EU Declaration of Conformity

Dentsply Sirona

Document No.: **GB 135 / 03**

Manufacturer and Address:	**SIRONA Dental Systems GmbH** **Fabrikstraße 31** **64625 Bensheim** **Germany**
Product Category:	**Digital X-ray imaging system, dental**
Medical Device Name:	**Orthophos E** **Orthophos E Ceph**
Product Identification (Ref.-Number):	**Type D3352**
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.

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*]

[Printed Name] Mr. M. Geil
Group Vice President
(Equipment & Instruments)

[*Signature*]

[*Printed Name*] Mr. T. 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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Article code	Product
6707488	Orthophos E
6707462	Orthophos E Pan
6708429	Orthophos E Ceph
6707470	Orthophos E individ.