



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.

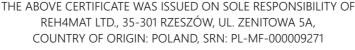
PN-EN ISO 14971:2020-05

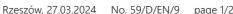
Medical devices -- Application of risk management to medical devices.





President of the board
Sławomir Wroński













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-05 (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).









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. 59/D/EN/9 page 2/2

