

DECLARATION OF CONFORMITY

No. 44/D/EN/3

COMPANY

REH4MAT Sławomir Wroński

DECLARES

that product:

VACUUM POSITIONING SYSTEM BODYMAP FOR TRUNK,
HEAD AND LIMBS STABILIZATION

LIST OF ITEMS IN APPENDIX NO.1

marked with the CE sign is Class I medical device, of rule 1, consistent with the requirements of the Council Directive 93/42 / EEC of 14 June 1993 on medical devices and the Law of 20 May 2010 on medical devices (Journal of Laws of 2015, No. 876, as amended).
Conformity assessment was carried out on the basis of the VII Council Directive 93/42 /EEC.

The product meets the requirements of the harmonized standards:

PN-EN 1041+A1:2013-12	Information supplied by the manufacturer of medical devices
PN-EN 12182:2012	Assistive products for persons with disability. General requirements and test methods
PN-EN ISO 13485:2016	Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes
PN-EN ISO 14971:2012	Medical devices. Application of risk management to medical device
PN-EN ISO 15223-1:2017-02	Medical devices Symbols to be used with medical device labels,labelling and information to be supplied - Part 1:General requirements

THIS DECLARATION HAS BEEN ISSUED ON THE RESPONSIBILITY OF THE COMPANY
REH4MAT Sławomir Wroński, 36-060 Głogów Małopolski, ul. Piaski 47, POLAND

Country of origin: **POLAND**

Company owner


Sławomir Wroński

APPENDIX NO. 1

TO DECLARATION OF CONFORMITY No. 44/D/EN/3

PRODUCT:

VACUUM POSITIONING SYSTEM BODYMAP FOR TRUNK,
HEAD AND LIMBS STABILIZATION

MODEL:

Seat cushion BodyMap A
U cut seat cushion BodyMap A
Upper limb support for wheelchairs, strollers and standing frames BodyMap E
Frames BodyMap
Vismemo thermoactive cover BodyMap VisMemo
Derotation stabilizer BodyMap G
Lower limb support BodyMap F
Stabilizing mattress BodyMap K
Upper limb support BodyMap J
Headrest BodyMap D
Butterfly headrest BodyMap DX
Straight headrest BodyMap DY
Triangular headrest BodyMap DZ
Head stabilization BodyMap I
Unilateral trunk support BodyMap H
Back cushion with headrest and lateral support BodyMap C
Back cushion BodyMap B
Positioning chair BodyMap AB
Positioning chair with headrest and lateral support BodyMap AC
Cushion BodyMap L
Sitting positioning cushion with thigh abductor wedge and lateral supports BodyMap A+
Cushion stabilizing the upper limbs BodyMap M
Feet correction cushion BodyMap N
Backrest cushion with lateral supports BodyMap B+
Neck cushion BodyMap DW
Stabilizing roller BodyMap O
Vacuum limb immobilizer BodyMap P
Sensory bean bag floor cushion BodyMap R
Sensory bean bag floor cushion BodyMap R+
Orthopedic seat for children with pelvic, trunk and head stabilization BodyMap AB+
Bath ring BodyMap S Swimmer

Company owner


Sławomir Wroński