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## EU MDR Declaration of Conformity (DoC)

| | |
|---|---|
| **Manufacturer:** | Align Technology Ltd.<br>1 Yitzhak Rabin Rd.,<br>Petach Tikva 4925110<br>Israel |
| **Manufacturer SRN:** | IL-MF-000000745 |
| **Authorized Representative:** | Align Technology, BV.<br>Herikerbergweg 312<br>1101 CT, Amsterdam<br>The Netherlands |
| **Authorized Representative SRN:** | NL-AR-000000061 |
| **Notified Body:** | DEKRA Certification B.V., Arnhem, The Netherlands<br>Notified Body Identification Number 0344 |
| **Device basic UDI-DI:** | iTero Element 5D Family - 081606302DISBH<br>iTero Element Scanner Sleeves(p/n-109236 and p/n) 221963) -081606302SLEEVE6S |
| **GMDN Code:** | iTero Element 5D Family - 63669<br>iTero Element Scanner Sleeve - 44711 |
| **EMDN Code:** | iTero Element 5D Family - Z110601 Laser imaging scanner<br>iTero Element Scanner Sleeve - Z12119085 Various Dental Stomatology Instruments - Consumables |
| **Product and Trade name:** | iTero Element 5D, Dental Imaging Systems |
| **Product Catalogue Number:** | See annex |
| **Intended Purpose:** | Dental Imaging |
| **Conformity Assessment Procedure:** | Annex IX Chapter I and III together with Article 19 of the EU MDR 2017/745. |
| **Conformity Assessment Certificate(s):** | EU Quality Management System Certificate number 3903048CE01, Certification Notice 3901332CN, issued by Dekra Certification B.V as Notified Body 0344, |
| **Risk Class:** | Class IIa devices according to the following rules of Annex VIII of EU MDR 2017/745:<br>iTero Element 5D Family - Rule 10<br>iTero Element 5D Software – Rule 11<br>iTero Element Scanner Sleeve – 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.

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

Aviva Touati

Director Regulatory Affairs

Israel

Signature: _____

Align Technology Ltd.
312026936

Date: 05/03/25





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## Annex

## Product List

| Product Catalogue Number | Product Trade Name | Device UDI-DI |
|---|---|---|
| 205929 | **iTero Element 5D**<br>• 5D Scanning unit<br>• PC Panel<br>• Wheel Stand<br>• iTero Element 5D software<br>• iTero Element Scanner Sleeve | 00816063020493 |
| 212096 | **iTero Element 5D Rental**<br>• 5D Scanning unit<br>• PC Panel<br>• Wheel Stand<br>• iTero Element 5D software<br>• iTero Element Scanner Sleeve | 00816063020929 |
| 206160 | **iTero Element 5D Laptop Configuration**<br>• 5D Scanning unit<br>• Hub<br>• iTero Element 5D software<br>• iTero Element Scanner Sleeve | 00816063020509 |
| 212097 | **iTero Element 5D Laptop Configuration**<br>• 5D Scanning unit<br>• Hub<br>• iTero Element 5D software<br>• iTero Element Scanner Sleeve | 00816063020936 |
| 206855 | **iTero Element 5D Upgrade Kit**<br>• 5D Scanning unit<br>• iTero Element 5D software | 00816063020561 |





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| Product Catalogue Number | Product Trade Name | Device UDI-DI |
|---|---|---|
| 206856 | **iTero Element 5D Laptop Configuration Upgrade Kit**<br>• 5D Scanning unit<br>• Hub<br>• iTero Element 5D software | 00816063020578 |
| 211484 | **iTero Element 5D Plus**<br>• iTero Element 5D Plus Scanning Unit<br>• iTero Element 5D software (includes software configuration referred to commercially as iTero Element 5D Plus Lite or iTero Element 5D Plus) | 00816063020691 |
| 211491 | **iTero Element 5D Plus,** *Mobile Configuration*<br>• iTero Element 5D Plus Scanning Unit<br>• iTero Element 5D software (includes software configuration referred to commercially as iTero Element 5D Plus Lite or iTero Element 5D Plus) | 00816063020745 |
| 211783 | E5D Plus Scanning Unit | 00816063020868 |
| 217604 | **iTero Element 5D Plus mobile configuration**<br>*(Go Digital)*<br>• iTero Element 5D Plus<br>• iTero Software | 00816063022596 |
| 218557 | **iTero Element 5D**<br>• 5D Scanning unit<br>• PC Panel<br>• iTero Element 5D software | 00816063022473 |





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| Product Catalogue Number | Product Trade Name | Device UDI-DI |
|---|---|---|
| 217102 | **iTero Element 5D Plus**<br>• iTero Element 5D Plus<br>iTero Element 5D software (includes software configuration referred commercially as iTero element 5D Plus Lite) | 00816063022541 |
| 207279 | **iTero Element 5D Laptop Configuration**<br>• 5D Scanning unit<br>• Hub<br>• iTero Element 5D software | 00816063022565 |

**Accessories List**

| Product Catalogue Number | Product Trade Name | Device UDI-DI |
|---|---|---|
| 109236 | iTero Element Scanner Sleeve | 00816063020585 |
| 221963 | iTero Element Scanner Sleeve | 00816063022183 |

**Service Items and Spare Parts List**

| Product Catalogue Number | Product Trade Name | Device UDI-DI |
|---|---|---|
| 212260 | iTero Element 5D Plus Scanning Unit, RMA | 00816063021001 |
| 226077 | iTero Element 5D Plus Scanning Unit, RMA, Brazil | 00816063023388 |
| 206955 | iTero Element 5D scanning unit, RMA | 00816063021735 |





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| Product Catalogue Number | Product Trade Name | Device UDI-DI |
|---|---|---|
| 226074 | iTero Element 5D scanning unit, RMA, Brazil | 00816063023357 |
| 206517 | iTero Element 5D DOA Kit | 00816063022053 |
| 212269 | iTero Element 5D Plus DOA Kit | 00816063021087 |
| 206954 | iTero Element Packed Panel PC ASSY, 5D RMA | 00816063021704 |
| 226076 | Packed Panel PC ASSY, 5D iTero Element RMA, Brazil | 00816063023371 |





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