EC Declaration of Conformity

Document No.: **GE 0150/12**

Dentsply Sirona

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

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DC Validation & Design Transfer, Conformity Assesment & Clearance ♦ Template: PLP_T_0071 ♦ Rev.1 ♦ valid from: 2019-04-01