

# DECLARATION OF CONFORMITY EC

## No. 82/D/EN/5

THE REH4MAT MANUFACTURER DECLARES THAT

**PRODUCT: LOWER-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. 82/D/EN/5

## PRODUCT: LOWER-EXTREMITY SUPPORT

### MODELS:

OKD-31(Basic UDI-DI 59009497OKD-31L6);  
OKD-32(Basic UDI-DI 59009497OKD-32L8);  
OKD-33(Basic UDI-DI 59009497OKD-33LA);  
OKD-34(Basic UDI-DI 59009497OKD-34LC);  
OKD-35(Basic UDI-DI 59009497OKD-35LE);  
OKD-36(Basic UDI-DI 59009497OKD-36LG);  
OKD-37(Basic UDI-DI 59009497OKD-37LJ);  
OKD-38(Basic UDI-DI 59009497OKD-38LL);  
OKD-39(Basic UDI-DI 59009497OKD-39LN);  
OKD-40(Basic UDI-DI 59009497OKD-40L7);  
OKD-41(Basic UDI-DI 59009497OKD-41L9);  
OKD-42(Basic UDI-DI 59009497OKD-42LB);  
OKD-43(Basic UDI-DI 59009497OKD-43LD);  
OKD-44(Basic UDI-DI 59009497OKD-44LF);  
OKD-45(Basic UDI-DI 59009497OKD-45LH);  
OKD-46(Basic UDI-DI 59009497OKD-46LK);  
OKD-47(Basic UDI-DI 59009497OKD-47LM);  
OKD-48(Basic UDI-DI 59009497OKD-48LP);  
OKD-49(Basic UDI-DI 59009497OKD-49LR);  
OKD-50(Basic UDI-DI 59009497OKD-50LA);  
OKD-51(Basic UDI-DI 59009497OKD-51LC);  
OKD-52(Basic UDI-DI 59009497OKD-52LE);  
OKD-53(Basic UDI-DI 59009497OKD-53LG);  
OKD-54(Basic UDI-DI 59009497OKD-54LJ);  
OKD-55(Basic UDI-DI 59009497OKD-55LL);  
OKD-56(Basic UDI-DI 59009497OKD-56LN);  
OKD-57(Basic UDI-DI 59009497OKD-57LQ);  
OKD-58(Basic UDI-DI 59009497OKD-58LS);  
OKD-59(Basic UDI-DI 59009497OKD-59LU);  
OKD-60(Basic UDI-DI 59009497OKD-60LD);  
OKD-61(Basic UDI-DI 59009497OKD-61LF);  
OKD-62(Basic UDI-DI 59009497OKD-62LH);  
OKD-63(Basic UDI-DI 59009497OKD-63LK);  
OKD-64(Basic UDI-DI 59009497OKD-64LM);  
OKD-65(Basic UDI-DI 59009497OKD-65LP);  
OKD-66(Basic UDI-DI 59009497OKD-66LR );  
OKD-67(Basic UDI-DI 59009497OKD-67LT);  
OKD-68(Basic UDI-DI 59009497OKD-68LV);  
OKD-69(Basic UDI-DI 59009497OKD-69LX);  
OKD-70(Basic UDI-DI 59009497OKD-70LG);  
OKD-71(Basic UDI-DI 59009497OKD-71LJ);  
OKD-72(Basic UDI-DI 59009497OKD-72LL);  
OKD-73(Basic UDI-DI 59009497OKD-73LN);  
OKD-74(Basic UDI-DI 59009497OKD-74LQ);  
OKD-75(Basic UDI-DI 59009497OKD-75LS);  
OKD-76(Basic UDI-DI 59009497OKD-76LU);  
OKD-77(Basic UDI-DI 59009497OKD-77LW);  
OKD-78(Basic UDI-DI 59009497OKD-78LY );  
OKD-79(Basic UDI-DI 59009497OKD-79M2);  
OKD-80(Basic UDI-DI 59009497OKD-80LK);  
OKD-81(Basic UDI-DI 59009497OKD-81LM);  
OKD-82(Basic UDI-DI 59009497OKD-82LP);  
OKD-83(Basic UDI-DI 59009497OKD-83LR );  
OKD-84(Basic UDI-DI 59009497OKD-84LT);  
OKD-85(Basic UDI-DI 59009497OKD-85LV);  
OKD-86(Basic UDI-DI 59009497OKD-86LX );  
OKD-87(Basic UDI-DI 59009497OKD-87LZ );  
OKD-88(Basic UDI-DI 59009497OKD-88M3);  
OKD-89(Basic UDI-DI 59009497OKD-89M5);  
OKD-90(Basic UDI-DI 59009497OKD-90LN);

  
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