



DECLARATION OF CONFORMITY

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

Conformity Assessment Procedures Annex VII per Article 11-5

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

Product Name..... Orthodontic Hand Instruments

GMDN Code 33209

Catalog Numbers See Attached List of Devices

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Certificate Number CE 02013

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) and carries the CE marking accordingly.

Regulatory Affairs Manager

12 February, 2020

Date



List of Devices Covered

Class I Transient Orthodontic Hand Instruments

Catalog Number	Product Description	GMDN Code
631-023	Lancer Bird Break Square Serrated Tips Plier	33209
631-301	Lancer Optical Plier	33209
631-307	Lancer Band Pusher	33209
631-114	Lancer Band Pusher Blue	33209
631-115	Lancer Band Pusher Green	33209
631-316	Lancer Bracket Positioning .018	33209
631-317	Lancer Bracket Positioning .022	33209
631-320	Lancer Gram Gauge-Dontrix 500Gm	33209
631-330	Lancer Bracket Placing-Slim	33209
652-001	Stealth Distal End Cutter-Slim	33209
652-002	Stealth Distal End Cutter-Slim Handle	33209
652-003	Stealth Regular Pin and Ligature Cutter	33209
652-004	Stealth Pin & Ligature Cutter-Premium	33209
652-006	Stealth Hard Wire Cutter	33209
652-101	Stealth Distal End Safety Cutter - Regular	33209
652-109	Stealth Wire Cutter – Regular w/ Spring	33209
652-011	Stealth Loop Forming Plier w/ Tungsten Carbide Tip	33209
652-012	Stealth Tweed Arch Bending Plier	33209
652-013	Stealth Heavy Three Jaw Plier	33209
652-014	Stealth Hollow Chop Plier	33209
652-017	Stealth Hook Crimping Plier	33209
652-018	Stealth Bracket Placing Tweezer	33209
652-019	Stealth DB Bracket Removing Plier – Angled	33209
652-023	Stealth Ligature Tying Plier – Coon Style	33209
652-024	Stealth Mathieu Plier	33209
652-025	Stealth Posterior Band Removing Plier	33209
652-028	Stealth Self-Ligating Instrument	33209
652-113	Stealth How Plier Regular	33209
652-115	Stealth How Plier Offset	33209
652-117	Stealth Weingart Plier Regular	33209
652-118	Stealth Weingart Plier w/ Tungsten Carbide Tip	33209
652-121	Stealth Bird Beak Pliers w/ Tungsten Carbide Tip	33209
652-124	Stealth Light Wire Plier w/ Grooved Square Tip	33209
652-126	Stealth Light Wire Plier – Regular	33209
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



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Catalog Number	Product Description	GMDN Code
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
652-001HD	Stealth Premium Slim Distal end Safety Cutter	33209
652-002HD	Stealth Premium Slim Long Distal end Safety Cutter	33209
652-003HD	Stealth Premium Pin and Ligature Cutter	33209
652-004HD	Stealth Miniature Pin and Ligature Cutter	33209
652-006HD	Stealth Premium Hard Wire Cutter	33209
652-025HD	Stealth Premium Band Removing Plier	33209
626-100	LANCER BRACKET PLACER CHROME	33209
626-1000HWB	LANCER HARD WIRE CUTTER 15 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
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 SAFETY CUTTER	33209
626-122L	LANCER DISTAL END SAFETY CUTTER 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 REMOVING LONG	33209
626-134T	LANCER REPLACEMENT PAD 4.6mm 3/PK	33209
626-135	LANCER BRACKET REMOVING PLIER	33209
626-135T	LANCER REPLACEMENT BLADE FOR 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 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