

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

Rzeszów, 27.03.2024 NO. 52/D/EN/10 page 1/8

APPENDIX NO. 1

TO DECLARATION OF CONFORMITY

PRODUCT: LOWER - EXTREMITY SUPPORT
MODELS:

LOWER-EXTREMITY SUPPORT OKD-10	(Basic UDI-DI 59009497OKD-10KW),
LOWER-EXTREMITY SUPPORT OKD-11	(Basic UDI-DI 59009497OKD-11KY),
LOWER-EXTREMITY SUPPORT OKD-12	(Basic UDI-DI 59009497OKD-12L2),
LOWER-EXTREMITY SUPPORT OKD-13	(Basic UDI-DI 59009497OKD-13L4),
LOWER-EXTREMITY SUPPORT OKD-14	(Basic UDI-DI 59009497OKD-14L6),
LOWER-EXTREMITY SUPPORT OKD-15	(Basic UDI-DI 59009497OKD-15L8),
LOWER-EXTREMITY SUPPORT OKD-16	(Basic UDI-DI 59009497OKD-16LA),
LOWER-EXTREMITY SUPPORT OKD-17	(Basic UDI-DI 59009497OKD-17LC),
LOWER-EXTREMITY SUPPORT OKD-18	(Basic UDI-DI 59009497OKD-18LE),
LOWER-EXTREMITY SUPPORT OKD-19	(Basic UDI-DI 59009497OKD-19LG),
LOWER-EXTREMITY SUPPORT OKD-20	(Basic UDI-DI 59009497OKD-20KZ),
LOWER-EXTREMITY SUPPORT OKD-21	(Basic UDI-DI 59009497OKD-21L3),
LOWER-EXTREMITY SUPPORT OKD-22	(Basic UDI-DI 59009497OKD-22L5),
LOWER-EXTREMITY SUPPORT OKD-23	(Basic UDI-DI 59009497OKD-23L7),
LOWER-EXTREMITY SUPPORT OKD-24	(Basic UDI-DI 59009497OKD-24L9),
LOWER-EXTREMITY SUPPORT OKD-25	(Basic UDI-DI 59009497OKD-25LB),
LOWER-EXTREMITY SUPPORT OKD-26	(Basic UDI-DI 59009497OKD-26LD),
LOWER-EXTREMITY SUPPORT OKD-27	(Basic UDI-DI 59009497OKD-27LF),
LOWER-EXTREMITY SUPPORT OKD-28	(Basic UDI-DI 59009497OKD-28LH),
LOWER-EXTREMITY SUPPORT OKD-29	(Basic UDI-DI 59009497OKD-29LK),
LOWER-EXTREMITY SUPPORT OKD-30	(Basic UDI-DI 59009497OKD-30L4),
LOWER-EXTREMITY SUPPORT AM-OSS-21	(Basic UDI-DI 59009497AM-OSS-216L),
LOWER-EXTREMITY SUPPORT AM-OSS-22	(Basic UDI-DI 59009497AM-OSS-226N),
LOWER-EXTREMITY SUPPORT AM-OSS-23	(Basic UDI-DI 59009497AM-OSS-236Q),
LOWER-EXTREMITY SUPPORT AM-OSS-24	(Basic UDI-DI 59009497OSS-OS-02/CCAC4),
LOWER-EXTREMITY SUPPORT AM-OSS-25	(Basic UDI-DI 59009497AM-OSS-256U),
LOWER-EXTREMITY SUPPORT AM-OSS-26	(Basic UDI-DI 59009497AM-OSS-266W),
LOWER-EXTREMITY SUPPORT AM-OSS-27	(Basic UDI-DI 59009497AM-OSS-276Y),
LOWER-EXTREMITY SUPPORT AM-OSS-28	(Basic UDI-DI 59009497AM-OSS-2872),
LOWER-EXTREMITY SUPPORT AM-OSS-29	(Basic UDI-DI 59009497AM-OSS-2974),
LOWER-EXTREMITY SUPPORT AM-OSS-30	(Basic UDI-DI 59009497AM-OSS-306M),
LOWER-EXTREMITY SUPPORT AM-SB-06	(Basic UDI-DI 59009497AM-SB-06LW),
LOWER-EXTREMITY SUPPORT AM-SB-07	(Basic UDI-DI 59009497AM-SB-07LY),
LOWER-EXTREMITY SUPPORT AM-SB-08	(Basic UDI-DI 59009497AM-SB-08M2),
LOWER-EXTREMITY SUPPORT AM-SB-09	(Basic UDI-DI 59009497AM-SB-09M4),
LOWER-EXTREMITY SUPPORT AM-SB-10	(Basic UDI-DI 59009497AM-SB-10LM),



President of the board

Sławomir Wroński

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