

# EU Declaration of Conformity



Document No.: SDS\_EU\_DoC\_202\_01



Manufacturer and Address:	<b>SIRONA Dental Systems GmbH</b> Fabrikstraße 31 64625 Bensheim Germany
SRN:	<b>DE-MF-000000029</b>
REF-No:	<b>Type D3632</b>
Medical Device Name:	<b>Orthophos SL 2D</b> <b>Orthophos SL 3D</b>
Basic UDI-DI:	<b>++E276EOImaging0154</b>
Classification according to Annex VIII (2017/745/EU):	<b>Class II b</b>
Common Specifications:	<b>N/A</b>

*Intended Use:*  
The X-ray system creates digital exposures in the maxillofacial area and in Subareas for dentistry and paediatric dentistry, for hard-tissue diagnostics within ENT medicine, and for carpal exposures

We declare under our sole responsibility the compliance of the medical device concerned with the requirements of the Council Regulation 2017/745/EU and 2011/65/EU.  
Any modification to the product, not authorized by us, will invalidate this declaration.

Valid from manufacturing date: 2022-10-07

The conformity of the full quality assurance system (Regulation 2017/745/EU, Annex IX) is certified by:  
TÜV SÜD Product Service GmbH  
Ridlerstraße 65  
80339 München  
Germany  
Certificate ID: G10 031247 0089 Rev. 01  
The identification number of the notified body for implementation of the procedure is 0123.

Bensheim: 2022-10-07  
Place and date  
[Signature]  \_\_\_\_\_ [Signature]  \_\_\_\_\_  
Niels Plate  
Group Vice President  
(Digital Devices & Solutions)  
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.

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<i>Product Models / Types and Identification (Ref.-Number):</i>	<b>6467042</b>	<b>Orthophos SL 2D</b>
	<b>6464957</b>	<b>Orthophos SL 2D</b>
	<b>6440395</b>	<b>Orthophos SL 2D individ.</b>
	<b>6466580</b>	<b>Orthophos SL 3D</b>
	<b>6464973</b>	<b>Orthophos SL 3D 8x8 DCS</b>
	<b>6464999</b>	<b>Orthophos SL 3D 11x10 DCS</b>
	<b>6466440</b>	<b>Orthophos SL 3D individ.</b>

*End of document.*