ERKODENT®	Info_4_2_3_201f / Revision 5 valid from: April 30, 2025

EU-Declaration of Conformity

- Manufacturer: Erkodent Erich Kopp GmbH
  (Siemensstr. 3, 72285 Pfalzgrafenweiler, Germany, info@erkodent.com, +49 (0) 7445 8501-0)
- SRN of manufacturer: DE-MF-000006243
- Product group: Dental thermoplastic material class IIa
- Conformity assessment procedure: According to Annex IX (conformity assessment based on a QM system and an assessment of the technical documentation)
- References to applied common specifications: none
- Product risk class: Class IIa according to rule 5 of Annex VIII
- This declaration of conformity is valid until: April 29, 2030 (at the latest, expiry of the certificate)
- Notified body: TÜV Rheinland LGA Products GmbH, Tillystraße 2, 90431 Nürnberg, Germany, identification number 0197
- Identification of the issued certificate: HZ 1073124-1

Erkodent Erich Kopp GmbH declares under sole responsibility according to Article 19 and Annex IV of the MDR (Medical Device Regulation) the conformity (the products meet the requirements and comply with the regulation) of the following Erkodent products with the regulation (EU) 2017/745 in the currently valid version (on the date of issue of this declaration of conformity).

- Product (trade name): **Silensor-sl - parts** (variant of product group dental thermoplastic material class IIa)
- Basic-UDI-DI: ++ERKO062aNNNNN1209UD
- intended use: Manufacture of the Silensor-sl anti-snoring splint, an appliance for dental treatment, recommended for:
  - Silensor-sl anti-snoring device
- Sub-variants (trade names):
  - none

Pfalzgrafenweiler, April 29, 2025

Hans-Peter Kopp
Owner and managing director
for and on behalf of Erkodent Erich Kopp GmbH