

DECLARATION OF CONFORMITY

No. 65/D/EN/2

COMPANY

REH4MAT Sławomir Wroński

DECLARES

that 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 (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. 65/D/EN/2

PRODUCT:

POSTURAL AIDS SYSTEM IN THE LYING POSITION STABILO-BED

MODEL:

- 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

Company owner


Sławomir Wroński