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 for class I device.
Device basic UDI-DI:	iTero Lumina™ System - 081606302LMNSYS9L iTero Lumina™ Scanner Sleeve - 081606302LMNSLV8K
EMDN Code:	iTero Lumina™ System - Z110601, Laser imaging scanner iTero Lumina™ Scanner Sleeve - Z12119085, Various Dental Stomatology Instruments - Consumables
GMDN Code:	iTero Lumina™ System – 38597 , Dental CAD/CAM system, chairside iTero Lumina™ Scanner Sleeve – 44711, Optical medical device procedural cover
Product and Trade name:	iTero Lumina™
Product Catalogue Number:	See annex
Intended Purpose/Intended use:	iTero Lumina is an intraoral scanner intended to record and display the topographical images of teeth, oral tissue and bite relationship and to obtain optical impressions for use in CAD/CAM of dental devices.
Indications for use	iTero Lumina scans can be used for computer aided design and manufacturing of restorative dental devices, orthodontic devices and other dental devices such as night guards and bite splints. Data generated from iTero Lumina may be used by dental healthcare professionals for assessing intraoral topographical images of hard and soft tissue and visual assessments. iTero Lumina does not treat or diagnose any disease.
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 self for CE marking. ISO 13485 certificate Dekra Nr. 3901332.

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Risk Class:	Class I devices according to the following rules of Annex VIII of EU MDR 2017/745: iTero Lumina System - Rule 13 iTero Lumina Scanner Sleeve – Rule 5
Common Specifications:	None

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.

EN ISO 13485, EN ISO 14971, IEC/EN 60601-1

Aviva Touati

Director Regulatory Affairs

Israel

Date: 16 July 2024

Align Technology LTD

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

Annex

Product List

Product Catalogue Number	Product Trade Name	Device UDI-DI	First Serial Number:	Date of first Serial Number
213782	iTero Lumina Cart Configuration	00816063021414	NA	NA
213783	iTero Lumina Mobile Configuration	00816063021438	NA	NA
224166	iTero Lumina Mobile Configuration	00816063022893	NA	NA
213340	iTero Lumina Cart upgrade from Element Plus	00816063021421	NA	NA
213341	iTero Lumina Mobile upgrade from Element Plus	00816063021445	NA	NA
213356	iTero Lumina DOA Kit, cart	00816063021452	NA	NA

Accessories List

Product Catalogue Number	Product Trade Name	Device UDI-DI
215470	iTero Lumina Scanner Sleeve	00816063021483

Service and Spare Parts List

Product Catalogue Number	Product Trade Name	Device UDI-DI
213353	iTero Lumina Scanning Unit RMA Configuration	00816063021469
213355	iTero Lumina Scanning Unit RMA Configuration	00816063021476

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Product Catalogue Number	Product Trade Name	Device UDI-DI
216498	iTero Lumina Scanning Unit RMA	00816063022954
223169	iTero Lumina Scanning Unit	00816063022961

Scanning unit information

Product Catalogue Number	Product Trade Name	Device UDI-DI	First Serial Number	Date of first Serial Number
214500	iTero Lumina Scanning Unit	00816063021599	11000200 21000300	March 2023
222100	iTero Lumina Scanning Unit	00816063022138	12000001 22000300	NA
222984	iTero Scanning Unit Lumina	00816063022916	NA	NA

For Internal transportation purposes only

Product Catalogue Number	Product Trade Name	Device UDI-DI	First Serial Number:	Date of first Serial Number
221961	iTero Lumina Cart Configuration	00816063022831	NA	NA
221962	iTero Lumina Mobile Configuration	00816063022848	NA	NA

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