

# DECLARATION

## OF EC CONFORMITY

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

of intended use: prevent against the deformations by maintaining correct position of body. Furthermore, they are made of special fabrics that promote anti bed sore treatment.

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 be '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

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# APPENDIX NO. 1

## TO DECLARATION OF CONFORMITY

PRODUCT - CUSHION  
MODELS:

CUSHION KO-PU-B  
CUSHION KW-PU-01  
CUSHION PP-FF-02  
CUSHION PP-FF-03  
CUSHION PP-VM-Z  
CUSHION PP-VM-B  
CUSHION PA-VM-04  
CUSHION PA-VM-05  
CUSHION PA-VM-06  
CUSHION PA-VM-07  
CUSHION PA-FF-01  
CUSHION PA-VM-01  
CUSHION PA-VM-02  
CUSHION PA-VM-03  
CUSHION PA-VM-08  
CUSHION PA-VM-09  
CUSHION PA-VM-10  
CUSHION PA-VM-11  
CUSHION PA-VM-12  
CUSHION PA-VM-13  
CUSHION PA-VM-14  
CUSHION PA-VM-15

(Basic UDI-DI 590128913KO-PU-BF5),  
(Basic UDI-DI 590128913KW-PU-01T5),  
(Basic UDI-DI 590128913PP-FF-02KQ),  
(Basic UDI-DI 59009497PP-FF-03TM),  
(Basic UDI-DI 59009497PP-VM-ZV2),  
(Basic UDI-DI 59009497PP-VM-BTJ),  
(Basic UDI-DI 59009497PA-VM-04SR),  
(Basic UDI-DI 59009497PA-VM-05ST),  
(Basic UDI-DI 59009497PA-VM-06SV),  
(Basic UDI-DI 59009497PA-VM-07SX),  
(Basic UDI-DI 59009497PA-FF-01KJ),  
(Basic UDI-DI 59009497PA-VM-01SK),  
(Basic UDI-DI 59009497PA-VM-02SM),  
(Basic UDI-DI 59009497PA-VM-03SP),  
(Basic UDI-DI 59009497PA-VM-08SZ),  
(Basic UDI-DI 59009497PA-VM-09T3),  
(Basic UDI-DI 59009497PA-VM-10SL),  
(Basic UDI-DI 59009497PA-VM-11SN),  
(Basic UDI-DI 59009497PA-VM-12SQ),  
(Basic UDI-DI 59009497PA-VM-13SS),  
(Basic UDI-DI 59009497PA-VM-14SU),  
(Basic UDI-DI 59009497PA-VM-15SW).



*President of the board*  
  
Sławomir Wroński

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