align

invisalign | iTero

CRT-400000-02, Rev. R

EU MDR Declaration of Conformity (DoC)

Manufacturer:	Align Technology Ltd. 1 Yitzhak Rabin Rd., Petach Tikva, 4925110 Israel
Manufacturer SRN:	IL-MF-000000745
Authorized Representative:	Align Technology, BV. Herikerbergweg 312 1101 CT, Amsterdam The Netherlands
Authorized Representative SRN:	NL-AR-000000061
Notified Body:	Not applicable. The iTero Element Family System is Class I self-certified for CE marking. The company's quality management system is certified for EN ISO 13485 by DEKRA Certification B.V., Arnhem, The Netherlands, NB Identification Number 0344
Device basic UDI-DI:	081606302ELEMENT6L
GMDN Codes:	38597 Dental CAD/CAM system, chairside
EMDN	Z110601 Laser imaging scanner
Product and Trade name:	iTero Element family
Product Code / Catalogue Number:	See annex

| Align Technology Ltd., 1 Yitzhak Rabin Rd., Petach Tikva 4925110 Israel; Tel: +972-3-634-1441; Fax: +972-3-634-1440 |

Intended Purpose:	The iTero Element 2, iTero Element Flex and iTero Element 2 Plus systems are intra-oral scanners with the following features and intended use: • The optical impression (CAD/CAM) feature of scanner is intended/indicated for use to record the topographical images of teeth and oral tissue. Data generated from iTero may be used in conjunction with the production of dental devices (e.g., aligners, braces, appliances, etc.) and accessories. • iTero software is used with the iTero scanner in capturing 3D digital impressions of teeth, oral soft tissue and structures, and bite relationship. The software controls the processing of the data, facilitating the integration of data, and exporting of the data for CAD/CAM fabrication of dental restorations, orthodontic devices, abutments, and accessories. In addition to scan data, various patient and case information can be imported/exported or used for simulation purposes. Other functions are available for verification and service of the system, and to serve as an order management tool.
Conformity Assessment Procedure:	Annex IV together with Article 19 of the EU MDR 2017/745.
Conformity Assessment Certificate(s):	Not Applicable, Class I self-certified for CE marking
Risk Class:	Class I according to Rule 13 of Annex VIII of Medical device Regulation (EU) 2017/745 - Type of device o Active medical device - Duration of Use o Transient, less than 60 min iTero Element Scanner Sleeves – Rule 5
Common Specifications:	None

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Statement:

According to Article 19 and Annex IV of the EU Medical Device Regulation 2017/745, Align Technology Ltd. hereby declares under its sole responsibility that the products specified herein conform with the provisions of the EU Medical Device Regulation 2017/745 which applies to them, and the following relevant Union Legislation that provides for the issuing of an EU Declaration of Conformity.

Aviva Touati

Director Regulatory Affairs,

PRRC (Person Responsible for Regulatory Compliance)

Israel

Date: 26 February 2025

Align Technology LTD
512020934

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Annex

Product List

Product Code / Catalogue Number	Product and Trade name	Device UDI-DI
202965	iTero Element 2 • Scanning unit • PC Panel • Wheel Stand • iTero Element Software • iTero Element Scanner Sleeve • Counter Stand • Articulator	00816063020288
212095	iTero Element 2 • Scanning unit • PC Panel • Wheel Stand • iTero Element Software • iTero Element Scanner Sleeve • Articulator	00816063020912
218556	iTero Element 2 Paired Unit w/o accessories • Scanning unit PC Panel • Wheel Stand • iTero Element Software • iTero Element Scanner Sleeve • Articulator	00816063022480
202933	iTero Element 2 DOA • Scanning unit • PC Panel • iTero Element Software • iTero Element Scanner Sleeve	00816063022046
202964	iTero Element Flex • Scanning unit • Hub • iTero Element Software • iTero Element Scanner Sleeve • Articulator	00816063020295
212094	iTero Element Flex • Scanning unit • Hub • iTero Element Software • iTero Element Scanner Sleeve • Articulator	00816063020905

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Product Code / Catalogue Number	Product and Trade name	Device UDI-DI
217106	iTero Element Flex Paired Unit w/o accessories • Scanning unit • Hub • iTero Element Software • iTero Element Scanner Sleeve	00816063022527
212074	iTero Element Flex CPO • Scanning Unit • HUB • iTero Element Software • iTero Element Scanner Sleeve	00816063021124
218530	iTero Element Flex CPO Paired Unit w/o accessories • Scanning Unit • HUB • iTero Element Software • iTero Element Scanner Sleeve	00816063022497
211483	iTero Element 2 Plus • iTero Element Plus scanning unit • iTero Element Software • iTero Plus Computing Unit • iTero Wheel Stand • iTero Element Scanner Sleeve • Articulator	00816063020684
217105	iTero Element 2 Plus Paired Unit w/o accessories • iTero Element Plus scanning unit • iTero Element Software iTero Plus Computing Unit	00816063022534
211789	iTero Element 2 Plus DOA Service Kit • iTero Element Plus scanning unit • iTero Element Software • iTero Plus Computing Unit • iTero Wheel Stand • iTero Element Scanner Sleeve	00816063021070
211782	iTero Element 2 Plus • iTero Element Plus scanning unit • iTero Element software	00816063020851
211490	iTero Element 2 Plus mobile configuration • iTero Element Plus scanning unit • iTero Element Software • iTero Plus Mobile Computing Unit • iTero Element Scanner Sleeve • Articulator	00816063020738

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Product Code / Catalogue Number	Product and Trade name	Device UDI-DI
217110	iTero Element 2 Plus, mobile configuration Paired Unit w/o accessories • iTero Element Plus scanning unit • iTero Element Software • iTero Plus Mobile Computing Unit • iTero Element Scanner Sleeve	00816063022503

Spare parts List

Product Code / Catalogue Number	Product and Trade name	Device UDI-DI
211889	iTero Element 2 Plus (RMA)	00816063020998
226073	iTero Element Wand Replacement, Brazil	00816063023340
226075	Packed Panel PC ASSY, RMA, iTero Element 2, Brazil	00816063023364

Accessories List:

Product Name	GMDN Code	EMDN code	Basic UDI-DI	Device UDI-DI
iTero Element Scanner Sleeve (p/n-217596)	44711	Z12119085 Various dental stomatology instruments consumables	081606302LCISLV42	00816063022039

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