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	Diamond Burs FG	increased by increments from 801 to 909
Dia-Tessin	Diamond Burs FG	increased by increments from 368 to 392
Dia-Tessin	Diamond Burs FG	increased by increments from 801L to 837L
Dia-Tessin	Diamond Burs FG	increased by increments from 835KR to 847KR
Dia-Tessin	Diamond Burs FG	increased by increments from 868K to 879K
Dia-Tessin	Diamond Burs FG	increased by increments from R837 to R848
Dia-Tessin	Diamond Burs FG	increased by increments from RD837 to RD848
Dia-Tessin	Diamond Burs FG	increased by increments from 829 to 829L
Dia-Tessin	Diamond Burs FG	increased by increments from 830M to 953M
Dia-Tessin	Diamond Burs FG	increased by increments from 830RM to 953AM
Dia-Tessin	Diamond Burs FG	801LE, 834A, 868B, 844RF, 850XL, GF844, 859E, 833A, 880P, 881P, 856P, 878KP, 372P, 372PL, DM, 878KT
Dia-Tessin	Diamond Burs RA	RAP368L, RAP868L, RAP368XL, RAP868XL
Dia-Tessin	Diamond Burs FG	increased by increments from ZG801L to ZG880
Dia-Tessin	Diamond Burs FG	increased by increments from Z379 to Z862
Dia-Tessin	Diamond Burs FG	increased by increments from ZF379 to ZF862
Dia-Tessin	Diamond Burs 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, 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 13485:2021, ISO13485:2016.
Certificate No. ICIM-13485-009662-02, IQNet registration Number IT-116615.

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	:	ICIM S.P.A.	NB0425
Address	:	ICIM S.P.A. Piazza Don Enrico Mapelli, 75 20099 - Sesto San Giovanni (MI)	Italy

VANETTI SA
Via Municipio 12a
CH-6672 GORDEVIO

EU-Representative : Kiron di Mechelli Claudio, Via F. Guglielmino, 55, I-00137 Roma, Italy

Name: Vanetti First name: Pablo Function: CEO

Place: 6672 Gordevio Date: 13.11.2023 Signature:

Validity: 26.05.2024