

EC Declaration of Conformity



Document No.: GB 136 / 02 / MDD

Manufacturer:	SIRONA Dental Systems GmbH
Address:	Fabrikstraße 31 64625 Bensheim Germany
Product Category:	Digital X-ray imaging system, dental
Medical Device Name:	Axeos
Product Identification (e.g. Ref.- / Type-Number):	Type D3644
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: 2020-08-06

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: August 06, 2020

Place and date

[Signature]

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

[Signature]

[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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Article code	Product
67 28 930	Axeos
67 28 914	Axeos (ww)
67 28 922	Axeos (individ.)