

DECLARATION OF CONFORMITY EC

No. 65/D/EN/7

THE REH4MAT MANUFACTURER 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 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

Conformity assessment was carried out in accordance with the requirements of the Regulation (EU) 2017/745 of the European Parliament and of the Council.

In order to demonstrate the safety and effectiveness of the medical device, the following standards were used to assess conformity:

PN-EN 1041+A1:2013-12

Information provided by the producer together with the medical product.

PN-EN 12182:2012

Assistive products for persons with disability - General requirements and research methods.

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.

PN-EN ISO 13485:2016

Medical products - Quality management systems - Requirements for law regulations aims.

PN-EN ISO 14971:2020

Medical devices - Application of risk management to medical devices.

THIS DECLARATION HAS BEEN ISSUED ON THE RESPONSIBILITY
OF THE MANUFACTURER

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

SINGLE REGISTRATION NUMBER (SRN): PL-MF-000009271


COMPANY OWNER
Sławomir Wroński

APPENDIX NO. 1

To declaration of conformity no. 65/D/EN/7

PRODUCT: POSTURAL AIDS SYSTEM IN THE LYING POSITION STABILO-BED

MODELS:

Lower extremity abduction pillow P-SS-01 (Basic UDI-DI 59009497P-SS-01L8);
Abduction block for knees P-SS-03 (Basic UDI-DI 59009497P-SS-03LC);
Calf wedge P-SS-06 (Basic UDI-DI 59009497P-SS-06LJ);
Lower extremity abduction pillow P-SS-11 (Basic UDI-DI 59009497P-SS-11LB);
Thermoactive lower limb raising wedge K-SS-06 (Basic UDI-DI 59009497K-SS-06HV);
Anatomic-shaped cushion under head P-SS-04 (Basic UDI-DI 59009497P-SS-04LE);
V' pillow P-SS-15 (Basic UDI-DI 59009497P-SS-15LK);
Silicone pillow P-SS-21 (Basic UDI-DI 59009497P-SS-21LE);
Thermoactive support cushion P-SS-22 (Basic UDI-DI 59009497P-SS-22LG);
Lateral positioning cushion P-SS-08 (Basic UDI-DI 59009497P-SS-08LN);
Semi-soft bolster pillows P P-SS-14 (Basic UDI-DI 59009497P-SS-14LH);
Backrest with self-gripping function K-SS-05 (Basic UDI-DI 59009497K-SS-05HT);
Upper extremity support with protector P-SS-20 (Basic UDI-DI 59009497P-SS-20LC);
Wedge with self-gripping function K-SS-02 (Basic UDI-DI 59009497K-SS-02HM);
Cylindrical cushion P-SS-02 (Basic UDI-DI 59009497P-SS-02LA);
Pillow between legs P-SS-05 (Basic UDI-DI 59009497P-SS-05LG);
Knee wedge P-SS-10 (Basic UDI-DI 59009497P-SS-10L9);
Universal big cushion P-SS-16 (Basic UDI-DI 59009497P-SS-16LM);
Thermoactive braun splint K-SS-07 (Basic UDI-DI 59009497K-SS-07HX);
Anti bed sore round cushion P-SS-09 (Basic UDI-DI 59009497P-SS-09LQ);
Zagłówek P-SS-18 (Basic UDI-DI 59009497P-SS-18LR);
Headrest P-SS-19 (Basic UDI-DI 59009497P-SS-19LT);
Neck ring cushion P-SS-13 (Basic UDI-DI 59009497P-SS-13LF);
Lateral positioning wedge P-SS-12 (Basic UDI-DI 59009497P-SS-12LD);
Semi-rigid bolster pillows for trunk support P-SS-17 (Basic UDI-DI 59009497P-SS-17LP);
Ipediatric immobilizer P-SS-23 (Basic UDI-DI 59009497P-SS-23LJ);
Thermoactive elevation arm wedge K-SS-01 (Basic UDI-DI 59009497K-SS-01HK);


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MODELS:

Shaped wedge K-SS-08 (Basic UDI-DI 59009497K-SS-08HZ);
Anti-bedsores donut cushion P-SS-24 (Basic UDI-DI 59009497P-SS-24LL);
Head cushion P-SS-25 (Basic UDI-DI 59009497P-SS-25LN);
Orthopedic neck pillow P-SS-26 (Basic UDI-DI 59009497P-SS-26LQ);
Reflux baby wedge P-SS-27 (Basic UDI-DI 59009497P-SS-27LS);
Pediatric lower limbs abduction wedge P-SS-28 (Basic UDI-DI 59009497P-SS-28LU);
Universal positioning cushion P-SS-29 (Basic UDI-DI 59009497P-SS-29LW);
Lower limbs positioning wedge P-SS-30 (Basic UDI-DI 59009497P-SS-30LF);
Universal cushion P-SS-31 (Basic UDI-DI 59009497P-SS-31LH);
Cylindrical cushion with the abduction wedge and side supports P-SS-32 (Basic UDI-DI 59009497P-SS-32LK);
Lower limbs positioning cushion P-SS-33 (Basic UDI-DI 59009497P-SS-33LM);
Lower limbs positioning cushion P-SS-34 (Basic UDI-DI 59009497P-SS-34LP);
Lower limbs positioning cushion P-SS-35 (Basic UDI-DI 59009497P-SS-35LR);
Lower limbs positioning cushion P-SS-36 (Basic UDI-DI 59009497P-SS-36LT);
Upper limbs positioning cushion P-SS-37 (Basic UDI-DI 59009497P-SS-37LV);
Sensory bean bag floor cushion P-SS-38 (Basic UDI-DI 59009497P-SS-38LX);
Trunk positioning cushion P-SS-39 (Basic UDI-DI 59009497P-SS-39LZ);
Trunk positioning cushion P-SS-40 (Basic UDI-DI 59009497P-SS-40LJ);
Trunk positioning cushion P-SS-41 (Basic UDI-DI 59009497P-SS-41LL);
Trunk positioning cushion P-SS-42 (Basic UDI-DI 59009497P-SS-42LN);
Trunk positioning cushion P-SS-43 (Basic UDI-DI 59009497P-SS-43LQ);
Head positioning cushion P-SS-44 (Basic UDI-DI 59009497P-SS-44LS);
Neck positioning cushion P-SS-45 (Basic UDI-DI 59009497P-SS-45LU);
Trunk positioning cushion P-SS-46 (Basic UDI-DI 59009497P-SS-46LW);
Trunk positioning cushion P-SS-47 (Basic UDI-DI 59009497P-SS-47LY);


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Trunk positioning cushion P-SS-48 (Basic UDI-DI 59009497P-SS-48M2);
Trunk positioning cushion P-SS-49 (Basic UDI-DI 59009497P-SS-49M4);
Trunk positioning cushion P-SS-50 (Basic UDI-DI 59009497P-SS-50LM);
Universal limb separator P-SS-51 (Basic UDI-DI 59009497P-SS-51LP
Anti-bedsores cushion for the lower limbs P-SS-52 (Basic UDI-DI 59009497P-SS-52LR);
Patient transfer belt P-SS-53 (Basic UDI-DI 59009497P-SS-53LT);
Long lower limb separator K-SS-31 (Basic UDI-DI 59009497K-SS-31HU);
Lower limb raising wedge K-SS-09 (Basic UDI-DI 59009497K-SS-09J3);
Braun splint K-SS-10 (Basic UDI-DI 59009497K-SS-10HL);
Thermoactive braun splint with foot support K-SS-11 (Basic UDI-DI 59009497K-SS-11H);
Wedge K-SS-12 (Basic UDI-DI 59009497K-SS-12HQ);
Wedge K-SS-13 (Basic UDI-DI 59009497K-SS-13HS);
Wedge K-SS-14 (Basic UDI-DI 59009497K-SS-14HU);
Wedge K-SS-15 (Basic UDI-DI 59009497K-SS-15HW);
Wedge K-SS-16 (Basic UDI-DI 59009497K-SS-16HY);
Wedge K-SS-17 (Basic UDI-DI 59009497K-SS-17J2);
Wedge K-SS-18 (Basic UDI-DI 59009497K-SS-18J4);
Wedge K-SS-19 (Basic UDI-DI 59009497K-SS-19J6);
Wedge K-SS-20 (Basic UDI-DI 59009497K-SS-20HP);
Wedge K-SS-21 (Basic UDI-DI 59009497K-SS-21HR);
Wedge K-SS-22 (Basic UDI-DI 59009497K-SS-22HT);
Wedge K-SS-23 (Basic UDI-DI 59009497K-SS-23HV);
Wedge K-SS-24 (Basic UDI-DI 59009497K-SS-24HX);
Wedge K-SS-25 (Basic UDI-DI 59009497K-SS-25HZ);
Wedge K-SS-26 (Basic UDI-DI 59009497K-SS-26J3);


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MODELS:

Wedge K-SS-27 (Basic UDI-DI 59009497K-SS-27J5);
Wedge K-SS-28 (Basic UDI-DI 59009497K-SS-28J7);
Wedge K-SS-29 (Basic UDI-DI 59009497K-SS-29J9);
Wedge K-SS-30 (Basic UDI-DI 59009497K-SS-30HS);
Rehabilitation roller W-SS-01 (Basic UDI-DI 59009497W-SS-01PX);
Rehabilitation roller W-SS-02 (Basic UDI-DI 59009497W-SS-02PZ);
Rehabilitation roller W-SS-03 (Basic UDI-DI 59009497W-SS-03Q3);
Rehabilitation roller W-SS-04 (Basic UDI-DI 59009497W-SS-04Q5);
Rehabilitation roller W-SS-05 (Basic UDI-DI 59009497W-SS-05Q7);
Rehabilitation roller W-SS-06 (Basic UDI-DI 59009497W-SS-06Q9);
Rehabilitation roller W-SS-07 (Basic UDI-DI 59009497W-SS-07QB);
Rehabilitation roller W-SS-08 (Basic UDI-DI 59009497W-SS-08QD);
Rehabilitation roller W-SS-09 (Basic UDI-DI 59009497W-SS-09QF);
Rehabilitation roller W-SS-10 (Basic UDI-DI 59009497W-SS-10PY);
Form F-SS-01 (Basic UDI-DI 59009497F-SS-01EW);
Form F-SS-02 (Basic UDI-DI 59009497F-SS-02EY);
Form F-SS-03 (Basic UDI-DI 59009497F-SS-03F2);
Form F-SS-04 (Basic UDI-DI 59009497F-SS-04F4);
Form F-SS-05 (Basic UDI-DI 59009497F-SS-05F6);
Form F-SS-06 (Basic UDI-DI 59009497F-SS-06F8);
Form F-SS-07 (Basic UDI-DI 59009497F-SS-07FA);
Form F-SS-08 (Basic UDI-DI 59009497F-SS-08FC);
Form F-SS-09 (Basic UDI-DI 59009497F-SS-09FE);
Form F-SS-10 (Basic UDI-DI 59009497F-SS-10EX).


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