

EU-Declaration of Conformity

Manufacturer: Erkodent Erich Kopp GmbH
(Siemensstraße 3, 72285 Pfalzgrafenweiler,
Germany)
info@erkodent.com

SRN of the Manufacturer: DE-MF-000006243

Product group: Thermoforming sheets for the production of appliances for dental and orthodontic treatment

Conformity assessment procedure according to Annex:

IX

References to applied common specifications: none

Product risk class: IIa according to the rules5_3 of Annex VIII

Notified body: TÜV Rheinland LGA Products GmbH

Identification of the certificate issued: HZ 1073124-1

Validity of this declaration of conformity until: 29.04.2030 (Certificate expiry)

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

Product variant (trade name): Erkodur

Basis-UDI-DI: ++ERK0022aNNNNN1209PR

- Subvariants (trade names): Erkodur
- Subvariants (trade names): Erkodur 240
- Subvariants (trade names): Erkodur freeze
- Subvariants (trade names): Erkodur-0M1
- Subvariants (trade names): Erkodur-A1
- Subvariants (trade names): Erkodur-A2
- Subvariants (trade names): Erkodur-A3

General purpose: Thermoforming sheets for the production of appliances for dental and orthodontic treatment: Detailed purpose:

Erkodur

- Temporary appliances (dental)
- Dressing plate (dental)
- Planning templates, X-ray templates, Orientation templates (implantology)
- Stabilization splints (also: Miniplast splints, Retainer) (dental)
- Protective splints (implantology)
- Silensor-sl anti-snoring device

- Occlusal splints - Bruxism splints (dental)

Erkodur 240

- Temporary appliances (dental)
- Aligners (orthodontic)
- Stabilization splints (also: Miniplast splints, Retainer) (dental)
- Protective splints (implantology)
- Occlusal splints - Bruxism splints (dental)

Erkodur freeze

- Silensor-sl anti-snoring device
- Occlusal splints - Bruxism splints (dental)

Erkodur-0M1

- Temporary appliances (dental)
- Stabilization splints (also: Miniplast splints, Retainer) (dental)
- Silensor-sl anti-snoring device
- Occlusal splints - Bruxism splints (dental)

Erkodur-A1

- Temporary appliances (dental)
- Stabilization splints (also: Miniplast splints, Retainer) (dental)
- Silensor-sl anti-snoring device
- Occlusal splints - Bruxism splints (dental)

Erkodur-A2

- Temporary appliances (dental)
- Stabilization splints (also: Miniplast splints, Retainer) (dental)
- Silensor-sl anti-snoring device
- Occlusal splints - Bruxism splints (dental)

Erkodur-A3

- Temporary appliances (dental)
- Stabilization splints (also: Miniplast splints, Retainer) (dental)
- Silensor-sl anti-snoring device
- Occlusal splints - Bruxism splints (dental)
- Friction-generating coping (Usig)

Pfalzgrafenweiler,

Hans-Peter Kopp

Owner and Chief Executive Officer

for and on behalf of Erkodent Erich Kopp GmbH