

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
Cambridge, Ontario N3C 1V1
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

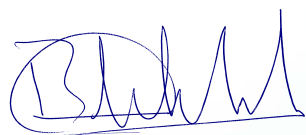
Documents that form the basis of this certificate:

Certification Notice 2113337CN, initially dated 19 May 2008
Addendum, initially dated 1 June 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: **26 May 2024**
Issued for the first time: 16 November 2005
Reissued: 13 April 2020

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.A. van Vugt
Certification Manager

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

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
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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
Cambridge, Ontario N3C 1V1
Canada**

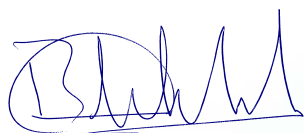
This certificate covers the following product(s):

The SPEED System™ Metal, Orthodontic Braces (Class IIa)

Initial date: 1 June 2011

Revision date: 18 May 2017

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.A. van Vugt
Certification Manager

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