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: Foot orthopedic thermoplastic material
- References to applied common specifications: none
- Product risk class: Class I according to rule 1 of Annex VIII
- This declaration of conformity is valid until: April 29, 2025 (at the latest)
- Intended use: Apparatus for orthopedic treatment of the feet

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 group foot orthopedic thermoplastic material

Variant (trade name)	Basic-UDI-DI:	order numbers
Erkoflex, transparent and coloured	++ERKO191NNNNN1205DU	56xxxx (only in the field of foot orthopedics, without 566000 and 566001), 58xxxx (only in the field of foot orthopedics)

Pfalzgrafenweiler, July 12, 2022

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

Erkodent Erich Kopp GmbH
Siemensstraße 3
72285 Pfalzgrafenweiler · Germany
+49 (0) 7445-8501-0 · +49 (0) 7445-8501-15
info@erkodent.com · www.erkodent.com