

DECLARATION OF CONFORMITY EC

No. 44/D/EN/4

MANUFACTURER

REH4MAT

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** 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 MANUFACTURER

REH4MAT, 36-060 Głogów Małopolski, ul. Piaski 47, Poland



reh:mat **COMPANY OWNER**
Sławomir Wronski

Głogów Małopolski 27.09.2019

APPENDIX NO. 1

To declaration of conformity no. 44/D/4

PRODUCT:

VACUUM POSITIONING SYSTEM BODYMAP FOR TRUNK,
HEAD AND LIMBS STABILIZATION

MODELS:

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



rehamat 
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