



EC CERTIFICATE

American Orthodontics Corp

3524 Washington Avenue
Sheboygan, WI 53081 United States

Production Quality Assurance System Approval Certificate

Annex V, section 3 of Council Directive 93/42/EEC concerning medical devices

Scope of Certificate:

Manufacture of non-sterile orthodontic wire devices.

Device Classification:
Ila

G/UMDN Code:
See Attachments

Device Descriptions:
See Attachments

Model Type:
See Attachments

We hereby declare that an examination of the production quality assurance system has been carried out per report SR3710636, following the requirements of the national legislation to which the undersigned is subject, transposing Annex V of Council Directive 93/42/EEC on Medical Devices. We certify that the production quality assurance system conforms with the relevant provisions of the aforementioned directive and is subject to periodic surveillance as required by 93/42/EEC, Annex V, Section 4. For Class IIb & III devices where they are covered by this certificate, an EC Design Examination certificate according to 93/42/EEC, Annex III is required. This certificate is issued with 2 attachments listing model numbers covered by this certificate.

File Number A4041
Certificate No. 859.170201

Cycle Start Date 01 February 2017
Effective Date 01 February 2017
Expiry Date 04 March 2019

Authorised by

Deborah Stubbs
Certification Manager

For and on Behalf of UL International (UK) Ltd

Notified Body
0843



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Attachment 1 of 2

The products detailed below are covered under the scope of this certificate

Product Family	Product Sub-Group	Model/Type	Classification	G/UMDN Code
Fixed & Functional	Orthodontic Appliance System, Adjustable	Palatal Arches	Ila	41678
Orthodontic Wire	Orthodontic Wire	Beta Titanium Wire	Ila	16204
		Stainless Steel Wire	Ila	16204
		Stainless Steel Multi-Strand	Ila	16204
		Force Two NiTi Wire	Ila	16204
		Gold Tone	Ila	16204
		Gold Coated	Ila	16204
		Orthodontic Wire	Orthodontic Ligature	Kobayashi Hooks
Orientation Pin	Ila			41677

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Attachment 2 of 2

The products detailed below are covered under the scope of this certificate

Product Family	Product Sub-Group	Model/Type	Classification	G/UMDN Code
Orthodontic Wire-Springs	Orthodontic Spring	Nickel Titanium Memory Springs	Ila	31797
		Stainless Steel Springs	Ila	31797
		Uprighting Spring	Ila	31797
		Rotation Spring	Ila	31797
		Compliance Spring	Ila	31797
		Kilroy Spring	Ila	31797
		Auxiliary Light Torquing Arch	Ila	31797
		NiTi Springs	Ila	31797
		Ulysses/Extrusion Spring	Ila	31797

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