



MEDICAL DEVICES



DECLARATION of CONFORMITY FT RR
BASIC UDI-DI: 805572750RAPIDCOUPLERBL

Products:

Trade name GYROFLEX, trade mark TKD, models REF 316.30 and REF 316.40, batch number starting from LOT29DD to LOT29DN

Trade name GYROFLEX L, trade mark TKD, model REF 316.60, batch number starting from LOT29DD to LOT29DN

Trade name GYROFLEX LED, trade mark TKD, models REF 316.62 and REF 316.62.09, batch number starting from LOT29DE to LOT29DN

The company **TeKne Dental s.r.l.**, legal address on Via del Pescinale 77 - 50041 Calenzano (FI) – Italy, single registration number IT-MF-000026680, hereby declares on its own exclusive responsibility that:

1. Listed devices are being manufactured according to the requirements dictated by the Medical Device Regulation (EU) 2017/745, Annex IX Chapter I.
2. Listed devices belong to Class I, according to Rule 1 Annex VIII of the Medical Device Regulation (EU) 2017/745.
3. All documentation regarding these devices is kept on the Technical File FT RR and is preserved for a period of at least 10 years since the date of last production.
4. The manufacturing process, described on the company Quality Management System, complies to Annex IX Chapter I of the mentioned Regulation.
5. This Quality Management System complies to the requirements dictated by UNI CEI EN 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 devices 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.

Calenzano, 16th June 2024

Eng. R. Ravalli
(The President)

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Azienda con Sistema di Qualità Certificato

