

# EU Certificate

## Quality Management System REGULATION (EU) 2017/745 on Medical Devices Annex IX Chapter I, Section 2 and 3 and Chapter III

Registration No.: HZ 1073124-1

Manufacturer: Erkodent Erich Kopp GmbH  
Siemensstr. 3  
72285 Pfalzgrafenweiler  
Germany

EUDAMED Single  
Registration No.: DE-MF-000006243

Products: Products of class IIa:  
  
Q010699 - MATERIALS FOR THE PREPARATION OF  
CUSTOM-MADE DENTAL DEVICES - OTHER

Authorized representative(s): N/A

Certificate history		
Revision:	Description:	Issue date:
1	Initial revision	2021-05-25
2	Re-certification. Replaces certificate HZ 1073124-1 rev. 1 and update of the Q010699 EMDN- official term description	2025-04-29

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled.

If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

Report No.: 1182431-10

Effective date: 2025-04-30

Expiry date: 2030-04-29

Issue date: 2025-04-29

This certificate can be validated on <https://www.certipedia.com>

  
Dipl.-Ing. U. Frenkert  
TÜV Rheinland LGA Products GmbH  
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.



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**EU-Declaration of Conformity**

- Manufacturer: Erkodent Erich Kopp GmbH  
(Siemensstr. 3, 72285 Pfalzgrafenweiler, Germany, [info@erkodent.com](mailto: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): **Erkodur** (variant of product group dental thermoplastic material class IIa)
- Basic-UDI-DI: ++ERKO022aNNNNN1209PR
- Sub-variants (trade names):
  - Erkodur clear / Erkodur 240
  - Erkodur freeze
  - Erkodur-0M1
  - Erkodur-A1
  - Erkodur-A2
  - Erkodur-A3
- General intended use: Thermoforming sheets for the manufacture of apparatus for dental and orthodontic treatment. Purpose in detail:
  - Aligner: Sub-variants Erkodur clear / Erkodur 240
  - Occlusal splints: All sub-variants
  - Friction-generating coping
  - Planning templates: Sub-variants Erkodur clear / Erkodur 240
  - Temporary appliances: Sub-variants Erkodur clear/Erkodur 240/Erkodur-0M1/Erkodur-A1/Erkodur-A2/Erkodur-A3
  - Protection splints: Sub-variants Erkodur clear / Erkodur 240
  - Silensor-sl: Sub-variants Erkodur clear / Erkodur 240 / Erkodur freeze
  - Stabilization splints: Erkodur clear / Erkodur 240 / Erkodur-0M1 / Erkodur-A1 / Erkodur-A2 / Erkodur-A3
  - Dressing plates: Sub-variants Erkodur clear / Erkodur 240

Pfalzgrafenweiler, April 29, 2025



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



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- 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
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- Product (trade name): **Erkodur-al** (variant of product group dental thermoplastic material class IIa)
- Basic-UDI-DI: ++ERKO071NNNNN1209AZ
- Intended use: Manufacture of appliances for dental and orthodontic treatment. Recommended for
  - aligners (orthodontics)
  - retainers (orthodontics)
- Sub-variants (trade names):
  - Erkodur-al / Erkodur-al 240
- General purpose: thermoforming sheets for the production of appliances for dental and orthodontic treatment. Detailed purpose:
  - aligner: sub-variants Erkodur-al / Erkodur-al 240 /
  - retainer: sub-variants Erkodur-al / Erkodur-al 240

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- 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
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- Product (trade name): **Erkoloc-pro** (variant of product group dental thermoplastic material class IIa)
- Basic-UDI-DI: ++ERKO052aNNNNN1209T8
- Intended use: Manufacture of appliances for dental and orthodontic treatment, recommended for:
  - Aligners (orthodontics)
  - Occlusal splints (bruxism splints, michigan splints, CMD-splints)
  - Fluoride trays
  - Stabilization splints
  - Retainers (orthodontics)
  - Silensor-sl anti-snoring device
- Sub-variants (trade names):
  - Erkoloc-pro / Erkoloc-pro 240
  - Erkoloc-pro blu
  - Erkoloc-pro green
  - Erkoloc-pro pink

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- 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
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- Product (trade name): **Erkoflex** (variant of product group dental thermoplastic material class IIa)
- Basic-UDI-DI: ++ERKO032aNNNNN1209QW
- Intended use: manufacture of appliances for dental and orthodontic treatment and for personal protective equipment, recommended for:
  - Occlusal splints
  - Bracket transfer splints (orthodontics)
  - Fluoride trays
  - Positioners (orthodontics)
  - Protection splints (implantology)
  - Radiation protection splints
- Sub-variants (trade names):
  - Erkoflex *transparent und 1-farbig*
  - Erkoflex-95
  - Erkoflex-bleach / Erkoflex-bleach 240
  - Erkoflexsticks-82
  - Erkoflexsticks-95

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- References to applied common specifications: none
- Product risk class: Class IIa according to rule 5 of Annex VIII
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- 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

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