



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
Sławgmir 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

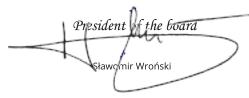
PRODUCT - HIP ORTHOSIS MODELS:

AM-SB-12	
AM-SB-13	
AM-SB-14	
AM-SB-15	
AM-SB-16	
AM-SB-17	
AM-SB-18	
AM-SB-19	
ΔM-SR-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).









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