EC Declaration of Conformity

Document No.: GB 131 / 09

Manufacturer: SIRONA Dental Systems GmbH
Address: Fabrikstraße 31
64625 Bensheim
Germany

Product Category: Digital X-ray imaging system, dental
Medical Device Name: Sidexis 4
Product Identification (e.g. Ref.- / Type-Number): Type D3592
Classification according to Annex IX (93/42/EEC): Class IIa

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: January 25, 2019
Place and date

[Signature] [Signature]

[Printed Name] M. Geil
[Printed Name] E. Kouda
SBU Head for Imaging 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.