



## 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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Notified Body ..... BSI  
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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

28 March, 2019

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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