# EU Declaration of Conformity

Dentsply Sirona

***Document No.:*** **SDS_EU_DoC_329_02**

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|---|---|
| *Manufacturer and Address:* | **SIRONA Dental Systems GmbH**<br>**Fabrikstraße 31**<br>**64625 Bensheim**<br>**Germany** |
| *SRN:* | **DE-MF-000000029** |
| *Medical Device Name:* | **Primescan Connect, Primescan Connect OEM** |
| *Basic UDI-DI:* | **++E276OpticalImprV01DT** |
| *Classification according to Annex VIII (2017/745/EU):* | **Class I, Rule 13** |
| *Common Specifications:* | **Not applicable** |

*Intended Use:*
The Primescan Connect acquisition unit creates digital impressions for dental treatments. This unit must not be used for any other purpose. If the unit is used for any purpose other than the one mentioned above, it may be damaged. Intended use also includes compliance with the Operating Instructions and the relevant maintenance instructions.

*We declare under our sole responsibility the compliance of the medical device concerned with the requirements of the Council Regulation 2017/745/EU.*

*Any modification to the product, not authorized by us, will invalidate this declaration.*

*Valid from manufacturing date: 2024-06-06*

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| *Product Models / Types and Identification:* | **Primescan Connect** | **REF: 6795491** |
| | **Primescan Connect Connection Kit OEM long** | **REF: 6828730** |
| | **Primescan Connect Connection Kit OEM short** | **REF: 6831296** |

Bensheim: 2024-06-11
*Place and date*

[*Signature*]

Mr. Niels Plate
*Group Vice President*

[*Signature*]

Mr. Thorsten Fabian
*Regulatory Compliance Manager*

*The declaration certifies the compliance according to Annex I of Regulation 2017/745/EU.*
*Conditions of guarantee and liability are dealt within our General Conditions of Sale.*