EC Declaration of Conformity



Document No.: GE 0150 / 04

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SIRONA Dental Systems GmbH

Address:

Fabrikstraße 31

64625 Bensheim

Germany

Medical device:

SINIUS

(with dentist element side track)

SINIUS CS (w. dentist element continental style)
SINIUS TS (w. dentist element traditional style)

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

Type D3561

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

Class II a

We declare 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 (Annex II excluding 4) of Directive 93/42/ECC 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, September 24th, 2013

Place and date

[Signature]

[Printed Name] Mr. M. Geil

Vice President Treatment Unit Division

[Signature]

[Printed Name] Mr. K. Hennemann

Approval-Engineer

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