



## DECLARATION OF CONFORMITY

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

Conformity Assessment Procedures ..... Annex V per Article 11.2

Classification ..... Class IIa per Annex IX, Rule 5

Product Name ..... Orthodontic Face Bows

GMDN Code ..... 40468

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 and Notified Body Number (2797) according to the specified Council Directive.

Certificate Number ..... CE 02013

Date CE Certificate First Issued ..... 16 July 1998

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).

Regulatory Affairs Manager

12 February, 2020

Date



## List of Devices Covered Class IIa Orthodontic Face Bows

<b>Catalog Number</b>	<b>Product Description</b>	<b>GMDN Code</b>
711-111	FACEBOW-ADJ SIZE-1 SHT YELLOW 1/PK	40468
711-112	FACEBOW-ADJ SIZE-2 SHT RED 1/PK	40468
711-113	FACEBOW-ADJ SIZE-3 SHT PINK 1/PK	40468
711-114	FACEBOW-ADJ SIZE-4 SHT BLUE 1/PK	40468
711-115	FACEBOW-ADJ SIZE-5 SHT GREEN 1/PK	40468
711-116	FACEBOW-ADJ SIZE-6 SHT WHITE 1/PK	40468
711-201	FACEBOW-PLAIN SUPER SHORT	40468
711-202	FACEBOW-PLAIN SHORT	40468
711-203	FACEBOW-PLAIN REGULAR	40468
711-204	FACEBOW-PLAIN LONG	40468
711-211	FACEBOW-ADJ SIZE-1 REG YELLOW	40468
711-212	FACEBOW-ADJ SIZE-2 REG RED	40468
711-213	FACEBOW-ADJ SIZE-3 REG PINK	40468
711-214	FACEBOW-ADJ SIZE-4 REG BLUE	40468
711-215	FACEBOW-ADJ SIZE-5 REG GREEN	40468
711-216	FACEBOW-ADJ SIZE-6 REG WHITE	40468

\*End of list