

# EU Declaration of Conformity

Document No.: SDS\_EU\_DoC\_203\_01

Manufacturer and Address:	<b>SIRONA Dental Systems GmbH Fabrikstraße 31 64625 Bensheim Germany</b>
SRN:	<b>DE-MF-000000029</b>
REF-No:	<b>Type D3632</b>
Medical Device Name:	<b>Orthophos S 2D Orthophos S 3D</b>
Basic UDI-DI:	<b>++E276E0Imaging0154</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

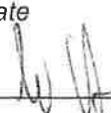

The conformity of the full quality assurance system (Regulation 2017/745/EU, Annex IX) is certified by:

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

<p>[Signature] </p> <p>Niels Plate Group Vice President (Digital Devices &amp; Solutions)</p>	<p>[Signature] </p> <p>Thorsten Fabian Regulatory Compliance Manager</p>
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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>6679646</b>	<b>Orthophos S 2D</b>
	<b>6679604</b>	<b>Orthophos S 2D</b>
	<b>6679596</b>	<b>Orthophos S 2D individ.</b>
	<b>6679653</b>	<b>Orthophos S 3D</b>
	<b>6679620</b>	<b>Orthophos S 3D 8x8</b>
	<b>6679638</b>	<b>Orthophos S 3D 11x10</b>
	<b>6679612</b>	<b>Orthophos S 3D individ.</b>

*End of document.*

I hereby certify, that this copy is  
a true copy of the original.

Bensheim, 02<sup>th</sup> December 2022

  
Rechtsanwalt und Notar a.D.  
Dr. Dirk Aretz  
as the officially appointed  
representative of the notary Dr. Lena Kuzbida

