2023/607/EU SELF-DECLARATION

Gordevio, 07 March 2024.

We,

Vanetti SA
Via Municipio 12 a
6672 Gordevio
Switzerland
Tel. +41 (0) 91 753 12 02 / E-mail: mail@vanetti.ch

do hereby declare that the products listed in ANNEX I of this self-declaration are in scope of the European Regulation 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices by complying with the following requirements:

a) Devices continue to comply with Directive 93/42/EEC,

b) There are no significant changes in design and intended purpose,

c) Devices do not present an unacceptable risk to the health or safety of patients, users, or other persons, or to other aspects of the protection of public health,

d) No later than 26 May 2024, the manufacturer has put in a QMS in accordance with EU MDR,

e) No later than 26 May 2024, the manufacturer has lodged a formal application with a notified body, and, no later than 26 September 2024, the notified body and the manufacturer have signed a written agreement in accordance with EU MDR.

Therefore, the EC Certificate is considered as valid until the 31 December 2028.

Yours Sincerely,

Pablo Vanetti
CEO

VANETTI SA
Via Municipio 12a
CH-6672 GORDEVIO

Annex I

According to MDD Extension, the devices for the continued placing on the market.

Notified Body	ICIM SPA / Identification on NANDO CE0425
Date of Extension Agreement	25 October 2023
Expiration Date of Extension	31 December 2028
Standard(s)	MDD 93/42/EEC
Agreement Scope(s)	Dental rotary instruments
Extension Reason	To maintain the MDD Certificate while MDR Audit is not completed
Contact Information of NB	Tel. +39 02 725341 / info@icim.it
Contact Address of NB	ICIM SPA Piazza Don Enrico Mapelli, 75 2099 Sesto San Giovanni MI Italy
Device Name	- Diamond burs. Class IIa - Tungsten carbide burs. Class IIa - Ceramic soft tissue trimmer CSTT. Class IIa
MDD Certificate Reference(s)	0425-MED-003892-00

Note: Certificate 0425-MED-003892-00 was originally expired on 26 may 2024 date and now it is under the MDD certification Extension Agreement provided by ICIM SPA in 25 October 2023, the transition timeline that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3 of MDR (as amended by EU 2023/607), are 31 December 2028.