

# DECLARATION OF CONFORMITY EC

## No. 53/D/EN/6

THE REH4MAT MANUFACTURER DECLARES THAT

**PRODUCT: UPPER-EXTREMITY SUPPORT**

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. 53/D/EN/6

## PRODUCT: UPPER-EXTREMITY SUPPORT

### MODELS:

**UPPER-EXTREMITY SUPPORT EB-L-01** (Basic UDI-DI 59009497EB-L-0189);  
**UPPER-EXTREMITY SUPPORT EB-L-02** (Basic UDI-DI 59009497EB-L-028B);  
**UPPER-EXTREMITY SUPPORT AS-L/F** (Basic UDI-DI 59009497AS-L/FHY);  
**AS-L/A** (Basic UDI-DI 59009497AS-L/AHN);  
**UPPER-EXTREMITY SUPPORT AM-TL-01** (Basic UDI-DI 59009497AM-TL-01P5);  
**U-SL** (Basic UDI-DI 59009497U-SLSN);  
**EB-L** (Basic UDI-DI 59009497EB-LNT);  
**UPPER-EXTREMITY SUPPORT AM-SOB-01** (Basic UDI-DI 59009497AM-SOB-012X);  
**UPPER-EXTREMITY SUPPORT AM-AO-KG-01** (Basic UDI-DI 59009497AM-AO-KG-01PX);  
**UPPER-EXTREMITY SUPPORT AM-AO-KG-02** (Basic UDI-DI 59009497AM-AO-KG-02PZ);  
**UPPER-EXTREMITY SUPPORT AM-SOB-04** (Basic UDI-DI 59009497AM-SOB-0435);  
**UPPER-EXTREMITY SUPPORT AM-SOB-05** (Basic UDI-DI 59009497AM-SOB-0537);  
**UPPER-EXTREMITY SUPPORT AM-SOB-06** (Basic UDI-DI 59009497AM-SOB-0639);  
**UPPER-EXTREMITY SUPPORT AM-SOB-07** (Basic UDI-DI 59009497AM-SOB-073B);  
**UPPER-EXTREMITY SUPPORT AM-BX-01** (Basic UDI-DI 59009497AM-BX-01KK);  
**UPPER-EXTREMITY SUPPORT AM-BX-02** (Basic UDI-DI 59009497AM-BX-02KM);  
**UPPER-EXTREMITY SUPPORT AM-BX-03** (Basic UDI-DI 59009497AM-BX-03KP);  
**UPPER-EXTREMITY SUPPORT MASTER-01** (Basic UDI-DI 59009497MASTER-01QK);  
**UPPER-EXTREMITY SUPPORT MASTER-02** (Basic UDI-DI 59009497MASTER-02QM);  
**UPPER-EXTREMITY SUPPORT MASTER-03** (Basic UDI-DI 59009497MASTER-03QP);  
**UPPER-EXTREMITY SUPPORT MASTER-04** (Basic UDI-DI 59009497MASTER-04QR);  
**UPPER-EXTREMITY SUPPORT OKG-01** (Basic UDI-DI 59009497OKG-01LJ);  
**UPPER-EXTREMITY SUPPORT OKG-02** (Basic UDI-DI 59009497OKG-02LL);  
**UPPER-EXTREMITY SUPPORT OKG-03** (Basic UDI-DI 59009497OKG-03LN);  
**UPPER-EXTREMITY SUPPORT OKG-04** (Basic UDI-DI 59009497OKG-04LQ);  
**UPPER-EXTREMITY SUPPORT OKG-05** (Basic UDI-DI 59009497OKG-05LS);  
**AM-SOB** (Basic UDI-DI 59009497AM-SOBKN);  
**AM-SOB-02** (Basic UDI-DI 59009497AM-SOB-022Z);  
**AM-KOB** (Basic UDI-DI 59009497AM-KOBJE);  
**AS-B** (Basic UDI-DI 59009497AS-BPY);  
**AM-SOB-03** (Basic UDI-DI 59009497AM-SOB-0333);  
**AM-SOB-03 NI** (Basic UDI-DI 59009497AM-SOB-03NIZ3);  
**AM-SOB-03 PO** (Basic UDI-DI 59009497AM-SOB-03POZM);

  
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### MODELS:

**AM-SOB-03 CZ** (Basic UDI-DI 59009497AM-SOB-03CZZ4);  
**AM-AO-KG** (Basic UDI-DI 59009497AM-AO-KGLZ);  
**AM-KG-AM/1RE** (Basic UDI-DI 59009497AM-KG-AM/1REC4);  
**UPPER-EXTREMITY SUPPORT 4ARMY-SN-01** (Basic UDI-DI 590094974ARMY-SN-01C5);  
**UPPER-EXTREMITY SUPPORT 4ARMY-SN-02** (Basic UDI-DI 590094974ARMY-SN-02C7);  
**UPPER-EXTREMITY SUPPORT 4ARMY-SN-03** (Basic UDI-DI 590094974ARMY-SN-03C9);  
**UPPER-EXTREMITY SUPPORT 4ARMY-SN-04** (Basic UDI-DI 590094974ARMY-SN-04CB);  
**UPPER-EXTREMITY SUPPORT 4ARMY-SN-05** (Basic UDI-DI 590094974ARMY-SN-05CD);  
**UPPER-EXTREMITY SUPPORT 4ARMY-SN-06** (Basic UDI-DI 590094974ARMY-SN-06CF);  
**UPPER-EXTREMITY SUPPORT 4ARMY-SN-07** (Basic UDI-DI 590094974ARMY-SN-07CH);  
**UPPER-EXTREMITY SUPPORT 4ARMY-SN-08** (Basic UDI-DI 590094974ARMY-SN-08CK);  
**UPPER-EXTREMITY SUPPORT 4ARMY-SN-09** (Basic UDI-DI 590094974ARMY-SN-09CM);  
**UPPER-EXTREMITY SUPPORT 4ARMY-SN-10** (Basic UDI-DI 590094974ARMY-SN-10C6);  
**UPPER-EXTREMITY SUPPORT 4ARMY-SN-11** (Basic UDI-DI 590094974ARMY-SN-11C8);  
**UPPER-EXTREMITY SUPPORT 4ARMY-SN-12** (Basic UDI-DI 590094974ARMY-SN-12CA);  
**UPPER-EXTREMITY SUPPORT 4ARMY-SN-13** (Basic UDI-DI 590094974ARMY-SN-13CC);  
**UPPER-EXTREMITY SUPPORT 4ARMY-SN-14** (Basic UDI-DI 590094974ARMY-SN-14CE);  
**UPPER-EXTREMITY SUPPORT 4ARMY-SN-15** (Basic UDI-DI 590094974ARMY-SN-15CG);  
**UPPER-EXTREMITY SUPPORT 4ARMY-SL-01** (Basic UDI-DI 590094974ARMY-SL-01BP);  
**UPPER-EXTREMITY SUPPORT 4ARMY-SL-02** (Basic UDI-DI 590094974ARMY-SL-02BR);  
**UPPER-EXTREMITY SUPPORT 4ARMY-SL-03** (Basic UDI-DI 590094974ARMY-SL-03BT);  
**UPPER-EXTREMITY SUPPORT 4ARMY-SL-04** (Basic UDI-DI 590094974ARMY-SL-04BV);  
**UPPER-EXTREMITY SUPPORT 4ARMY-SL-05** (Basic UDI-DI 590094974ARMY-SL-05BX);  
**UPPER-EXTREMITY SUPPORT 4ARMY-SL-06** (Basic UDI-DI 590094974ARMY-SL-06BZ);  
**UPPER-EXTREMITY SUPPORT 4ARMY-SL-07** (Basic UDI-DI 590094974ARMY-SL-07C3);  
**UPPER-EXTREMITY SUPPORT 4ARMY-SL-08** (Basic UDI-DI 590094974ARMY-SL-08C5);  
**UPPER-EXTREMITY SUPPORT 4ARMY-SL-09** (Basic UDI-DI 590094974ARMY-SL-09C7);  
**UPPER-EXTREMITY SUPPORT 4ARMY-SL-10** (Basic UDI-DI 590094974ARMY-SL-10BQ);  
**UPPER-EXTREMITY SUPPORT 4ARMY-SL-11** (Basic UDI-DI 590094974ARMY-SL-11BS);  
**UPPER-EXTREMITY SUPPORT 4ARMY-SL-12** (Basic UDI-DI 590094974ARMY-SL-12BU);  
**UPPER-EXTREMITY SUPPORT 4ARMY-SL-13** (Basic UDI-DI 590094974ARMY-SL-13BW);  
**UPPER-EXTREMITY SUPPORT 4ARMY-SL-14** (Basic UDI-DI 590094974ARMY-SL-14BY);  
**UPPER-EXTREMITY SUPPORT 4ARMY-SL-15** (Basic UDI-DI 590094974ARMY-SL-15C2);

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## PRODUCT: UPPER-EXTREMITY SUPPORT

### MODELS:

**UPPER-EXTREMITY SUPPORT 4ARMY-B-01** (Basic UDI-DI 590094974ARMY-B-01F6);  
**UPPER-EXTREMITY SUPPORT 4ARMY-B-02** (Basic UDI-DI 590094974ARMY-B-02F8);  
**UPPER-EXTREMITY SUPPORT 4ARMY-B-03** (Basic UDI-DI 590094974ARMY-B-03FA);  
**UPPER-EXTREMITY SUPPORT 4ARMY-B-04** (Basic UDI-DI 590094974ARMY-B-04FC);  
**UPPER-EXTREMITY SUPPORT 4ARMY-B-05** (Basic UDI-DI 590094974ARMY-B-05FE);  
**UPPER-EXTREMITY SUPPORT 4ARMY-B-06** (Basic UDI-DI 590094974ARMY-B-06FG);  
**UPPER-EXTREMITY SUPPORT 4ARMY-B-07** (Basic UDI-DI 590094974ARMY-B-07FJ);  
**UPPER-EXTREMITY SUPPORT 4ARMY-B-08** (Basic UDI-DI 590094974ARMY-B-08FL);  
**UPPER-EXTREMITY SUPPORT 4ARMY-B-09** (Basic UDI-DI 590094974ARMY-B-09FN);  
**UPPER-EXTREMITY SUPPORT 4ARMY-B-10** (Basic UDI-DI 590094974ARMY-B-10F7);  
**UPPER-EXTREMITY SUPPORT 4ARMY-B-11** (Basic UDI-DI 590094974ARMY-B-11F9);  
**UPPER-EXTREMITY SUPPORT 4ARMY-B-12** (Basic UDI-DI 590094974ARMY-B-12FB);  
**UPPER-EXTREMITY SUPPORT 4ARMY-B-13** (Basic UDI-DI 590094974ARMY-B-13FD);  
**UPPER-EXTREMITY SUPPORT 4ARMY-B-14** (Basic UDI-DI 590094974ARMY-B-14FF);  
**UPPER-EXTREMITY SUPPORT 4ARMY-B-15** (Basic UDI-DI 590094974ARMY-B-15FH);  
**UPPER-EXTREMITY SUPPORT OKG-06** (Basic UDI-DI 590094970KG-06LU);  
**UPPER-EXTREMITY SUPPORT OKG-07** (Basic UDI-DI 590094970KG-07LW);  
**UPPER-EXTREMITY SUPPORT OKG-08** (Basic UDI-DI 590094970KG-08LY);  
**UPPER-EXTREMITY SUPPORT OKG-09** (Basic UDI-DI 590094970KG-09M2);  
**UPPER-EXTREMITY SUPPORT OKG-10** (Basic UDI-DI 590094970KG-10LK);  
**UPPER-EXTREMITY SUPPORT OKG-11** (Basic UDI-DI 590094970KG-11LM);  
**UPPER-EXTREMITY SUPPORT OKG-12** (Basic UDI-DI 590094970KG-12LP);  
**UPPER-EXTREMITY SUPPORT OKG-13** (Basic UDI-DI 590094970KG-13LR);  
**UPPER-EXTREMITY SUPPORT OKG-14** (Basic UDI-DI 590094970KG-14LT);  
**UPPER-EXTREMITY SUPPORT OKG-15** (Basic UDI-DI 590094970KG-15LV);  
**UPPER-EXTREMITY SUPPORT OKG-16** (Basic UDI-DI 590094970KG-16L);  
**UPPER-EXTREMITY SUPPORT AM-OSN-U-16** (Basic UDI-DI 59009497AM-OSN-U-168Y);  
**UPPER-EXTREMITY SUPPORT AM-OSN-U-17** (Basic UDI-DI 59009497AM-OSN-U-1792);  
**UPPER-EXTREMITY SUPPORT AM-OSN-U-18** (Basic UDI-DI 59009497AM-OSN-U-1894);  
**UPPER-EXTREMITY SUPPORT AM-OSN-U-19** (Basic UDI-DI 59009497AM-OSN-U-1996);  
**UPPER-EXTREMITY SUPPORT AM-OSN-U-20** (Basic UDI-DI 59009497AM-OSN-U-208P);  
**UPPER-EXTREMITY SUPPORT AM-OSN-U-21** (Basic UDI-DI 59009497AM-OSN-U-218R);  
**UPPER-EXTREMITY SUPPORT AM-OSN-U-22** (Basic UDI-DI 59009497AM-OSN-U-228T);

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### MODELS:

**UPPER-EXTREMITY SUPPORT AM-OSN-U-23** (Basic UDI-DI 59009497AM-OSN-U-238V);  
**UPPER-EXTREMITY SUPPORT AM-OSN-U-24** (Basic UDI-DI 59009497AM-OSN-U-248X);  
**UPPER-EXTREMITY SUPPORT AM-OSN-U-25** (Basic UDI-DI 59009497AM-OSN-U-258Z);  
**UPPER-EXTREMITY SUPPORT AM-OSN-L-11** (Basic UDI-DI 59009497AM-OSN-L-116P);  
**UPPER-EXTREMITY SUPPORT AM-OSN-L-12** (Basic UDI-DI 59009497AM-OSN-L-126R);  
**UPPER-EXTREMITY SUPPORT AM-OSN-L-13** (Basic UDI-DI 59009497AM-OSN-L-136T);  
**UPPER-EXTREMITY SUPPORT AM-OSN-L-14** (Basic UDI-DI 59009497AM-OSN-L-146V);  
**UPPER-EXTREMITY SUPPORT AM-OSN-L-15** (Basic UDI-DI 59009497AM-OSN-L-156X);  
**FIX-KG-01** (Basic UDI-DI 59009497FIX-KG-01B6);  
**FIX-KG-02** (Basic UDI-DI 59009497FIX-KG-02B8 );  
**FIX-KG-03** (Basic UDI-DI 59009497FIX-KG-03BA);  
**FIX-KG-04** (Basic UDI-DI 59009497FIX-KG-04BC );  
**FIX-KG-05** (Basic UDI-DI 59009497FIX-KG-05BE );  
**FIX-KG-06** (Basic UDI-DI 59009497FIX-KG-06BG);  
**FIX-KG-07** (Basic UDI-DI 59009497FIX-KG-07BJ);  
**FIX-KG-08** (Basic UDI-DI 59009497FIX-KG-08BL);  
**FIX-KG-09** (Basic UDI-DI 59009497FIX-KG-09BN);  
**FIX-KG-10** (Basic UDI-DI 59009497FIX-KG-10B7);  
**FIX-KG-11** (Basi (Basic UDI-DI 59009497FIX-KG-11B9);  
**FIX-KG-12** (Basic UDI-DI 59009497FIX-KG-12B);  
**FIX-KG-13** (Basic UDI-DI 59009497FIX-KG-13BD);  
**FIX-KG-14** (Basic UDI-DI 59009497FIX-KG-14B);  
**FIX-KG-15** (Basic UDI-DI 59009497FIX-KG-15BH);  
**FIX-KG-16** (Basic UDI-DI 59009497FIX-KG-16BK);  
**FIX-KG-17** (Basic UDI-DI 59009497FIX-KG-17BM);  
**FIX-KG-18** (Basic UDI-DI 59009497FIX-KG-18BP);  
**FIX-KG-19** (Basic UDI-DI 59009497FIX-KG-19BR);  
**FIX-KG-20** (Basic UDI-DI 59009497FIX-KG-20BA);  
**AM-OSN-U-01/CCA** (Basic UDI-DI 59009497AM-OSN-U-01/CCAF6 );  
**AM-AO-KG-02 CLEVER 2 ROTATOR** (Basic UDI-DI 59009497AM-AO-KG-02PZ);  
**AM-AO-KG-02 CLEVER 2 ABDUCTOR** (Basic UDI-DI );  
**AM-SOB-03/AIR** (Basic UDI-DI 59009497AM-SOB-03/AIR8D );

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