

DECLARATION

OF EC CONFORMITY

MANUFACTURER REH4MAT LTD. DECLARE, THAT
PRODUCT: LOWER - EXTREMITY SUPPORT
LIST OF ITEMS IN APPENDIX NO. 1

of intended use: stabilizes the lower limb joints. Constant compression relieves the pain and improves the healing. The support is used in case of rheumatic, orthopedic and neurological disorders, as a treatment after surgery and in physical therapy.

Marked with the CE sign is Class I medical device, of rule 1, consistent with the requirements of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

The above product to which this declaration applies complies with Regulation (EU) 2017/745 of the European Parliament and of the Council.

Conformity assessment was carried out in accordance with the requirements of the Regulation (EU) 2017/745 of the European Parliament and of the Council.

In order to demonstrate the safety and effectiveness of the medical device, the following standards were used to assess conformity:

PN-EN ISO 20417:2021-10

Medical devices -- Information to be supplied by the manufacturer.

PN-EN ISO 21856:2023-01

Assistive products -- General requirements and test methods.

PN-EN ISO 15223-1:2022-01

Medical devices -- Symbols to be used with information to be supplied by the manufacturer
-- Part 1: General requirements.

PN-EN ISO 13485:2016-04

Medical devices -- Quality management systems -- Requirements for regulatory purposes.

PN-EN ISO 14971:2020-05

Medical devices -- Application of risk management to medical devices.



President of the board
A handwritten signature in black ink, appearing to read 'Sławomir Wroński'.
Sławomir Wroński

THE ABOVE CERTIFICATE WAS ISSUED ON SOLE RESPONSIBILITY OF
REH4MAT LTD., 35-301 RZESZÓW, UL. ZENITOWA 5A,
COUNTRY OF ORIGIN: POLAND, SRN: PL-MF-000009271

APPENDIX NO. 1

TO DECLARATION OF CONFORMITY

PRODUCT - LOWER - EXTREMITY SUPPORT
MODELS:

OKD-31	(Basic UDI-DI 59009497OKD-31L6);	OKD-65	(Basic UDI-DI 59009497OKD-65LP),
OKD-32	(Basic UDI-DI 59009497OKD-32L8);	OKD-66	(Basic UDI-DI 59009497OKD-66LR),
OKD-33	(Basic UDI-DI 59009497OKD-33LA);	OKD-67	(Basic UDI-DI 59009497OKD-67LT),
OKD-34	(Basic UDI-DI 59009497OKD-34LC);	OKD-68	(Basic UDI-DI 59009497OKD-68LV),
OKD-35	(Basic UDI-DI 59009497OKD-35LE);	OKD-69	(Basic UDI-DI 59009497OKD-69LX),
OKD-36	(Basic UDI-DI 59009497OKD-36LG);	OKD-70	(Basic UDI-DI 59009497OKD-70LG),
OKD-37	(Basic UDI-DI 59009497OKD-37LJ);	OKD-71	(Basic UDI-DI 59009497OKD-71LJ),
OKD-38	(Basic UDI-DI 59009497OKD-38LL);	OKD-72	(Basic UDI-DI 59009497OKD-72LL),
OKD-39	(Basic UDI-DI 59009497OKD-39LN);	OKD-73	(Basic UDI-DI 59009497OKD-73LN),
OKD-40	(Basic UDI-DI 59009497OKD-40L7);	OKD-74	(Basic UDI-DI 59009497OKD-74LQ),
OKD-41	(Basic UDI-DI 59009497OKD-41L9);	OKD-75	(Basic UDI-DI 59009497OKD-75LS),
OKD-42	(Basic UDI-DI 59009497OKD-42LB);	OKD-76	(Basic UDI-DI 59009497OKD-76LU),
OKD-43	(Basic UDI-DI 59009497OKD-43LD);	OKD-77	(Basic UDI-DI 59009497OKD-77LW),
OKD-44	(Basic UDI-DI 59009497OKD-44LF);	OKD-78	(Basic UDI-DI 59009497OKD-78LY),
OKD-45	(Basic UDI-DI 59009497OKD-45LH);	OKD-79	(Basic UDI-DI 59009497OKD-79M2),
OKD-46	(Basic UDI-DI 59009497OKD-46LK);	OKD-80	(Basic UDI-DI 59009497OKD-80LK),
OKD-47	(Basic UDI-DI 59009497OKD-47LM);	OKD-81	(Basic UDI-DI 59009497OKD-81LM),
OKD-48	(Basic UDI-DI 59009497OKD-48LP);	OKD-82	(Basic UDI-DI 59009497OKD-82LP),
OKD-49	(Basic UDI-DI 59009497OKD-49LR);	OKD-83	(Basic UDI-DI 59009497OKD-83LR),
OKD-50	(Basic UDI-DI 59009497OKD-50LA);	OKD-84	(Basic UDI-DI 59009497OKD-84LT),
OKD-51	(Basic UDI-DI 59009497OKD-51LC);	OKD-85	(Basic UDI-DI 59009497OKD-85LV),
OKD-52	(Basic UDI-DI 59009497OKD-52LE);	OKD-86	(Basic UDI-DI 59009497OKD-86LX),
OKD-53	(Basic UDI-DI 59009497OKD-53LG);	OKD-87	(Basic UDI-DI 59009497OKD-87LZ),
OKD-54	(Basic UDI-DI 59009497OKD-54LJ);	OKD-88	(Basic UDI-DI 59009497OKD-88M3),
OKD-55	(Basic UDI-DI 59009497OKD-55LL);	OKD-89	(Basic UDI-DI 59009497OKD-89M5),
OKD-56	(Basic UDI-DI 59009497OKD-56LN);	OKD-90	(Basic UDI-DI 59009497OKD-90LN).
OKD-57	(Basic UDI-DI 59009497OKD-57LQ);		
OKD-58	(Basic UDI-DI 59009497OKD-58LS);		
OKD-59	(Basic UDI-DI 59009497OKD-59LU);		
OKD-60	(Basic UDI-DI 59009497OKD-60LD);		
OKD-61	(Basic UDI-DI 59009497OKD-61LF);		
OKD-62	(Basic UDI-DI 59009497OKD-62LH);		
OKD-63	(Basic UDI-DI 59009497OKD-63LK);		
OKD-64	(Basic UDI-DI 59009497OKD-64LM);		



President of the board

Sławomir Wroński

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