EC Declaration of Conformity

Document No.: GE 0176 / 11



Manufacturer:	SIRONA Dental Systems GmbH
Address:	Fabrikstraße 31 64625 Bensheim Germany
Product Category:	Dental Unit
Medical Device Name:	Intego, Intego Pro, Intego CS, Intego TS, In- tego Pro CS, Intego Pro TS
Product Identification (e.g. Ref / Type-Number):	Type D3543 Ref.: 6427285, 6427277, 6645910, 6645936, 6645928, 6666726
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 9 th , 2021		
Place and date		
Halt	JU	
Mr/M. Geil	Mr. T. Wenzel	
Vice President	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.

Sirona Dental Systems

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