



## 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.  
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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 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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