



EC DECLARATION OF CONFORMITY

Applicable Council Directive..... 93/42/EEC (as amended)

Conformity Assessment Procedures Annex V per Article 11-2

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

Product Name..... Orthodontic Protraction Face Mask

GMDN Code 31757

Catalog Numbers 830-704L: Protraction Face Mask, Lilac
830-704B: Protraction Face Mask, Blue

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.

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 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