

The company

**Swissdentacare SA**

Via della Posta 3  
6934 Bioggio  
Switzerland

declares

that the medical devices belonging to the products family  
“**Oscillating instruments for orthodontic treatments and dental restoration**”,  
NBOG codes MD 0401, risk class IIa (Rule 5) of Annex IX of the procedure 93/42/EEC and subsequent  
amendments, including Directive 2007/47/EC,

are produced and marketed in accordance with directives and reference standards as shown in the  
technical file n. FT SDC 003 dated 21.01.2021.

Furthermore these medical devices are manufactured in accordance with the Quality Management  
System which complies with the essential requirements of Annexes I and II of this Decree, as  
confirmed by the Certificate No. 0425-MED-004304-00 issued by ICIM SpA, Piazza Don Enrico Mapelli  
75, 20099 Sesto San Giovanni (MI), on the 22/02/2021

Notified Body n° 0425

This declaration of conformity is issued under the sole responsibility of Swissdentacare SA.

Legal Representative



Urs-Holger Spiecker

Bioggio, 01.03.2021