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 830-715: Standard Face Mask, Hearts 830-716: Standard Face Mask, Abstract 830-721: Standard Face Mask, Leopard 830-711: Standard Face Mask, Spider 830-720: Standard Face Mask, Zebra
Manufacturer Name and Address	Lancer Orthodontics, Inc. 2726 Loker Avenue West Carlsbad, California 92010 USA
European Representative	Kristal S.r.l. Via Claudio Cogorano 25 IT-57123 Livorno (LI) Italy Tel: +39 024453401 Fax: +39 0248408305 e-mail: info@kristalsrl.net
Notified Body	BSI Say Building John M. Keynesplein 9 1066 EP Amsterdam The Netherlands

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 Vista, Carlsbad 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

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