

CERTIFICATE

Number: **3826580**

The management system of:

Hespeler Orthodontics Limited

298 Shepherd Avenue
Cambridge, Ontario N3C 1V1
Canada

Manufacturer Facility Identifier: F004093

Conforms with the following standard and regulatory requirements:

ISO 13485:2016

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002 and Schedule 3 Part 4 -
Production Quality Assurance Procedure

Canada: Medical Devices Regulations - Part 1- SOR 98/282

United States: 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D and 21 CFR 820

Scope:

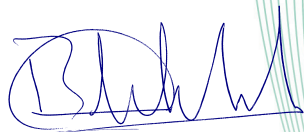
Manufacture and distribution of metal orthodontic brackets and related components for an alignment system in the area of orthodontics.

Certificate expiry date: 2026-05-18

Certificate effective date: 2023-05-18

Certified since: 2020-05-18

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.M.A. McKenzie
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed

The validation of the validity of this certificate can be checked through DEKRA's website using the following link:

<https://www.dekra-product-safety.com/en/certified-organizations>

DEKRA Certification B.V. is recognized under the Medical Devices Single Audit Program.

