

# EC Declaration of Conformity



Document No.: GB 129 / 18 / MDD

Manufacturer:	SIRONA Dental Systems GmbH
Address:	Fabrikstraße 31 64625 Bensheim Germany
Product Category:	Digital X-ray imaging system, dental
Medical Device Name:	<b>Heliodent Plus</b> <small>(wall mounted version / mobile stand version D3507; ceiling mounted version / dental treatment center version D3578)</small>
Product Identification (e.g. Ref.- / Type-Number):	<b>Type D3507 / D3578</b>
Classification according to Annex IX (93/42/EEC):	<b>Class II b</b>

We declare under our sole responsibility the compliance of the medical device concerned with the requirements of the Council Directive 93/42/EEC.

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

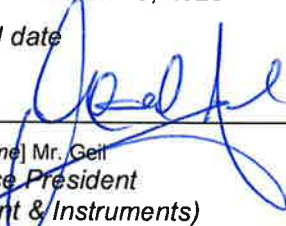

Valid from manufacturing date: 2020-03-09

The conformity of the full quality assurance system (Directive 93/42/EEC, Annex II excluding 4) is certified by:

TÜV SÜD Product Service GmbH  
Ridlerstraße 65  
80339 München  
Germany

The identification number of the notified body for implementation of the procedure is 0123.

Bensheim: March 09, 2020  
Place and date

 [Signature]	 [Signature]
[Printed Name] Mr. Geil Group Vice President (Equipment & Instruments)	[Printed Name] Mr. Fabian Regulatory Compliance Manager

The declaration certifies the compliance according to Annex II of Directive 93/42/EEC.  
Conditions of guarantee and liability are dealt within our General Conditions of Sale.

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Type code	Article code	Product
D3507	6483726	HD PLUS Wall version (square)
	6483692	HD PLUS complete w/o support arm (wall module, square)
	6483700	HD PLUS cpl. w/o support arm JP
	6483718	HD PLUS cpl. w/o support arm CN
	6483734	HD Plus Wall version (round)
	6175744	HD Plus complete w/o support arm (wall module, round)
	6487370	HD Plus complete w/o support arm BR
	6345453	HD Plus complete w/o support arm CN
	6400126	HD Plus complete w/o support arm JP
D3578	6489624	HELIODENT Plus, Unit model
	6489632	HD Plus complete, w/o support arm (on Treatment Center)
	6602234	Ceiling Version HELIODENT Plus
	6489632	HD Plus complete, w/o support arm (ceiling)
JP == Japan; CN == China; BR == Brazil		