

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.: No registration number available yet

Products: Products of class IIa:
Q010699 - Dentistry Devices, Fabrication Materials - others

Authorised
representative(s): N/A

Certificate history		
Revision:	Description:	Issue date:
1	Initial revision	2021-05-25
2		
3		

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.: 3313027-50

Effective date: 2021-05-25

Expiry date: 2025-04-29

Issue date: 2021-05-25



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zfp.de
BS-MDR-091


Dipl.-Ing. J. 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.

EU-Declaration of Conformity

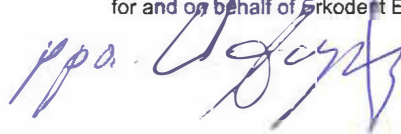
- Manufacturer: Erkodent Erich Kopp GmbH
(Siemensstr. 3, 72285 Pfalzgrafenweiler, Germany, info@erkodent.com, +49 (0) 7445 8501-0)
- SRN of manufacturer: DE-MF-000006243
- Product group: Dental thermoplastic material class IIa
- Conformity assessment procedure: According to Annex IX (conformity assessment 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, 2025 (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
 - Usig-foil
- 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: Usig-foil
 - 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, March 6, 2024

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



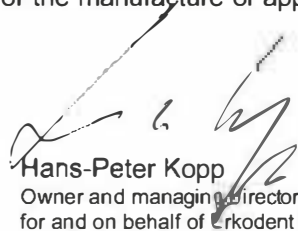
EU-Declaration of Conformity

- 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, 2025 (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
- Validity of this declaration of conformity until: 29.04.2025 at the latest (expiry of certificate)

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-al** (variant of product group dental thermoplastic material class IIa)
- Basic-UDI-DI: ++ERKO071NNNNN1209AZ
- Sub-variants (trade names):
 - Erkodur-al / Erkodur-al 240
- Intended use in general: Thermoforming sheets for the manufacture of apparatus for dental and orthodontic treatment. Intended use in detail:
 - aligners: subvariants Erkodur-al / Erkodur-al 240
 - retainers: subvariants Erkodur-al / Erkodur-al 240

Pfalzgrafenweiler, February 17, 2025



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

EU-Declaration of Conformity

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(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, 2025 (at the latest, expiry of the certificate)
- Notified body: TÜV Rheinland LGA Products GmbH, Tillystraße 2, 90431 Nürnberg, Germany, identification number 0197
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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): **Erkoflex** (variant of product group dental thermoplastic material class IIa)
- Basic-UDI-DI: ++ERKO032aNNNNN1209QW
- Intended use: Material for creating dental splints, recommended for
 - Occlusal splints
 - Bleaching trays
 - 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

Pfalzgrafenweiler, August 13, 2021



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

EU-Declaration of Conformity

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(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, 2025 (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

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- Product (trade name): **Erkoloc-pro** (variant of product group dental thermoplastic material class IIa)
- Basic-UDI-DI: ++ERKO052aNNNNN1209T8
- Intended use: Material for creating dental splints, recommended for
 - Aligners (orthodontics)
 - Occlusal splints (bruxism splints, michigan splints, CMD-splints)
 - Bleaching trays
 - 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

Pfalzgrafenweiler, August 13, 2021



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

EU-Declaration of Conformity

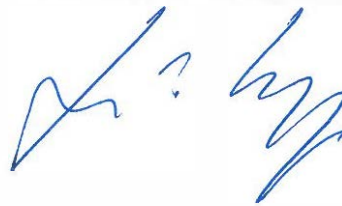
- Manufacturer: Erkodent Erich Kopp GmbH
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- SRN of manufacturer: DE-MF-000006243
- Product group: Dental thermoplastic material class IIa
- Conformity assessment procedure: According to Annex IX (conformity assessment based on a QM system and an assessment 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, 2025 (at the latest, expiry of the certificate)
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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: Recommended for
 - Silensor-sl anti-snoring device
- Sub-variants (trade names):
 - none

Pfalzgrafenweiler, June 2, 2021

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



 **Erkodent Erich Kopp GmbH**
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