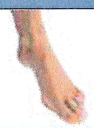
PRODUCTS Declaration of Conformity

(Regulation 745/2017 MDR, for Class I products)

1. Manufacturer's name, trade name, trademark: **Berkemann Hungary Bt.**
2. Manufacturer's unique registration number **(SRN): HU-MF-000007044**
3. Manufacturer's registered office:
   H – 6100 Magyarország
   Kiskunfélegyháza,
   Majsai út 30.

This declaration of conformity is issued under the sole responsibility of our company as the manufacturer.
We declare that the following products are manufactured by us:

Model Photo	Device Item number*	Device UDI-DI code*
Device name and trade name *: Toe aligner		
	508157/002/990-universal	04049261008093
Device name and trade name *: Hammer toe night splint		
	508140/002/990- universal	04049261008321
Device name and trade name *: Toe pad		
	508154/002/652 L-left	04049261008307
	508154/002/651 L-right	04049261008291
	508154/002/641 M-right	04049261008277
	508154/002/642 M-left	04049261008284
	508154/002/631 S-right	04049261008215
	508154/002/632 S-left	04049261008253

Hammer toe correction and relief from pressure pain
Berkemann products relieve the pain caused by pressure and rubbing.
Adjusting and specialty bandages provide gentle position correction

berkemann

Berkemann Hungary Bt.
H – 6100 Magyarország
Kiskunfélegyháza,
Majsai út 30.

Telefon.: 00 36 76 561 010
Telefax.: 00 36 76 561 022

Adószám : 29094420-2-03
Steuernummer : HU 29094420
Cégjegyzékszám : 03-06-107 493

www.berkemann.hu

Risk class: I
Basic UDI:* 4049261KBL
Product EMDN code: Y061203

Uniform specifications, harmonised standards, directives and regulations have been used to determine product conformity.
Based on these

MEETS with

EU Regulation 745/2017 on medical devices.
All supporting documentation is available from the manufacturer.

Kiskunfélegyháza, 15.02.2023.

Company signature:

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Csaba Balla	Márta Csőke
Company director	Company representative