

EU-Declaration of Conformity

- Manufacturer: Erkodent Erich Kopp GmbH
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- SRN of manufacturer: DE-MF-000006243
- Product group: Dental thermoplastic material class I
- References to applied common specifications: none
- Product risk class: Class I according to rule 5 of Annex VIII
- This declaration of conformity is valid until: April 29, 2025 (at the latest)

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).

Dental thermoplastic material class I:

Variant (trade name)	Basic-UDI-DI:	intended use
Bite-help strip	++ERKO081NNNNN1209BY	<ul style="list-style-type: none">• for the quick removal of possible morning malocclusion (in connection with the Silensor-sl [snore protection])
Erkolen	++ERKO091NNNNN1209CX	<ul style="list-style-type: none">• molded parts / caps (not a medical device)• placeholder for fluoride gel• temporary restorations (only molded part [molded part for shaping a temporary restoration extra- or intraoral]; temporary restoration of aesthetics and chewing function up to restoration with the final prosthesis)• etching mask for bracket transfer (etching mask in the form of a splint with cut-out etching or bracket positioning windows [transfer]; exact transfer of the start of orthodontic treatment to the patient; orthodontics)
Erkoplast PLA	++ERKO101NNNNN12095D	<ul style="list-style-type: none">• base plates• bite plates• functional trays• individual impression trays
PLA-handles	++ERKO111NNNNN12096C	<ul style="list-style-type: none">• the handles can be securely attached to thermoformed Erkoplast PLA impression trays with heat. In suitable devices, this is already possible during the thermoforming process
prebite Dott. Pelosi / prebite Dott. Pelosi up	++ERKO121NNNNN12097B	<ul style="list-style-type: none">• occlusal splint blank for immediate, direct adaptation to the patient. For the production of temporary, semi-hard occlusal splints for immediate pain relief and for testing the effectiveness of splints
sl-protrusion gauges	++ERKO131NNNNN12098A	<ul style="list-style-type: none">• snoring protection (gauge for taking a construction bite with changed advanced bite). The sl-protrusion gauge enables the desired or recommended advancement of the Silensor-sl to be registered in a most simple way

Pfalzgrafenweiler, February 07, 2023

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



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