

DECLARATION

OF EC CONFORMITY

MANUFACTURER REH4MAT LTD. DECLARE, THAT
PRODUCT: POSTURAL AIDS SYSTEM IN THE LYING POSITION STABILO-BED
LIST OF ITEMS IN APPENDIX NO. 1

of intended use: for precise positioning the user. stabilization and compensation of deficits resulting from deformation of the osteoarticular system and weakening of postural muscles. For people who are immobilized for a long time, at risk of developing pressure ulcers.

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 - POSTURAL AIDS SYSTEM IN THE LYING POSITION STABILO-BED
MODELS:

LOWER EXTREMITY ABDUCTION PILLOW P-SS-01	(Basic UDI-DI 59009497P-SS-01L8),
ABDUCTION BLOCK FOR KNEES P-SS-03	(Basic UDI-DI 59009497P-SS-03LC),
CALF WEDGE P-SS-06	(Basic UDI-DI 59009497P-SS-06LJ),
LOWER EXTREMITY ABDUCTION PILLOW P-SS-11	(Basic UDI-DI 59009497P-SS-11LB),
THERMOACTIVE LOWER LIMB RAISING WEDGE K-SS-06	(Basic UDI-DI 59009497K-SS-06HV),
ANATOMIC-SHAPED CUSHION UNDER HEAD P-SS-04	(Basic UDI-DI 59009497P-SS-04LE),
V' PILLOW P-SS-15	(Basic UDI-DI 59009497P-SS-15LK),
SILICONE PILLOW P-SS-21	(Basic UDI-DI 59009497P-SS-21LE),
THERMOACTIVE SUPPORT CUSHION P-SS-22	(Basic UDI-DI 59009497P-SS-22LG),
LATERAL POSITIONING CUSHION P-SS-08	(Basic UDI-DI 59009497P-SS-08LN),
SEMI-SOFT BOLSTER PILLOWS P P-SS-14	(Basic UDI-DI 59009497P-SS-14LH),
BACKREST WITH SELF-GRIPPING FUNCTION K-SS-05	(Basic UDI-DI 59009497K-SS-05HT),
UPPER EXTREMITY SUPPORT WITH PROTECTOR P-SS-20	(Basic UDI-DI 59009497P-SS-20LC),
WEDGE WITH SELF-GRIPPING FUNCTION K-SS-02	(Basic UDI-DI 59009497K-SS-02HM),
CYLINDRICAL CUSHION P-SS-02	(Basic UDI-DI 59009497P-SS-02LA),
PILLOW BETWEEN LEGS P-SS-05	(Basic UDI-DI 59009497P-SS-05LG),
KNEE WEDGE P-SS-10	(Basic UDI-DI 59009497P-SS-10L9),
UNIVERSAL BIG CUSHION P-SS-16	(Basic UDI-DI 59009497P-SS-16LM),
THERMOACTIVE BRAUN SPLINT K-SS-07	(Basic UDI-DI 59009497K-SS-07HX),
ANTI BEDSORE ROUND CUSHION P-SS-09	(Basic UDI-DI 59009497P-SS-09LQ),
ZAGŁÓWEK P-SS-18	(Basic UDI-DI 59009497P-SS-18LR),
HEADREST P-SS-19	(Basic UDI-DI 59009497P-SS-19LT),
NECK RING CUSHION P-SS-13	(Basic UDI-DI 59009497P-SS-13LF),
LATERAL POSITIONING WEDGE P-SS-12	(Basic UDI-DI 59009497P-SS-12LD),
SEMI-RIGID BOLSTER PILLOWS FOR TRUNK SUPPORT P-SS-17	(Basic UDI-DI 59009497P-SS-17LP),
IPEDIATRIC IMMOBILIZER P-SS-23	(Basic UDI-DI 59009497P-SS-23LJ),
THERMOACTIVE ELEVATION ARM WEDGE K-SS-01	(Basic UDI-DI 59009497K-SS-01HK),
SHAPED WEDGE K-SS-08	(Basic UDI-DI 59009497K-SS-08HZ),
ANTI-BEDSORE DONUT CUSHION P-SS-24	(Basic UDI-DI 59009497P-SS-24LL),
HEAD CUSHION P-SS-25	(Basic UDI-DI 59009497P-SS-25LN),
ORTHOPEDIC NECK PILLOW P-SS-26	(Basic UDI-DI 59009497P-SS-26LQ),
REFLUX BABY WEDGE P-SS-27	(Basic UDI-DI 59009497P-SS-27LS),
PEDIATRIC LOWER LIMBS ABDUCTION WEDGE P-SS-28	(Basic UDI-DI 59009497P-SS-28LU),
UNIVERSAL POSITIONING CUSHION P-SS-29	(Basic UDI-DI 59009497P-SS-29LW),
LOWER LIMBS POSITIONING WEDGE P-SS-30	(Basic UDI-DI 59009497P-SS-30LF),



President of the board

Sławomir Wroński

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TO DECLARATION OF CONFORMITY

PRODUCT - POSTURAL AIDS SYSTEM IN THE LYING POSITION STABILO-BED
MODELS:

UNIVERSAL CUSHION P-SS-31 CYLINDRICAL CUSHION WITH THE ABDUCTION WEDGE AND SIDE SUPPORTS P-SS-32	(Basic UDI-DI 59009497P-SS-31LH), (Basic UDI-DI 59009497P-SS-32LK), (Basic UDI-DI 59009497P-SS-33LM), (Basic UDI-DI 59009497P-SS-34LP), (Basic UDI-DI 59009497P-SS-35LR), (Basic UDI-DI 59009497P-SS-36LT), (Basic UDI-DI 59009497P-SS-37LV), (Basic UDI-DI 59009497P-SS-38LX), (Basic UDI-DI 59009497P-SS-39LZ), (Basic UDI-DI 59009497P-SS-40LJ), (Basic UDI-DI 59009497P-SS-41LL), (Basic UDI-DI 59009497P-SS-42LN), (Basic UDI-DI 59009497P-SS-43LQ), (Basic UDI-DI 59009497P-SS-44LS), (Basic UDI-DI 59009497P-SS-45LU), (Basic UDI-DI 59009497P-SS-46LW), (Basic UDI-DI 59009497P-SS-47LY), (Basic UDI-DI 59009497P-SS-48M2), (Basic UDI-DI 59009497P-SS-49M4), (Basic UDI-DI 59009497P-SS-50LM), (Basic UDI-DI 59009497P-SS-51LP), (Basic UDI-DI 59009497P-SS-52LR), (Basic UDI-DI 59009497P-SS-53LT), (Basic UDI-DI 59009497P-SS-54LV), (Basic UDI-DI 59009497K-SS-31HU), (Basic UDI-DI 59009497K-SS-09J3), (Basic UDI-DI 59009497K-SS-10HL), (Basic UDI-DI 59009497K-SS-11H), (Basic UDI-DI 59009497K-SS-12HQ), (Basic UDI-DI 59009497K-SS-13HS), (Basic UDI-DI 59009497K-SS-14HU), (Basic UDI-DI 59009497K-SS-15HW), (Basic UDI-DI 59009497K-SS-16HY),
LOWER LIMBS POSITIONING CUSHION P-SS-33	
LOWER LIMBS POSITIONING CUSHION P-SS-34	
LOWER LIMBS POSITIONING CUSHION P-SS-35	
LOWER LIMBS POSITIONING CUSHION P-SS-36	
UPPER LIMBS POSITIONING CUSHION P-SS-37	
SENSORY BEAN BAG FLOOR CUSHION P-SS-38	
TRUNK POSITIONING CUSHION P-SS-39	
TRUNK POSITIONING CUSHION P-SS-40	
TRUNK POSITIONING CUSHION P-SS-41	
TRUNK POSITIONING CUSHION P-SS-42	
TRUNK POSITIONING CUSHION P-SS-43	
HEAD POSITIONING CUSHION P-SS-44	
NECK POSITIONING CUSHION P-SS-45	
TRUNK POSITIONING CUSHION P-SS-46	
TRUNK POSITIONING CUSHION P-SS-47	
TRUNK POSITIONING CUSHION P-SS-48	
TRUNK POSITIONING CUSHION P-SS-49	
TRUNK POSITIONING CUSHION P-SS-50	
UNIVERSAL LIMB SEPARATOR P-SS-51	
ANTI-BEDSORE CUSHION FOR THE LOWER LIMBS P-SS-52	
PATIENT TRANSFER BELT P-SS-53	
CHANGING POSITION CUSHION P-SS-54	
TRAPEZOID HEADREST P-SS-55	
LONG LOWER LIMB SEPARATOR K-SS-31	
LOWER LIMB RAISING WEDGE K-SS-09	
BRAUN SPLINT K-SS-10	
THERMOACTIVE BRAUN SPLINT WITH FOOT SUPPORT K-SS-11	
WEDGE K-SS-12	
WEDGE K-SS-13	
WEDGE K-SS-14	
WEDGE K-SS-15	
WEDGE K-SS-16	



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WEDGE K-SS-17	(Basic UDI-DI 59009497K-SS-17J2),
WEDGE K-SS-18	(Basic UDI-DI 59009497K-SS-18J4),
WEDGE K-SS-19	(Basic UDI-DI 59009497K-SS-19J6),
WEDGE K-SS-20	(Basic UDI-DI 59009497K-SS-20HP),
WEDGE K-SS-21	(Basic UDI-DI 59009497K-SS-21HR),
WEDGE K-SS-22	(Basic UDI-DI 59009497K-SS-22HT),
WEDGE K-SS-23	(Basic UDI-DI 59009497K-SS-23HV),
WEDGE K-SS-24	(Basic UDI-DI 59009497K-SS-24HX),
WEDGE K-SS-25	(Basic UDI-DI 59009497K-SS-25HZ),
WEDGE K-SS-26	(Basic UDI-DI 59009497K-SS-26J3),
WEDGE K-SS-27	(Basic UDI-DI 59009497K-SS-27J5),
WEDGE K-SS-28	(Basic UDI-DI 59009497K-SS-28J7),
WEDGE K-SS-29	(Basic UDI-DI 59009497K-SS-29J9),
WEDGE K-SS-30	(Basic UDI-DI 59009497K-SS-30HS),
REHABILITATION ROLLER W-SS-01	(Basic UDI-DI 59009497W-SS-01PX),
REHABILITATION ROLLER W-SS-02	(Basic UDI-DI 59009497W-SS-02PZ),
REHABILITATION ROLLER W-SS-03	(Basic UDI-DI 59009497W-SS-03Q3),
REHABILITATION ROLLER W-SS-04	(Basic UDI-DI 59009497W-SS-04Q5),
REHABILITATION ROLLER W-SS-05	(Basic UDI-DI 59009497W-SS-05Q7),
REHABILITATION ROLLER W-SS-06	(Basic UDI-DI 59009497W-SS-06Q9),
REHABILITATION ROLLER W-SS-07	(Basic UDI-DI 59009497W-SS-07QB),
REHABILITATION ROLLER W-SS-08	(Basic UDI-DI 59009497W-SS-08QD),
REHABILITATION ROLLER W-SS-09	(Basic UDI-DI 59009497W-SS-09QF),
REHABILITATION ROLLER W-SS-10	(Basic UDI-DI 59009497W-SS-10PY),
FORM F-SS-01	(Basic UDI-DI 59009497F-SS-01EW),
FORM F-SS-02	(Basic UDI-DI 59009497F-SS-02EY),
FORM F-SS-03	(Basic UDI-DI 59009497F-SS-03F2),
FORM F-SS-04	(Basic UDI-DI 59009497F-SS-04F4),
FORM F-SS-05	(Basic UDI-DI 59009497F-SS-05F6),
FORM F-SS-06	(Basic UDI-DI 59009497F-SS-06F8),
FORM F-SS-07	(Basic UDI-DI 59009497F-SS-07FA),
FORM F-SS-08	(Basic UDI-DI 59009497F-SS-08FC),
FORM F-SS-09	(Basic UDI-DI 59009497F-SS-09FE),
FORM F-SS-10	(Basic UDI-DI 59009497F-SS-10EX),



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MODELS:

MODULAR MATTRESS M-SS	(Basic UDI - DI 59009497M-SSRC),
LOWER EXTREMITY ABDUCTION PILLOW PM-SS-01	(Basic UDI - DI 59009497PM-SS-01Z8),
CYLINDRICAL CUSHION PM-SS-02	(Basic UDI - DI 59009497PM-SS-02ZA),
CALF WEDGE PM-SS-06	(Basic UDI - DI 59009497PM-SS-06ZJ),
LATERAL POSITIONING CUSHION PM-SS-08	(Basic UDI - DI 59009497PM-SS-08ZN),
ANTI-BEDSORE ROUND CUSHION PM-SS-09	(Basic UDI - DI 59009497PM-SS-09ZQ),
KNEE WEDGE PM-SS-10	(Basic UDI - DI 59009497PM-SS-10Z9),
LATERAL POSITIONING WEDGE PM-SS-12	(Basic UDI - DI 59009497PM-SS-12ZD),
RING CUSHION PM-SS-13	(Basic UDI - DI 59009497PM-SS-13ZF),
SEMI-SOFT BOLSTER PILLOWS PM-SS-14	(Basic UDI - DI 59009497PM-SS-14ZH),
'V' PILLOW PM-SS-15	(Basic UDI - DI 59009497PM-SS-15ZK),
SEMI-RIGID BOLSTER PILLOWS FOR TRUNK SUPPORT PM-SS-17	(Basic UDI - DI 59009497PM-SS-17ZP),
HEADREST PM-SS-18	(Basic UDI - DI 59009497PM-SS-18ZR),
PEDIATRIC IMMOBILIZER PM-SS-23	(Basic UDI - DI 59009497PM-SS-23ZJ),
ORTHOPEDIC NECK PILLOW PM-SS-26	(Basic UDI - DI 59009497PM-SS-26ZQ),
LOWER LIMB POSITIONING WEDGE PM-SS-30	(Basic UDI - DI 59009497PM-SS-30ZF),
CYLINDRICAL CUSHION WITH THE ABDUCTION WEDGE AND SIDE SUPPORTS PM-SS-32	(Basic UDI - DI 59009497PM-SS-32ZK),
CUSHION FOR THE LOWER LIMBS WITH ABDUCTION WEDGE PM-SS-56	(Basic UDI - DI 59009497PM-SS-5624),
THERMOACTIVE ELEVATION ARM WEDGE KM-SS-01	(Basic UDI - DI 59009497KM-SS-01W9),
WEDGE KM-SS-02	(Basic UDI - DI 59009497KM-SS-02WB),
SHAPED WEDGE KM-SS-08	(Basic UDI - DI 59009497KM-SS-08WP),
BRAUN SPLINT KM-SS-10	(Basic UDI - DI 59009497KM-SS-10WA),
REHABILITATION HALF-ROLLER PW-SS-01	(Basic UDI - DI 59009497PW-SS-016M),
REHABILITATION HALF-ROLLER PW-SS-02	(Basic UDI - DI 59009497PW-SS-026P),
REHABILITATION HALF-ROLLER PW-SS-03	(Basic UDI - DI 59009497PW-SS-036R),
REHABILITATION HALF-ROLLER PW-SS-04	(Basic UDI - DI 59009497PW-SS-046T),
REHABILITATION HALF-ROLLER PW-SS-05	(Basic UDI - DI 59009497PW-SS-056V).



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