

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. 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
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) and carries the CE marking accordingly.

Regulatory Affairs Manager Date

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