



## DECLARATION OF CONFORMITY

Applicable Council Directive.....93/42/EEC (as amended by  
2007/47/EC)

Conformity Assessment Procedures .....Annex V per Article 11-2

Classification.....Class IIa per Annex IX, Rule 5

Product Name.....Rapid Palatal Expander

GMDN Code .....35310

Catalog Numbers .....See Attached List of Devices

Manufacturer Name and Address.....Lancer Orthodontics, Inc.  
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Carlsbad, California 92010  
USA

European Representative .....Kristal S.r.l.  
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Notified Body .....BSI  
Say Building  
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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 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



## List of Devices Covered Class IIa Rapid Palatal Expander

Catalog Number	Product Description	GMDN Code
620-001T	RPE PHILOSOPHY 1 ACT KEY TIP/EA	35310
620-002	RPE PHILOSOPHY 1 BENDING TOOL/EA	35310
620-004	RPE PHILOSOPHY 1 SIZE 4	35310
620-006	RPE PHILOSOPHY 1 SIZE 6	35310
620-008	RPE PHILOSOPHY 1 SIZE 8	35310
620-010	RPE PHILOSOPHY 1 SIZE 10	35310
620-013	RPE PHILOSOPHY 1 SIZE 13	35310
620-014	RPE PHILOSOPHY 1 SIZE 4 10/PK	35310
620-016	RPE PHILOSOPHY 1 SIZE 6 10/PK	35310
620-018	RPE PHILOSOPHY 1 SIZE 8 10/PK	35310
620-020	RPE PHILOSOPHY 1 SIZE 10 10/PK	35310
620-023	RPE PHILOSOPHY 1 SIZE 13 10/PK	35310
620-024	RPE PHILOSOPHY 1 SIZE 4 100/PK	35310
620-026	RPE PHILOSOPHY 1 SIZE 6 100/PK	35310
620-028	RPE PHILOSOPHY 1 SIZE 8 100/PK	35310
620-030	RPE PHILOSOPHY 1 SIZE 10 100/PK	35310
620-033	RPE PHILOSOPHY 1 SIZE 13 100/PK	35310
620-100	RPE PHILOSOPHY 1 PT. KEY 100/PK	35310
620-110	RPE PHILOSOPHY 1 PT. KEY 10/PK	35310
620-111	RPE PHILOSOPHY 1 PT. KEY EA	35310

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