.3mm 0T 0DO .022 UL/LR	31759
INSBBP-801	LP SG N/CONV BOND 4.3mm 0T 0DO .018 UR/LL	31759
INSBBP-802	LP SG N/CONV BOND 4.3mm 0T 0DO .018 UL/LR	31759
INSBBSP-201	LP SG N/CON BOND SM 4.3mm 0T 0DO .022 UR/LL	31759
INSBBSP-202	LP SG N/CON BOND SM 4.3mm 0T 0DO .022 UL/LR	31759
INSBBSP-801	LP SG N/CON BOND SM 4.3mm 0T 0DO .018 UR/LL	31759
INSBBSP-802	LP SG N/CON BOND SM 4.3mm 0T 0DO .018 UL/LR	31759
INSBW-201	LP SG N/CONV WELD 4.3mm 0T 0DO .022 UR/LL	31759
INSBW-202	LP SG N/CONV WELD 4.3mm 0T 0DO .022 UL/LR	31759
INSBW-801	LP SG N/CONV WELD 4.3mm 0T 0DO .018 UR/LL	31759
INSBW-802	LP SG N/CONV WELD 4.3mm 0T 0DO .018 UL/LR	31759
CSBBP-211	BT SG CV Bond 3.5mm -25T 5DO .022 LL6	31759
CSBBP-212	BT SG CV Bond 3.5mm -25T 5DO .022 LR6	31759
CSBBP-213	BT SG CV Bond 3.5mm -20T 0DO .022 LL6	31759
CSBBP-214	BT SG CV Bond 3.5mm -20T 0DO .022 LR6	31759
CSBBP-221	BT SG CV Bond 3.5mm -10T 8DO .022 UL6	31759
CSBBP-222	BT SG CV Bond 3.5mm -10T 8DO .022 UR6	31759
CSBBP-223	BT SG CV Bond 3.5mm -14T 10DO .022 UL6	31759
CSBBP-224	BT SG CV Bond 3.5mm -14T 10DO .022 UR6	31759
CSBBP-811	BT SG CV Bond 3.5mm -25T 5DO .018 LL6	31759
CSBBP-812	BT SG CV Bond 3.5mm -25T 5DO .018 LR6	31759
CSBBP-813	BT SG CV Bond 3.5mm -20T 0DO .018 LL6	31759
CSBBP-814	BT SG CV Bond 3.5mm -20T 0DO .018 LR6	31759
CSBBP-821	BT SG CV Bond 3.5mm -10T 8DO .018 UL6	31759
CSBBP-822	BT SG CV Bond 3.5mm -10T 8DO .018 UR6	31759
CSBBP-823	BT SG CV Bond 3.5mm -14T 10DO .018 UL6	31759
CSBBP-824	BT SG CV Bond 3.5mm -14T 10DO .018 UR6	31759
NS2BBP-2015	IP SG N/C BOND 3mm 0T 5DO .022 UL/LR	31759
NS2BBP-2015E	IP SG N/C BOND E 3mm 0T 5DO .022 LR	31759
NS2BBP-201E	IP SG N/C BOND E 3mm 0T 0DO .022 LR	31759
NS2BBP-2025	IP SG N/C BOND 3mm 0T 5DO .022 UR/LL	31759
NS2BBP-2025E	IP SG N/C BOND E 3mm 0T 5DO .022 LL	31759
NS2BBP-202E	IP SG N/C BOND E 3mm 0T 0DO .022 LL	31759
NS2BBP-2035	IP SG N/C BOND 3mm -14T 5DO .022 UL/LR	31759
NS2BBP-2035E	IP SG N/C BOND E 3mm -14T 5DO .022 LR	31759
NS2BBP-2039	IP SG N/C BOND 3mm -14T 10DO .022 UL/LR	31759
NS2BBP-2039E	IP SG N/C BOND E 3mm -14T 10DO .022 LR	31759
NS2BBP-203E	IP SG N/C BOND E 3mm -14T 0DO .022 LR	31759



## List of Devices Covered Class IIa Orthodontic Buccal Tubes

Catalog Number	Product Description	GMDN Code
NS2BBP-2045	IP SG N/C BOND 3mm -14T 5DO .022 UR/LL	31759
NS2BBP-2045E	IP SG N/C BOND E 3mm -14T 5DO .022 LL	31759
NS2BBP-2049	IP SG N/C BOND 3mm -14T 10DO .022 UR/LL	31759
NS2BBP-2049E	IP SG N/C BOND E 3mm -14T 10DO .022 LL	31759
NS2BBP-204E	IP SG N/C BOND E 3mm -14T 0DO .022 LL	31759
NS2BBP-2115	IP SG N/C BOND 3mm -25T 5DO .022 LL	31759
NS2BBP-2115E	IP SG N/C BOND E 3mm -25T 5DO .022 LL	31759
NS2BBP-211E	IP SG N/C BOND E 3mm -25T 0DO .022 LL	31759
NS2BBP-2125	IP SG N/C BOND 3mm -25T 5DO .022 LR	31759
NS2BBP-2125E	IP SG N/C BOND E 3mm -25T 5DO .022 LR	31759
NS2BBP-212E	IP SG N/C BOND E 3mm -25T 0DO .022 LR	31759
NS2BBP-2135	IP SG N/C BOND 3mm -20T 5DO .022 UR	31759
NS2BBP-213E	IP SG N/C BOND E 3mm -20T 0DO .022 LL	31759
NS2BBP-2145	IP SG N/C BOND 3mm -20T 5DO .022 UL	31759
NS2BBP-214E	IP SG N/C BOND E 3mm -20T 0DO .022 LR	31759
NS2BBP-2215	IP SG N/C BOND 3mm -10T 5DO .022 UL	31759
NS2BBP-2215E	IP SG N/C BOND E 3mm -10T 5DO .022 LR	31759
NS2BBP-2219	IP SG N/C BOND 3mm -10T 8DO .022 UL	31759
NS2BBP-221E	IP SG N/C BOND E 3mm -10T 0DO .022 LR	31759
NS2BBP-2225	IP SG N/C BOND 3mm -10T 5DO .022 UR	31759
NS2BBP-2225E	IP SG N/C BOND E 3mm -10T 5DO .022 LL	31759
NS2BBP-2229	IP SG N/C BOND 3mm -10T 8DO .022 UR	31759
NS2BBP-222E	IP SG N/C BOND E 3mm -10T 0DO .022 LL	31759
NS2BBP-8015	IP SG N/C BOND 3mm 0T 5DO .018 UL/LR	31759
NS2BBP-8015E	IP SG N/C BOND E 3mm 0T 5DO .018 LR	31759
NS2BBP-801E	IP SG N/C BOND E 3mm 0T 0DO .018 LR	31759
NS2BBP-8025	IP SG N/C BOND 3mm 0T 5DO .018 UR/LL	31759
NS2BBP-8025E	IP SG N/C BOND E 3mm 0T 5DO .018 LL	31759
NS2BBP-802E	IP SG N/C BOND E 3mm 0T 0DO .018 LL	31759
NS2BBP-8035	IP SG N/C BOND 3mm -14T 5DO .018 UL/LR	31759
NS2BBP-8035E	IP SG N/C BOND E 3mm -14T 5DO .018 LR	31759
NS2BBP-8039	IP SG N/C BOND 3mm -14T 10DO .018 UL/LR	31759
NS2BBP-8039E	IP SG N/C BOND E 3mm -14T 10DO .018 LR	31759
NS2BBP-803E	IP SG N/C BOND E 3mm -14T 0DO .018 LR	31759
NS2BBP-8045	IP SG N/C BOND 3mm -14T 5DO .018 UR/LL	31759
NS2BBP-8045E	IP SG N/C BOND E 3mm -14T 5DO .018 LL	31759
NS2BBP-8049	IP SG N/C BOND 3mm -14T 10DO .018 UR/LL	31759
NS2BBP-8049E	IP SG N/C BOND E 3mm -14T 10DO .018 LL	31759
NS2BBP-804E	IP SG N/C BOND E 3mm -14T 0DO .018 LL	31759
NS2BBP-8115	IP SG N/C BOND 3mm -25T 5DO .018 LL	31759
NS2BBP-8115E	IP SG N/C BOND E 3mm -25T 5DO .018 LL	31759
NS2BBP-811E	IP SG N/C BOND E 3mm -25T 0DO .018 LL	31759
NS2BBP-8125	IP SG N/C BOND 3mm -25T 5DO .018 LR	31759
NS2BBP-8125E	IP SG N/C BOND E 3mm -25T 5DO .018 LR	31759
NS2BBP-812E	IP SG N/C BOND E 3mm -25T 0DO .018 LR	31759
NS2BBP-8135	IP SG N/C BOND 3mm -20T 5DO .018 UR	31759
NS2BBP-813E	IP SG N/C BOND E 3mm -20T 0DO .018 LL	31759
NS2BBP-8145	IP SG N/C BOND 3mm -20T 5DO .018 UL	31759
NS2BBP-814E	IP SG N/C BOND E 3mm -20T 0DO .018 LR	31759
NS2BBP-8215	IP SG N/C BOND 3mm -10T 5DO .018 UL	31759
NS2BBP-8215E	IP SG N/C BOND E 3mm -10T 5DO .018 LR	31759
NS2BBP-8219	IP SG N/C BOND 3mm -10T 8DO .018 UL	31759
NS2BBP-821E	IP SG N/C BOND E 3mm -10T 0DO .018 LR	31759
NS2BBP-8225	IP SG N/C BOND 3mm -10T 5DO .018 UR	31759
NS2BBP-8225E	IP SG N/C BOND E 3mm -10T 5DO .018 LL	31759



## List of Devices Covered Class IIa Orthodontic Buccal Tubes

Catalog Number	Product Description	GMDN Code
NS2BBP-8229	IP SG N/C BOND 3mm -10T 8DO .018 UR	31759
NS2BBP-822E	IP SG N/C BOND E 3mm -10T 0DO .018 LL	31759
CSBWF-211	BT SINGLE CONV WELD ROTH .022 LL	31759
CSBWF-212	BT SINGLE CONV WELD ROTH .022 LR	31759
CSBWF-213	BT SINGLE CONV WELD MBT .022 LL	31759
CSBWF-214	BT SINGLE CONV WELD MBT .022 LR	31759
CSBWF-221	BT SINGLE CONV WELD ROTH .022 UL	31759
CSBWF-222	BT SINGLE CONV WELD ROTH .022 UR	31759
CSBWF-223	BT SINGLE CONV WELD MBT .022 UL	31759
CSBWF-224	BT SINGLE CONV WELD MBT .022 UR	31759
CSBWF-811	BT SINGLE CONV WELD ROTH .018 LL	31759
CSBWF-812	BT SINGLE CONV WELD ROTH .018 LR	31759
CSBWF-813	BT SINGLE CONV WELD MBT .018 LL	31759
CSBWF-814	BT SINGLE CONV WELD MBT .018 LR	31759
CSBWF-821	BT SINGLE CONV WELD ROTH .018 UL	31759
CSBWF-822	BT SINGLE CONV WELD ROTH .018 UR	31759
CSBWF-823	BT SINGLE CONV WELD MBT .018 UL	31759
CSBWF-824	BT SINGLE CONV WELD MBT .018 UR	31759

\*\*\*end of list