

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 *: Valex-N night bandage		
	508450/002/640-M	04049261059675
	508450/002/650- L	04049261059682
Device name and trade name *: Valex D Hallux valgus – day bandage		
	508440/002/661 XL-right	04049261008833
	508440/002/651 L-right	04049261008819
	508440/002/641 M-right	04049261008796
	508440/002/631 S-right	04049261008772
	508440/002/662 XL-left	04049261008840
	508440/002/652 L-left	04049261008826
	508440/002/642 M-left	04049261008802
	508440/002/632 S-left	04049261008789

They mildly correct the deformity of the big toe joint. (Hallux valgus) The products are special bandages.

Risk class: I
Basic UDI:* 4049261HVS2
Product EMDN code: Y061203




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

MEETS with

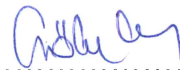
EU Regulation 745/2017 on medical devices.
All supporting documentation is available from the manufacturer.

Kiskunfélegyháza, 19.01.2023.

Company signature:

A blue ink signature of Csaba Balla, consisting of stylized, overlapping loops.

.....
Csaba Balla
Company director

A blue ink signature of Márta Csőke, featuring a more fluid, cursive style.

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Márta Csőke
Company representative