



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..... Orthodontic Wire Products

Catalog Numbers & GMDN Codes

Catalog Number	Product Description	GMDN Code
014-101	SS Closed Hook .016 x .016	35439
014-102	SS Closed Hook .015 x .025	35439
014-103	SS Closed Hook .036	35439
014-104	SS Stops 2mm length for wires .012 to .018	35439
014-114	SS Crimpable Ball Hook	35439
577-301	SS Steiner Spring Wedge	31797

Manufacturer Name and Address..... Lancer Orthodontics
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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).

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Regulatory Affairs Manager 12 March 2020
Date