EU DECLARATION OF CONFORMITY

By the present document, the Vanetti SA-Via Municipio 12a-CH-6672 Gordevio, Switzerland assumes the responsibility that the following range of products:

Mark	Type	Code N°
Dia-Tessin	Ceramic Instrument FG	CSTT / 015 & CSTT/015L

classified as Medical Devices - Class IIa according to Directive 93/42/EEC annex IX, par. 2.1, rule 5

is in conformity with the essential requirements of the medical devices Directive 93/42/EEC as amended by Directive 2007/47/EEC.

is subject to the assessment procedure set out in Annex II (excluding point 4) of Directive 93/42/EEC under the supervision of the Notified Body stated below. Certificate number 0425-MED-003892-00.

The products have been developed, manufactured and controlled within a Quality System meeting the requirements of EN ISO 13485:2016. Certificate ICIM No. 9662/0, IQNet registration Number IT-116615.

The main dental standards addressed are
EN 1639, EN-ISO 1797-1, EN-ISO 2157, EN-ISO 8325, EN-ISO 10993-1, EN-ISO 10993-5, EN-ISO 11737-1, EN-ISO 11737-2, EN-ISO 15223-1 and EN-ISO 17664.

These products do not need any specific certificate for clinical or technical tests in the country of origin according to the Swiss law for medical devices.

Notified body : ICIM S.P.A. NB0425

Address : ICIM S.P.A.
Piazza Don Enrico Mapelli, 75
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Italy

Name: Vanetti First name: Pablo Function: CEO

Place: 6672 Gordevio Date: 07.03.2020 Signature: P.V

Validity: 26.05.2024

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