

# DECLARATION OF CONFORMITY EC

No. 65/D/EN/4

**MANUFACTURER**

REH4MAT

**PRODUCT**

POSTURAL AIDS SYSTEM IN THE LYING POSITION STABILO-BED

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

# APPENDIX NO. 1

## To declaration of conformity no. 65/D/EN/4

### PRODUCT:

POSTURAL AIDS SYSTEM IN THE LYING POSITION STABILO-BED

### MODELS:

Lower extremity abduction pillow P-SS-01;  
 Abduction block for knees P-SS-03;  
 Calf wedge P-SS-06;  
 Lower extremity abduction pillow P-SS-11;  
 Thermoactive lower limb raising wedge K-SS-06;  
 Anatomic-shaped cushion under head P-SS-04;  
 V' pillow P-SS-15;  
 Silicone pillow P-SS-21;  
 Thermoactive support cushion P-SS-22;  
 Lateral positioning cushion P-SS-08;  
 Semi-soft bolster pillows P-SS-14;  
 Backrest with self-gripping function K-SS-05;  
 Upper extremity support with protector P-SS-20;  
 Wedge with self-gripping function K-SS-02;  
 Cylindrical cushion P-SS-02;  
 Pillow between legs P-SS-05;  
 Knee wedge P-SS-10;  
 Universal big cushion P-SS-16;  
 Thermoactive braun splint K-SS-07;  
 Anti bed sore round cushion P-SS-09;  
 Headrest P-SS-18;  
 Neck ring cushion P-SS-19;  
 Ring cushion P-SS-13;  
 Lateral positioning wedge P-SS-12;  
 Semi-rigid bolster pillows for trunk support P-SS-17;  
 Pediatric immobilizer P-SS-23;  
 Thermoactive elevation arm wedge K-SS-01;  
 Shaped wedge K-SS-08 ;  
 Anti-bed sore donut cushion P-SS-24;  
 Head cushion P-SS-25;  
 Orthopedic neck pillow P-SS-26;  
 Reflux baby wedge P-SS-27;  
 Pediatric lower limbs abduction wedge P-SS-28;  
 Universal positioning cushion P-SS-29;  
 Lower limbs positioning wedge P-SS-30;  
 Universal cushion P-SS-31

P-SS-32	K-SS-21
P-SS-33	K-SS-22
P-SS-34	K-SS-23
P-SS-35	K-SS-24
P-SS-36	K-SS-25
P-SS-37	K-SS-26
P-SS-38	K-SS-27
P-SS-39	K-SS-28
P-SS-40	K-SS-29
P-SS-41	K-SS-30
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