



DECLARATION

OF EC CONFORMITY

MANUFACTURER REH4MAT LTD. DECLARE, THAT
PRODUCT: HOT / COLD AND COMPRESSION THERAPY WRAP
LIST OF ITEMS IN APPENDIX NO. 1

of intended use: to stabilize the joint with the simultaneous hot or cold 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

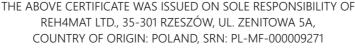
Medical devices -- Application of risk management to medical devices.





President of the board

Sławomir Wroński













APPENDIX NO. 1 TO DECLARATION OF CONFORMITY

PRODUCT - HOT / COLD AND COMPRESSION THERAPY WRAP MODELS:

TB-21			
TB-22			
TB-23			
TB-24			
TB-25			
TB-26			
TB-27			
TB-28			
TB-29			
TB-30			
TB-31			
TB-32			
TB-33			
TB-34			
TB-35			
TB-36			
TB-37			
TB-38			
TB-39			
TB-40			

(Basic UDI-DI 59009497TB-21KW), (Basic UDI-DI 59009497TB-22KY), (Basic UDI-DI 59009497TB-23L2), (Basic UDI-DI 59009497TB-24L4), (Basic UDI-DI 59009497TB-25L6), (Basic UDI-DI 59009497TB-26L8), (Basic UDI-DI 59009497TB-27LA), (Basic UDI-DI 59009497TB-28LC), (Basic UDI-DI 59009497TB-29LE), (Basic UDI-DI 59009497TB-30KX), (Basic UDI-DI 59009497TB-31KZ), (Basic UDI-DI 59009497TB-32L3), (Basic UDI-DI 59009497TB-33L5), (Basic UDI-DI 59009497TB-34L7), (Basic UDI-DI 59009497TB-35L9), (Basic UDI-DI 59009497TB-36LB), (Basic UDI-DI 59009497TB-37LD), (Basic UDI-DI 59009497TB-38LF), (Basic UDI-DI 59009497TB-39LH), (Basic UDI-DI 59009497TB-40L2).









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. 110/D/EN/4 page 2/2

