

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

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 1/2

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).



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