EC Declaration of Conformity

Manufacturer: SIRONA Dental Systems GmbH

Address: Fabrikstraße 31
64625 Bensheim
Germany

Product Category: Digital X-ray imaging system, dental

Medical Device Name: Heliodent Plus
(wall mounted version / mobile stand version D3507;
ceiling mounted version / dental treatment center version
D3578)

Product Identification (e.g. Ref.- / Type-Number): Type D3507
Type D3578

Classification according to Annex IX (93/42/EEC): Class II 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.

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: November, 07, 2018

[Signature]
[Printed Name] Mr. M. Bell
Vice President

[Signature]
[Printed Name] Mr. T. Fabian
Approval-Engineer

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.
# EC Declaration of Conformity

<table>
<thead>
<tr>
<th>Type code</th>
<th>Article code</th>
<th>Product</th>
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<td>HD PLUS cpl. w/o support arm CN</td>
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<td>HD Plus complete, w/o support arm (ceiling)</td>
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<sup>1</sup> Sales reference part number

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Sirona Dental Systems  
D3507.128.01.01.09  
05.2019  
Ä-Nr.: 000 000  
Bensheim  
67 25 928 D3507