

EC Declaration of Conformity

Document No.: GE 0150/12



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|---|---|
| <i>Manufacturer:</i> | SIRONA Dental Systems GmbH |
| <i>Address:</i> | Fabrikstraße 31 64625 Bensheim Germany |
| <i>Product Category:</i> | Dental Unit |
| <i>Medical Device Name:</i> | Sinius / Sinius CS / Sinius TS |
| <i>Product Identification (e.g. Ref.- / Type-Number):</i> | Type D3561 Ref.: 6308865 / 6308873 / 6408822 |
| <i>Classification according to Annex IX (93/42/EEC):</i> | Class II a |

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.

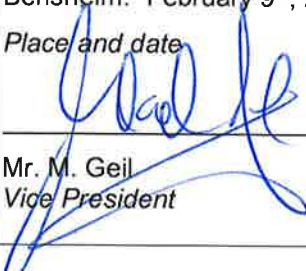
Valid from manufacturing date: 2021-02-09

The conformity of the full quality assurance system (Directive 93/42/EEC, Annex II excluding 4) is certified by:

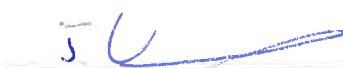
**TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München
Germany**

The identification number of the notified body for implementation of the procedure is 0123.

Bensheim: February 9th, 2021
Place and date



Mr. M. Geil
Vice President



Mr. T. Wenzel
Manager Regulatory Compliance

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.