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: Silicone
- References to applied common specifications: none
- Product risk class: Class I according to Regulation 1 of Annex VIII
- This declaration of conformity is valid until: April 29, 2025 (at the latest)

Erkodent Erich Kopp GmbH declares under its sole responsibility in accordance with 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 Regulation (EU) 2017/745 in the currently valid version (as of the date of issue of this declaration of conformity).

MD Class I silicone for foot orthopaedic use:

Variant (trade name)	Basic UDI-DI:	Purpose
Erkoton 20 (Order Numbers: 413820, 413825)	++ERKO211NNNNN120579	• Production of individual pressure protection orthoses in the foot orthopaedic field
Erkoton 30 (Order numbers: 413830, 413835)	++ERKO211NNNNN120579	• Production of individual pressure protection orthoses in the foot orthopaedic field

Pfalzgrafenweiler, 24.07.2024

Hans-Peter Kopp
Owner and Managing Director
for and on behalf of Erkodent Erich Kopp GmbH

Erkodent Erich Kopp GmbH
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