

# DECLARATION OF CONFORMITY EC

No. 65/D/EN/5

**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



**COMPANY OWNER**  
Sławomir Wroński



# APPENDIX NO. 1

## To declaration of conformity no. 65/D/EN/5

### 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 bedsores 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-bedsores 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  
Wedge K-SS-12  
Wedge K-SS-13  
Wedge K-SS-14  
Wedge K-SS-15  
Wedge K-SS-16  
Wedge K-SS-17  
Wedge K-SS-18  
Wedge K-SS-19  
Wedge K-SS-20  
Wedge K-SS-21  
Wedge K-SS-22  
Wedge K-SS-23  
Wedge K-SS-24  
Wedge K-SS-25  
Wedge K-SS-26  
Wedge K-SS-27  
Wedge K-SS-28  
Wedge K-SS-29  
Wedge K-SS-30  
Rehabilitation roller W-SS-01  
Rehabilitation roller W-SS-02  
Rehabilitation roller W-SS-03  
Rehabilitation roller W-SS-04  
Rehabilitation roller W-SS-05  
Rehabilitation roller W-SS-06  
Rehabilitation roller W-SS-07  
Rehabilitation roller W-SS-08  
Rehabilitation roller W-SS-09  
Rehabilitation roller W-SS-10



rehamat  
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# APPENDIX NO. 1

To declaration of conformity no. 65/D/EN/5

**PRODUCT:**

POSTURAL AIDS SYSTEM IN THE LYING POSITION STABILO-BED

**MODELS:**

Cylindrical cushion with the abduction wedge and side supports

P-SS-32

Form F-SS-01

Form F-SS-02

Lower limbs positioning cushion P-SS-33

Form F-SS-03

Lower limbs positioning cushion P-SS-34

Form F-SS-04

Lower limbs positioning cushion P-SS-35

Form F-SS-05

Lower limbs positioning cushion P-SS-36

Form F-SS-06

Upper limbs positioning cushion P-SS-37

Form F-SS-07

Sensory bean bag floor cushion P-SS-38

Form F-SS-08

Trunk positioning cushion P-SS-39

Form F-SS-09

Trunk positioning cushion P-SS-40

Form F-SS-10

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

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



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