EC CERTIFICATE

Number: 3902340CE01

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4)
(Devices in Class IIa, IIb or III)

Manufacturer:

Align Technology Ltd.

3 Ariel Sharon Boulevard
Or-Yehuda 6037606
Israel

For the product category(ies)

Intra-oral optical impression (CAD/CAM) system for dental fabrication feature and Near Infrared (NIR) feature intended for use as an aid in the detection and diagnosis of dental caries

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 3901332CN, initially dated 14 September 2015
Addendum, initially dated 10 December 2019

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 design, manufacture and final inspection for the above mentioned product category in accordance to the provisions of Annex II of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. For placing on the market of Class III devices an additional EC design examination certificate according to Annex II (4) is mandatory. The necessary information related to the quality management 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: 1 May 2024
Issued for the first time: 10 December 2019

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

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ADDENDUM

Belonging to certificate: 3902340CE01

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Intra-oral optical impression (CAD/CAM) system for dental fabrication feature and Near Infrared (NIR) feature intended for use as an aid in the detection and diagnosis of dental caries

Issued to:

Align Technology Ltd.
3 Ariel Sharon Boulevard
Or-Yehuda 6037606
Israel

This certificate covers the following product(s):

- iTero Element 5D Dental Imaging System (Class IIa)

Initial date: 10 December 2019

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

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