

**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	Diamond instruments FG	increased by increments from 801 to 909
Dia-Tessin	Diamond instruments FG	increased by increments from 368 to 392
Dia-Tessin	Diamond instruments FG	increased by increments from 801L to 837L
Dia-Tessin	Diamond instruments FG	increased by increments from 835KR to 847KR
Dia-Tessin	Diamond instruments FG	increased by increments from 868K to 879K
Dia-Tessin	Diamond instruments FG	increased by increments from R837 to R848
Dia-Tessin	Diamond instruments FG	increased by increments from RD837 to RD848
Dia-Tessin	Diamond instruments FG	increased by increments from 829 to 829L
Dia-Tessin	Diamond instruments FG	increased by increments from 830M to 953M
Dia-Tessin	Diamond instruments FG	increased by increments from 830RM to 953AM
Dia-Tessin	Diamond instruments FG	801LE/, 834A, 868B, 844RF, 850XL, GF844,
Dia-Tessin	Diamond instruments FG	859E, 833A, 880P, 881P, 856P, 878KP, 372P, 372PL, DM, 878KT,
Dia-Tessin	Diamond instruments FG	increased by increments from ZG801L to ZG880
Dia-Tessin	Diamond instruments FG	increased by increments from Z379 to Z862
Dia-Tessin	Diamond instruments FG	increased by increments from ZF379 to ZF862
Dia-Tessin	Diamond instruments FG	increased by increments from ZC379 to ZC862

classified as Medical Devices - Class IIa according to Directive 93/42/EEC annex IX, par. 2.1.1, 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, EN-ISO 2157, EN-ISO 7405, EN-ISO 7711-1, ISO 7711-3, 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.
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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