

# DECLARATION

## OF EC CONFORMITY

MANUFACTURER REH4MAT LTD. DECLARE, THAT  
PRODUCT: HIP ORTHOSIS  
LIST OF ITEMS IN APPENDIX NO. 1

of intended use: provides compression, stabilization and relief, reducing, inflammation and improving the healing.  
It can be used in orthopedics, neurology rheumatology and 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

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# APPENDIX NO. 1

## TO DECLARATION OF CONFORMITY

PRODUCT - HIP ORTHOSIS  
MODELS:

AM-SB/1RE  
AM-ADS-R  
AM-SB/2R  
HIP ORTHOSIS AM-SB-01  
HIP ORTHOSIS AM-SB-02  
HIP ORTHOSIS AM-SB-03  
HIP ORTHOSIS AM-SB-04  
HIP ORTHOSIS AM-SB-05  
HIP ORTHOSIS AM-SB-06

(Basic UDI-DI 59009497AM-SB/1REXC),  
(Basic UDI-DI 59009497AM-ADS-RNC),  
(Basic UDI-DI 59009497AM-SB/2RP4),  
(Basic UDI-DI 59009497AM-SB-01LL),  
(Basic UDI-DI 59009497AM-SB-02LN),  
(Basic UDI-DI 59009497AM-SB-03LQ),  
(Basic UDI-DI 59009497AM-SB-04LS),  
(Basic UDI-DI 59009497AM-SB-05LU),  
(Basic UDI-DI 59009497AM-SB-06LW).



*President of the board*  
  
Sławomir Wroński

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