



## EC 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 ..... Crimpable Orthodontic Tubes

GMDN Code ..... 41678

Catalog Numbers ..... 430-022, 017x025 Crimp. Tube  
430-023, 019x025 Crimp. Tube

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 (0086) 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

July 31, 2018

Date