



DECLARATION OF CONFORMITY

Applicable Council Directive..... 93/42/EEC (as amended)
Conformity Assessment Procedures Annex VII per Article 11-2
Classification..... Class IIa per Annex IX, Rule 5
Product Name..... Orthodontic Retainer Case
GMDN Code 31757
Catalog Numbers 825-106: Retainer Case Regular, Turquoise
825-103: Retainer Case Regular, Red
825-104: Retainer Case Regular, Blue
825-503: Retainer Case Regular, Neon Pink
825-504: Retainer Case Regular, Neon Purple

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 according to the specified Council Directive.

Certificate Number CE 02013
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