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	Carbide Burs	FG, FGS, FGXL, RA, RAL, RAXL, HP	increased by increments from 1 to 389
Dia-Tessin	Carbide Burs	FG, RA, RAL	increased by increments from 1S to Q1
Dia-Tessin	Carbide Burs	FG, HP	increased by increments from 21L to 33L
Dia-Tessin	Carbide Burs	FG, RA, HP	increased by increments from 21R to 36R
Dia-Tessin	Carbide Burs	FG	increased by increments from 21RX
Dia-Tessin	Carbide Burs	FG	increased by increments from 23RL
Dia-Tessin	Carbide Burs	FG	increased by increments from U41 to U247
Dia-Tessin	Carbide Burs	FG	increased by increments from 44E
Dia-Tessin	Carbide Burs	FG	increased by increments from U44E
Dia-Tessin	Carbide Burs	FG	increased by increments from 47L to 212L
Dia-Tessin	Carbide Burs	FGXL, RAL, HP	increased by increments from 162A
Dia-Tessin	Carbide Burs	FG	increased by increments from 212R
Dia-Tessin	Carbide Burs	FG	increased by increments from 212RL
Dia-Tessin	Carbide Burs	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 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 1797-1, 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 : 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