

# 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

Rzeszów, 27.03.2024 No. 114/D/EN/3 page 1/2

# APPENDIX NO. 1

## TO DECLARATION OF CONFORMITY

PRODUCT - HIP ORTHOSIS  
MODELS:

AM-SB-12  
AM-SB-13  
AM-SB-14  
AM-SB-15  
AM-SB-16  
AM-SB-17  
AM-SB-18  
AM-SB-19  
AM-SB-20

(Basic UDI-DI 59009497AM-SB-12LR),  
(Basic UDI-DI 59009497AM-SB-13LT),  
(Basic UDI-DI 59009497AM-SB-14LV),  
(Basic UDI-DI 59009497AM-SB-15LX),  
(Basic UDI-DI 59009497AM-SB-16LZ),  
(Basic UDI-DI 59009497AM-SB-17M3),  
(Basic UDI-DI 59009497AM-SB-18M5),  
(Basic UDI-DI 59009497AM-SB-19M7),  
(Basic UDI-DI 59009497AM-SB-20LQ).



*President of the board*  
  
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. 114/D/EN/3 page 2/2