

## 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.  
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USA

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Notified Body ..... BSI  
Say Building  
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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