

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): Erkoflex

Basis-UDI-DI: ++ERK0032aNNNNN1209QW

- Subvariants (trade names): Erkoflex transparent and 1-color
- Subvariants (trade names): Erkoflex-95
- Subvariants (trade names): Erkoflex-bleach
- Subvariants (trade names): Erkoflexsticks-82
- Subvariants (trade names): Erkoflexsticks-95

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

Erkoflex transparent and 1-color

- Positioners (orthodontics)
- Radiation protection splints (dental)
- Bracket transfer splint

Erkoflex-95

- Protective splints (implantology)
- Occlusal splints - Bruxism splints (dental)

Erkoflex-bleach

- Fluoridation trays (dental)

Erkoflexsticks-82

- Positioners (orthodontics)

Erkoflexsticks-95

- Occlusal splints - Bruxism splints (dental)

Pfalzgrafenweiler,

Hans-Peter Kopp

Owner and Chief Executive Officer

for and on behalf of Erkodent Erich Kopp GmbH