


DECLARATION OF CONFORMITY

Applicable Council Directive..... 93/42/EEC (as amended by M5)
Conformity Assessment Procedures Annex V per Article 11-2(b)
Classification..... Class I per Annex IX, Rule 5
Product Name..... Orthodontic Patient Home Care Kit
Catalog Number..... Blue: 826-01
Red: 826-02
Purple: 826-03
Green: 826-04
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.
Livorno (LI) Via Claudio
Cogorano 25 CAP 75123
Stradario 03530
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, 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

28 March, 2019

Date