

**EU DECLARATION OF CONFORMITY**

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

Mark	Type	Code N°
Dia-Tessin	Carbide Instruments FG, FGS, FGXL, RA, RAL, RAXL, HP	increased by increments from 1 to 389
Dia-Tessin	Carbide Instruments FG, RA, RAL	increased by increments from 1S to Q1
Dia-Tessin	Carbide Instruments FG, HP	increased by increments from 21L to 33L
Dia-Tessin	Carbide Instruments FG, RA, HP	increased by increments from 21R to 36R
Dia-Tessin	Carbide Instruments FG	increased by increments from 21RX
Dia-Tessin	Carbide Instruments FG	increased by increments from 23RL
Dia-Tessin	Carbide Instruments FG	increased by increments from U41 to U247
Dia-Tessin	Carbide Instruments FG	increased by increments from 44E
Dia-Tessin	Carbide Instruments FG	increased by increments from U44E
Dia-Tessin	Carbide Instruments FG	increased by increments from 47L to 212L
Dia-Tessin	Carbide Instruments FGXL, RAL, HP	increased by increments from 162A
Dia-Tessin	Carbide Instruments FG	increased by increments from 212R
Dia-Tessin	Carbide Instruments FG	increased by increments from 212RL
Dia-Tessin	Carbide Instruments FG	increased by increments from U212R

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 CH06/0485.

The products have been developed, manufactured and controlled within a Quality System meeting the requirements of EN ISO 13485:2016. Certificate number CH97/0206.

The main dental standards addressed are
EN 1639, EN-ISO 1797-1, EN-ISO 2157, EN-ISO 3823-1, EN-ISO 3823-2, 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	:	SGS	NB0120
Address	:	SGS United Kingdom Ltd. 202B Worle Parkway Weston-Super-Mare BS22 6WA UK	VANETTI SA Via Principale CH-6672 GORDEVIO

Name: Vanetti	First name: Pablo	Function: CEO
Place: 6672 Gordevio	Date: 10.07.2018	Signature:

Validity: 09.07.2023