



**MEDICAL DEVICES**



**DECLARATION of CONFORMITY FT IU**

**Products:**

Insert AX, trade mark TKD, REF 430.01.KV.0, starting from LOT64DA to LOT64DI;  
Insert BX, trade mark TKD, REF 430.02.KV.0, LOT64OL;  
Insert CX, trade mark TKD, REF 430.03.KV.0, LOT64BE;  
Insert PX, trade mark TKD, REF 430.04.KV.0, starting from LOT64CL to LOT64DN;  
Insert PSX, trade mark TKD, REF 430.05.KV.0, starting from LOT64FL to LOT64DN;  
Insert DX, trade mark TKD, REF 430.07.KV.0, LOT64OL;  
Insert EX, trade mark TKD, REF 430.08.KV.0, LOT63EA;  
Insert PLX1, trade mark TKD, REF 430.11.KV.0, LOT64CE;  
Insert PLX2, trade mark TKD, REF 430.12.KV.0, LOT64CE;  
Insert PLX3, trade mark TKD, REF 430.13.KV.0, starting from LOT64EA to LOT64EN;

The company **TeKne Dental s.r.l.**, legal address on Via del Pescinale 77 - 50041 Calenzano (FI) – Italy, hereby declares, on its own exclusive responsibility, that:

1. Listed devices are being manufactured according to the requirements dictated by 93/42/EEC and 2007/47/EC Directives, Annex II (Certificate no. 069/MDD, issued by Notified Body **IMQ S.p.A.** with identification number: 0051).
2. Listed devices belong to Class IIa, according to Rule 5, Annex IX of the 93/42/EEC Directive and amended by 2007/47/EEC Directive.
3. All documentation regarding these devices is kept on the Technical File FT IU and is preserved for a period of at least 5 years since the date of last production.
4. The manufacturing process, described on the company Quality Management System, complies to Annex II of the 93/42/EEC Directive and amended by 2007/47/EEC Directive.
5. This Quality Management System complies to the requirements dictated by ISO 13485:2016 Standard (Certificate no. 9124.TKD2 due on 16/07/2027).
6. **TeKne Dental s.r.l.** has notified the commercialization of the products listed above to the Relevant Authority, so as to guarantee after-sale surveillance.
7. **TeKne Dental s.r.l.** has carried out a proper procedure to guarantee after-sale surveillance of the devices.
8. Validity of this declaration is subject to the validity of the above-mentioned Certificates, except for significant changes carried out on the product or to the manufacturing process.

Calenzano, 10<sup>th</sup> January 2025

(Eng. R. Ravalli)  
The President

**TeKne Dental s.r.l.**  
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Azienda con Sistema di Qualità Certificato

