

DECLARATION

OF EC CONFORMITY

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

of intended use: provides stabilization and cooling the joint in case of injury or inflammation.

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

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 - ICE AND COMPRESSION THERAPY WRAP
MODELS:

TB-01
TB-02
TB-03
TB-04
TB-05
TB-06
TB-07
TB-08
TB-09
TB-10
TB-11
TB-12
TB-13
TB-14
TB-15
TB-16
TB-17
TB-18
TB-19
TB-20

(Basic UDI-DI 59009497TB-01KQ),
(Basic UDI-DI 59009497TB-02KS),
(Basic UDI-DI 59009497TB-03KU),
(Basic UDI-DI 59009497TB-04KW),
(Basic UDI-DI 59009497TB-05KY),
(Basic UDI-DI 59009497TB-06L2),
(Basic UDI-DI 59009497TB-07L4),
(Basic UDI-DI 59009497TB-08L6),
(Basic UDI-DI 59009497TB-09L8),
(Basic UDI-DI 59009497TB-10KR),
(Basic UDI-DI 59009497TB-11KT),
(Basic UDI-DI 59009497TB-12KV),
(Basic UDI-DI 59009497TB-13KX),
(Basic UDI-DI 59009497TB-14KZ),
(Basic UDI-DI 59009497TB-15L3),
(Basic UDI-DI 59009497TB-16L5),
(Basic UDI-DI 59009497TB-17L7),
(Basic UDI-DI 59009497TB-18L9),
(Basic UDI-DI 59009497TB-19LB),
(Basic UDI-DI 59009497TB-20KU).



President of the board

Sławomir Wroński

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