



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 per Annex IX
Definition 1.1 and Rule 1

Product Name..... Orthodontic Headgear

GMDN Code 33209

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

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 IIa Orthodontic Head Gear

Catalog Number	Product Description	GMDN Code
830-123	HIGH PULL HEAD CAP Black/Pink	31757
830-124	HIGH PULL HEAD CAP Black/Black	31757
830-125	HIGH PULL HEAD CAP Black/Light Blue	31757
830-126	HIGH PULL HEAD CAP Black/Teal	31757
830-127	HIGH PULL HEAD CAP Black/Purple	31757
830-306	HIGH PULL HEAD CAP w/ 600g SAFETY MODULE	31757
830-312	EQUA-PULL HIGH PLL HEAD CAPS	31757
830-512	HIGH PULL STRAPS – EXTRA SMALL	31757
830-513	HIGH PULL STRAPS – SMALL	31757
830-514	HIGH PULL STRAPS – MEDIUM	31757
830-515	HIGH PULL STRAPS – LARGE	31757
830-304	HIGH PULL COTTON HEAD CAP	31757
830-601	SAFETY MODULES BLUE 450G	31757
830-602	SAFETY MODULES BLACK 450G	31757
830-606	SAFETY MODULES BLUE 600G	31757
830-607	SAFETY MODULES BLACK 600G	31757
830-608	SAFETY MODULES GLOW 600G	31757
837-130	WEDGE NECK PAD BLACK	31757
837-131	WEDGE NECK PAD BLACK W/MODULE	31757
830-113	LANCER CERVICAL HEADGEAR BLACK/PINK (5 PK.)	31757
830-114	LANCER CERVICAL HEADGEAR BLACK/BLACK (5 PK.)	31757
830-115	LANCER CERVICAL HEADGEAR BLACK/LIGHT BLUE (5 PK.)	31757
830-116	LANCER CERVICAL HEADGEAR BLACK/TEAL (5 PK.)	31757
830-117	LANCER CERVICAL HEADGEAR BLACK/PURPLE (5 PK.)	31757
830-311	EQUA-PULL CERVICAL STRAPS ASSORTED (5 PK.)	31757
830-511	CERVICAL STRAP BLUE DENIM (5 PK.)	31757
830-202	EQUA PULL SAFETY MODULE BLACK 12 OZ. (10 PK.)	31757
830-300	CERVICAL STRAP NYLON W/MODULE (EA.)	31757
830-301	CERVICAL STRAP COTTON (5 PK.)	31757
830-302	CERVICAL STRAP COTTON W/MODULE (EA.)	31757

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