



## DECLARATION OF CONFORMITY

Applicable Council Directive..... 93/42/EEC (as amended)  
Conformity Assessment Procedures ..... Annex V per Article 11-2  
Classification..... Class IIa per Annex IX, Rule 5  
Product Name..... Orthodontic Springs  
GMDN Code ..... 31797  
Catalog Numbers ..... See Attached List of Devices  
Manufacturer Name and Address..... Lancer Orthodontics, Inc.  
2726 Loker Avenue West  
Carlsbad, California 92010  
USA  
European Representative ..... Kristal S.r.l.  
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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 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).

  
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Regulatory Affairs Manager

12 February, 2020  
Date



## List of Devices Covered Class IIa Orthodontic Springs

Catalog Number	Product Description	GMDN Code
410-200	NT POWER SPRING KIT – 36 PC.	31797
410-141	NT POWER OPENING SPRING LIGHT (.009 WIRE)	31797
410-142	NT POWER OPENING SPRING MEDIUM (.010 WIRE)	31797
410-143	NT POWER OPENING SPRING HEAVY (.012 WIRE)	31797
410-108	NT POWER CLOSING SPRING .010 W/.030 LUMEN – 9MM	31797
410-109	NT POWER CLOSING SPRING .010 W/.030 LUMEN – 12MM	31797
410-306	GOODMAN TORQUING SPRING (GTS) KIT	31797
410-302	GOODMAN TORQUING SPRING (GTS) SMALL	31797
410-304	GOODMAN TORQUING SPRING (GTS) LARGE	31797
015-507	STAINLESS STEEL OPENING SPRING .007 X .025	31797
015-518	STAINLESS STEEL OPENING SPRING .008 X .030	31797
015-519	STAINLESS STEEL OPENING SPRING .009 X .030	31797
015-520	STAINLESS STEEL OPENING SPRING .010 X .030	31797
015-530	STAINLESS STEEL OPENING SPRING .010 X .036	31797
015-540	STAINLESS STEEL OPENING SPRING .009 X .040	31797
015-719	STAINLESS STEEL CLOSED SPRING .009 X .030	31797
015-133	UPRIGHTING SPRING UR/LL .016 5MM ARM	31797
015-134	UPRIGHTING SPRING UL/LR .016 5MM ARM	31797
468-102	NEED SEPARATING SPRINGS	31797
550-300	LOKAR MOLAR DISTALIZER	31797

\*\*\*end of list