



EC CERTIFICATE

American Orthodontics Corp

3524 Washington Avenue
Sheboygan, WI 53081 United States

Full Quality Assurance System Approval Certificate

Annex II (excluding section 4.0) of Council Directive 93/42/EEC concerning medical devices

Scope of Certificate:

Design and manufacture of 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 full 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 II (with the exemption of section 4) of Council Directive 93/42/EEC on Medical Devices. We certify that the full 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 II, Section 5. For Class III devices where they are covered by this certificate, an EC Design Examination certificate according to 93/42/EEC, Annex II, Section 4 is required. This certificate is issued with 1 attachments listing model numbers covered by this certificate.

File Number A4041
Certificate No. 858.170201

Cycle Start Date 01 February 2017
Effective Date 01 February 2017
Expiry Date 17 September 2018

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 1

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	Orthodontic Wire	Therma-Ti®	Ila	16204
		Therma-Ti® Lite	Ila	16204
		Therma-Ti® "D"	Ila	16204
		Tritanium™	Ila	16204
		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
Orthodontic Wire-Springs	Orthodontic Spring	Nickel Titanium Memory Springs	Ila	31797
		NiTi Springs	Ila	31797

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