



DECLARATION OF CONFORMITY

Applicable Council Directive 93/42/EEC (as amended by M5)
Conformity Assessment Procedures Annex V per Article 11-2
Classification..... Class IIa per Annex IX, Rule 5
Product Name Straight Forward Philosophy SFP® Kit
GMDN Codes See Attached Kit Component Listing
Catalog Number..... 268-965
Manufacturer Name and Address..... Lancer Orthodontics, Inc.
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This product is marked with the CE Marking and Notified Body Number (0086) according to the specified Council Directive.

The undersigned hereby declares, on behalf of Lancer Orthodontics, Inc. of Vista, 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).

Certificate Number CE 02013
Date CE Certificate First Issued 16 July 1998
Date of Expiry 15 July 2023

Regulatory Affairs Manager

July 31, 2018
Date



List of Devices Covered
Class IIa SFP® Easy Kit REF 268-965

Kit Component Catalog Number	Kit Component Description	GMDN Code
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Ceramic Brackets

231-501	Optyc Central UR	58937
231-502	Optyc Central UL	58937
231-511	Optyc Lateral UR	58937
231-512	Optyc Lateral UL	58937
231-521	Optyc Cuspid UR	58937
231-522	Optyc Cuspid UL	58937

Stainless Steel Brackets

268-531	Praxis 2.0 SFP UR 4/5	46581
268-532	Praxis 2.0 SFP UL 4/5	46581
268-545	Praxis 2.0 SFP L1	46581
268-546	Praxis 2.0 SFP L2	46581
268-551	Praxis 2.0 SFP LR 3	46581
268-552	Praxis 2.0 SFP LL 3	46581
268-561	Praxis 2.0 SFP LR 4	46581
268-562	Praxis 2.0 SFP LL 4	46581
268-571	Praxis 2.0 SFP LR 5	46581
268-572	Praxis 2.0 SFP LL 5	46581
268-501	Praxis 2.0 SFP UR1	46581
268-502	Praxis 2.0 SFP UL1	46581
268-511	Praxis 2.0 SFP UR2	46581
268-512	Praxis 2.0 SFP UL2	46581
268-521	Praxis 2.0 SFP UR3	46581
268-522	Praxis 2.0 SFP UL3	46581

Buccal Tubes

3DL2-SN01	Velocity UR6	31759
3DL2-SN02	Velocity UL6	31759
3DL2-SN03	Velocity LR6	31759
3DL2-SN04	Velocity LL6	31759

Wires

54TU-014	.014U Thermal NiTi	16204
54TL-014	.014L Thermal NiTi	16204
54TU-016	.016U Thermal NiTi	16204
54TL-016	.016L Thermal NiTi	16204
54TU-1622	.016 X .022 U Thermal NiTi	16204
54TL-1622	.016 X .022 L Thermal NiTi	16204
51TU-1622	.016 X .022 U Stainless Steel	16204
51TL-1622	.016 X .022 L Stainless Steel	16204
56TU-1925	.019 X .025 U Beta Titanium	16204
56TL-1925	.019 X .025 L Beta Titanium	16204
50TU-1725	.017 X .025 U NiTi	16204
50TL-1725	.017 X .025 L NiTi	16204
51TU-018	.018 U Stainless Steel	16204
51TL-018	.018 L Stainless Steel	16204

Elastomerics

EST-00	Velocity Short Ligature Ties 1 Pack (Assorted Colors)	62074
ECC-29	Velocity Chain Continuous 1 Spool (Pearl Colors)	62074

***end of list