



DECLARATION OF CONFORMITY

Applicable Council Directive.....93/42/EEC (as amended by
2007/47/EC)

Conformity Assessment ProceduresAnnex VII per Article 11-5

Classification.....Class I Transient, per Annex IX
Definition 1.1 and Rule 1

Product Name.....Orthodontic Hand Instruments

GMDN Code33209

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 according to the specified Council Directive.

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

July 27, 2018

Date



List of Devices Covered

Class I Transient Orthodontic Hand Instruments

Catalog Number	Product Description	GMDN Code
652-130	Stealth Omega Tweed Loop Forming Plier	33209
652-131	Stealth Loop Forming Plier	33209
652-132	Stealth Quad Helix Bending Plier	33209
652-133	Stealth Replacement Tip	33209
652-134	Stealth Hex Wrench	33209
652-135	Stealth Replacement Tip	33209
652-136	Stealth Nance Closing Loop Plier	33209
652-138	Stealth Three Jaw Plier	33209
652-139	Stealth Three Jaw Plier	33209
652-141	Stealth Adams Plier	33209
652-142	Stealth Stop Plier	33209
652-144	Stealth Wire Bending Plier	33209
652-145	Stealth Angled Three Jaw Plier – Left	33209
652-146	Stealth Angled Three Jaw Plier – Right	33209
652-147	Stealth Head Gear Plier (Inner Bow)	33209
652-148	Stealth Head Gear Plier (Outer Bow)	33209
652-149	Stealth Arch Forming Plier – Grooved	33209
652-150	Stealth Arch Forming Plier – Non-Grooved	33209
652-151	Stealth Tube Crimping Plier	33209
652-152	Stealth Boon Bracket Positioning Gauge	33209
652-153	Stealth Ligature Tying Plier	33209
652-154	Stealth Elastic Placing Plier – Hook Tip	33209
652-155	Stealth Ligating Plier	33209
652-158	Stealth Mosquito Forceps - Straight	33209
652-159	Stealth Mosquito Forceps – Curved	33209
652-160	Stealth Ligature Director	33209
652-164	Stealth Band Contouring Plier	33209
652-165	Stealth De La Rosa Plier	33209
652-168	Stealth Crown Crimping Plier – Slim	33209
652-172	Stealth Posterior Band Removing Plier – Long	33209
652-175	Stealth Replacement Delrin Tip 3/pk.	33209
652-179	Stealth Replacement Metal Tip 1/pk.	33209
652-180	Stealth Replacement Delrin Tip 1/pk.	33209
652-181	Stealth Band Pusher – Trihedral Handle	33209
652-182	Stealth Separating Plier	33209
652-183	Stealth Adhesive Removing Plier	33209
652-184	Stealth Goose Neck Plier	33209
652-185	Stealth Replacement Tip, Adhesive Removing Plier	33209
652-186	Stealth Tie Back Plier	33209
652-187	Stealth Lingual How Plier	33209
652-188	Stealth Distal End Slim Long Flush Cut	33209
652-189	Stealth Lingual Pin & Ligature Cutter Angled Tip	33209
652-190	Mirror Lite Intro Kit	33209
652-191	Mirror Lite Handle	33209
626-100	LANCER BRACKET PLACER CHROME	33209
626-100HWB	LANCER HARD WIRE CUTTER15 DEGREES	33209
626-101	1mm Step Plier	33209
626-102	Deluxe Bracket Holder	33209
626-103	LANCER STOP PLIER	33209
626-104	BRACKETIZER	33209
626-115	LANCER HOOK CRIMPING	33209
626-116	KEAT TWEEZER	33209



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Catalog Number	Product Description	GMDN Code
626-117	LANCER PIN&LIG CUTTER 45DEGREES	33209
626-118	LANCER PIN&LIG CUTTER 15DEGREES	33209
626-119	LANCER PIN&LIG CUTTER 7DEGREES	33209
626-120	LANCER MICRO PIN&LIG CUTTER	33209
626-121	LANCER HARD WIRE CUTTER	33209
626-122	LANCER DISTAL END SAFETYCUTTER	33209
626-122L	LANCER DISTAL END SAFETYCUTTER LONG	33209
626-123	LANCER HOW-SMALL TIPS	33209
626-124	LANCER WEINGART ANGLED	33209
626-125	LANCER THREE JAW PLIER	33209
626-126	LANCER HOLLOW CHOP PLIER	33209
626-127	LANCER TWEED LOOP FORMING	33209
626-129	LANCER BIRD BEAK	33209
626-130	LANCER LINGUAL ARCH FORMING	33209
626-131	LANCER TORQUE PLIER	33209
626-133	LANCER BAND REMOVING-SHORT	33209
626-134	LANCER BAND REMOVINGLONG	33209
626-134T	LANCER REPLACEMENT PAD 4.6mm 3/PK	33209
626-135	LANCER BRACKET REMOVINGPLIER	33209
626-135T	LANCER REPLACEMENT BLADEFOR REMOVER	33209
626-136	LANCER TWEED PLIER	33209
626-138	LANCER ULTRA FINE TIP STR. MATHIEU	33209
626-140	LANCER HOW OFFSET TIPS	33209
626-150	LANCER FINISHING PLIER $\frac{3}{4}$ mm	33209
626-306	LANCER MOSQUITO HEMOSTAT	33209
626-309	LANCER BRACKET PLACING-SATIN	33209
626-312	LANCER UTILITY INSTRUMENT 5	33209
626-346	LANCER BRACKET REMOVING-STRAIGHT	33209
626-352T	LANCER TWEED LOOP FORMING TIP	33209

***end of list