

DECLARATION

OF EC CONFORMITY

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

of intended use: useful in case of neurological disorders, urological conditions or while climacteric. Therapeutic support of incontinence's treatment for medication or positional 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
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

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APPENDIX NO. 1

TO DECLARATION OF CONFORMITY

PRODUCT - WATERPROOF BED PAD
MODELS:

PN-01
PB-01
PG-01

WATERPROOF BED PAD PN-02
WATERPROOF BED PAD PN-03
WATERPROOF BED PAD PB-02
WATERPROOF BED PAD PB-03
WATERPROOF BED PAD PG-02
WATERPROOF BED PAD PG-03
WATERPROOF BED PAD P-01
WATERPROOF BED PAD P-02

(Basic UDI-DI 59009497PN-01LY),
(Basic UDI-DI 59009497PB-01JC),
(Basic UDI-DI 59009497PG-01KF),
(Basic UDI-DI 59009497PN-02M2),
(Basic UDI-DI 59009497PN-03M4),
(Basic UDI-DI 59009497PB-02JE),
(Basic UDI-DI 59009497PB-03JG),
(Basic UDI-DI 59009497PG-02KH),
(Basic UDI-DI 59009497PG-03KK),
(Basic UDI-DI 59009497P-01LR),
(Basic UDI-DI 59009497P-02LT).



President of the board
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Sławomir Wroński

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