

DECLARATION

OF EC CONFORMITY

MANUFACTURER REH4MAT LTD. DECLARE, THAT
PRODUCT: Vacuum positioning system BodyMap for trunk, head and limbs stabilization
LIST OF ITEMS IN APPENDIX NO. 1

of intended use: products which are designed for adults as well as children with cerebral palsy. All these products provide perfect stabilization during seating or lying position.

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

Rzeszów, 27.03.2024 No. 44/D/EN/9 page 1/2

APPENDIX NO. 1

TO DECLARATION OF CONFORMITY

PRODUCT - Vacuum positioning system BodyMap for trunk, head and limbs stabilization
MODELS:

Seat cushion BodyMap A	(Basic UDI-DI 59009497BMAZJ),
U cut seat cushion BodyMap A-	(Basic UDI-DI 59009497BMA-PS),
Frames BodyMap	(Basic UDI-DI 59009497BMD3),
Vismemo thermoactive cover VisMemo	(Basic UDI-DI 59009497BMVISMEMOYN),
Derotation stabilizer BodyMap G	(Basic UDI-DI 59009497BMGZW),
Lower limb support BodyMap F	(Basic UDI-DI 59009497BMFZU),
Stabilizing mattress BodyMap K	(Basic UDI-DI 59009497BMK29),
Upper limb support BodyMap J	(Basic UDI-DI 59009497BMJ27),
Upper limb support for wheelchairs, strollers and standing frames BodyMap E	(Basic UDI-DI 59009497BMEZS),
Headrest BodyMap D	(Basic UDI-DI 59009497BMDZQ),
Butterfly headrest BodyMap DX	(Basic UDI-DI 59009497BMDXSP),
Straight headrest BodyMap DY	(Basic UDI-DI 59009497BMDYSR),
Triangular headrest BodyMap DZ	(Basic UDI-DI 59009497BMDZST),
Head stabilization BodyMap I	(Basic UDI-DI 59009497BMI2S),
Unilateral trunk support BodyMap H	(Basic UDI-DI 59009497BMH23),
Back cushion with headrest and lateral support BodyMap C	(Basic UDI-DI 59009497BMCZN),
Back cushion BodyMap B	(Basic UDI-DI 59009497BMBZL),
Positioning chair BodyMap AB	(Basic UDI-DI 59009497BMAPR2),
Positioning chair with headrest and lateral support BodyMap AC	(Basic UDI-DI 59009497BMACR4),
Cushion BodyMap L	(Basic UDI-DI 59009497BML2B),
Sitting positioning cushion with thigh abductor wedge and lateral supports BodyMap A+	(Basic UDI-DI 59009497BMA+PN),
Cushion stabilizing the upper. BodyMap M	(Basic UDI-DI 59009497BMM2D),
Feet correction cushion BodyMap N	(Basic UDI-DI 59009497BMN2F),
Backrest cushion with lateral supports BodyMap B+	(Basic UDI-DI 59009497BMB+PR),
Neck cushion BodyMap DW	(Basic UDI-DI 59009497BMDWSM),
Walek stabilizujący BodyMap O	(Basic UDI-DI 59009497BMO2H),
Vacuum limb immobilizer BodyMap P	(Basic UDI-DI 59009497BMP2K),
Sensory bean bag floor cushion BodyMap R	(Basic UDI-DI 59009497BMR2P),
Sensory bean bag floor cushion BodyMap R+	(Basic UDI-DI 59009497BMR+R9),
Orthopedic seat for children with pelvic, trunk and head stabilization BodyMap AB+	(Basic UDI-DI 59009497BMAP+L5),
Bath ring BodyMap S Swimmer	(Basic UDI-DI 59009497BMSSWIMMERT2),
Sitting positioning cushion with thigh abductor wedge and lateral supports BodyMap A PRO	(Basic UDI-DI 59009497BMAPROQU).



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