

DECLARATION

OF EC CONFORMITY

MANUFACTURER REH4MAT LTD. DECLARE, THAT
PRODUCT: KNEE ORTHOSIS
LIST OF ITEMS IN APPENDIX NO. 1

of intended use: a bandage intended to be worn over the groin to prevent the protrusion of abdominal contents in adults with an inguinal hernia.

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
A handwritten signature in black ink, appearing to read 'Sławomir Wroński'.
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

APPENDIX NO. 1

TO DECLARATION OF CONFORMITY

PRODUCT - KNEE ORTHOSIS
MODELS:

EB-P/RZ
U-SK
U-SK-01
U-SK-02

KNEE ORTHOSIS AS-KX-06
KNEE ORTHOSIS AS-KX-05
KNEE ORTHOSIS AS-KX-04
KNEE ORTHOSIS AS-KX-08
KNEE ORTHOSIS AS-KX-07
KNEE ORTHOSIS AS-P/RZ
KNEE ORTHOSIS AS-KX-01
KNEE ORTHOSIS AS-KX-02
KNEE ORTHOSIS AS-KX-03

(Basic UDI-DI 59009497EB-P/RZF2),
(Basic UDI-DI 59009497U-SKSL),
(Basic UDI-DI 59009497U-SK-01M5),
(Basic UDI-DI 59009497U-SK-02M7),
(Basic UDI-DI 59009497AS-KX-06S6),
(Basic UDI-DI 59009497AS-KX-05S4),
(Basic UDI-DI 59009497AS-KX-04S2),
(Basic UDI-DI 59009497AS-KX-08SA),
(Basic UDI-DI 59009497AS-KX-07S8),
(Basic UDI-DI 59009497AS-P/RZKT),
(Basic UDI-DI 59009497AS-KX-01RU),
(Basic UDI-DI 59009497AS-KX-02RW),
(Basic UDI-DI 59009497AS-KX-03RY).



President of the board

Sławomir Wroński

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