

EC CERTIFICATE

Number: 2113337CE01

Production Quality Assurance

Directive 93/42/EEC on Medical devices, Annex V

(Devices in Class IIa, IIb or III and Devices in Class I with measuring function)

Manufacturer:

Hespeler Orthodontics Limited

298 Shepherd Avenue
N3C 1V1 Cambridge, Ontario
Canada

For the product category(ies)

Components for Orthodontic Realignment of Teeth, including Wires, Brackets, and Buccal Tubes comprising the SPEED System™

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

0344

Documents that form the basis of this certificate:

Certification Notice 2113337CN, initially dated May 19, 2008
Addendum, initially dated June 1, 2011

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for the manufacture and final inspection, that covers the aspects of manufacture concerned with the conformity of the devices with metrological requirements, for the above mentioned product category in accordance to the provisions of Annex V Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. For placing on the market of Class III or Class IIb devices an additional EC type-examination certificate according to Annex III is mandatory. The necessary information related to the quality assurance system of the manufacturer, including facilities and the reference to the relevant documentation of the products concerned and the assessments performed, are stated in the Certification Notice, which forms an integrative part of this certificate.

This certificate is valid until: **June 1, 2020**
Issued for the first time: November 16, 2005
Reissued: June 1, 2017

DEKRA Certification B.V.



drs. G.J. Zoetbrood
Managing Director



ing. A.A.M. Laan
Certification Manager

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DEKRA Certification B.V. is Notified Body with ID no 0344

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ADDENDUM

Belonging to certificate: 2113337CE01

1/1

CE MARKING OF CONFORMITY MEDICAL DEVICES

Components for Orthodontic Realignment of Teeth, including Wires, Brackets, and Buccal Tubes comprising the SPEED System™

Issued to:

Hespeler Orthodontics Limited

**298 Shepherd Avenue
N3C 1V1 Cambridge, Ontario
Canada**

This certificate covers the following product(s):

The SPEED System Metal, Orthodontic Braces (Class IIa)

Initial date: June 1, 2011

Revision date: May 18, 2017

DEKRA Certification B.V.

A blue ink signature of drs. G.J. Zoetbrood, written in a cursive style.

drs. G.J. Zoetbrood
Managing Director

A blue ink signature of ing. A.A.M. Laan, written in a cursive style.

ing. A.A.M. Laan
Certification Manager

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