



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.
Vista Technology Center
1493 Poinsettia Avenue, Suite 143
Vista, California 92081 USA

European Representative Kristal S.r.l.
Via Grande 225
Livorno 57123
Italy
Tel: +39 024453401
Fax: +39 0248408305
e-mail: info@kristalsrl.net

Notified Body BSI
Kitemark Court
Davey Avenue, Knowlhill
Milton Keynes, MK5 8PP
United Kingdom

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 13, 2017
Date