

# EU Declaration of Conformity




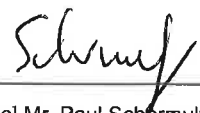
Document No.: SDS\_EU\_DoC\_321\_18

Manufacturer and Address:	<b>SIRONA Dental Systems GmbH Fabrikstraße 31 64625 Bensheim Germany</b>
SRN:	<b>DE-MF-000000029</b>
Medical Device Name:	<b>Primescan AC, CEREC Primescan AC, Omniscam AC, CEREC Omnicam AC</b>
Basic UDI-DI:	<b>++E276OpticalImprV01DT</b>
Classification according to Annex VIII (2017/745/EU):	<b>Class I, Rule 13</b>
Common Specifications:	<b>N/A</b>

*Intended Use:*  
The [CEREC] Primescan / Omnicam AC 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: 2023-09-19

Bensheim: 2023-09-19	
Place and date	
 [Signature]	 [Signature]
[Printed Name] Mr. Niels Plate Group Vice President	[Printed Name] Mr. Paul Schermuly 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.*

# EU Declaration of Conformity



Document No.: SDS\_EU\_DoC\_321\_18

Product Models	Product Name / Product Variants	
6622000	<b>CEREC Primescan AC</b>	
6692672	<b>Primescan AC</b>	
	consisting of one of the following product variants:	
	6622018	CEREC Primescan AC TB
	6622307	CEREC Primescan AC TP
	6695014	Primescan AC TB
	6692698	Primescan AC TP
	6656230	Primescan AC select
6717982	<b>CEREC Primescan AC Refurbished</b>	
	consisting of one of the following product variants:	
	6717990	CEREC Primescan AC TP Base Unit Refurbished
	6718006	CEREC Primescan AC TB Base Unit Refurbished
6718790	<b>Primescan AC Refurbished</b>	
	consisting of one of the following product variants:	
	6718808	Primescan AC TP Base Unit Refurbished
	6718816	Primescan AC TB Base Unit Refurbished
6622299	<b>CEREC Omnicam AC</b>	
6692680	<b>Omnicam AC</b>	
	consisting of one of the following product variants:	
	6656263	CEREC Omnicam AC TB
	6656271	CEREC Omnicam AC TP
	6695048	Omnicam AC TB
	6692706	Omnicam AC TP
	6656289	Omnicam AC select
6718824	<b>CEREC Omnicam AC Refurbished</b>	
	consisting of one of the following product variants	
	6718832	CEREC Omnicam AC TP Base Unit Refurbished
	6718840	CEREC Omnicam AC TB Base Unit Refurbished
6718857	<b>Omnicam AC Refurbished</b>	
	consisting of one of the following product variants	
	6718865	Omnicam AC TP Base Unit Refurbished
	6718873	Omnicam AC TB Base Unit Refurbished
6667211	<b>CEREC Primescan AC TP steel US</b>	
6692714	<b>Primescan AC TP steel US</b>	
6729615	<b>Primescan AC TP US SDC</b>	
6667237	<b>CEREC Omnicam AC TP US</b>	
6692730	<b>Omnicam AC TP US</b>	
6686880	<b>Disposable Sleeve Primescan</b>	
6632264	<b>Disposable Sleeve Omnicam</b>	
6724640	<b>Autoclavable Sleeve Primescan</b>	
6664267	<b>Slide-in window Primescan</b>	