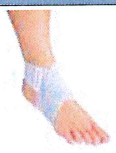
berkemann

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*: Splayfoot bandage		
	508310/002/630 -S	04049261008444
	508310/002/640 -M	04049261008451
	508310/002/650 -L	04049261008468
	508310/002/660 -XL	04049261008475
Device name and trade name*: Splayfoot bandage with pad		
	508320/002/630 -S	04049261008482
	508320/002/640 -M	04049261008499
	508320/002/650 -L	04049261008505
	508320/002/660 -XL	04049261008512
Device name and trade name*: Crossover Arch/Ankle bandage		
	508330/002/630 -S	04049261008529
	508330/002/640 -M	04049261008536
	508330/002/650 -L	04049261008543
	508330/002/660 -XL	04049261008550

Supports the longitudinal and transverse arches
Berkemann special bandages and pads use compression to guide the foot back to its original shape, while special cushions provide soft support for the forefoot.

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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:* **4049261TT00YA**
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, 16.01.2023.

Company signature:

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Csaba Balla	Márta Csőke
Company director	Company representative