

# DECLARATION OF CONFORMITY EC

## No. 83/D/EN/5

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. 83/D/EN/5

## PRODUCT: UPPER-EXTREMITY SUPPORT

### MODELS:

OKG-17(Basic UDI-DI 59009497OKG-17LZ);  
OKG-18(Basic UDI-DI 59009497OKG-18M3 );  
OKG-19(Basic UDI-DI 59009497OKG-19M5 );  
OKG-20(Basic UDI-DI 59009497OKG-20LN );  
OKG-21(Basic UDI-DI 59009497OKG-21LQ );  
OKG-22(Basic UDI-DI 59009497OKG-22LS );  
OKG-23(Basic UDI-DI 59009497OKG-23LU );  
OKG-24(Basic UDI-DI 59009497OKG-24LW );  
OKG-25(Basic UDI-DI 59009497OKG-25LY );  
OKG-26(Basic UDI-DI 59009497OKG-26M2 );  
OKG-27(Basic UDI-DI 59009497OKG-27M4 );  
OKG-28(Basic UDI-DI 59009497OKG-28M6);  
OKG-29(Basic UDI-DI 59009497OKG-29M8 );  
OKG-30(Basic UDI-DI 59009497OKG-30LR );  
OKG-31(Basic UDI-DI 59009497OKG-31LT );  
OKG-32(Basic UDI-DI 59009497OKG-32LV );  
OKG-33(Basic UDI-DI 59009497OKG-33LX );  
OKG-34(Basic UDI-DI 59009497OKG-34LZ );  
OKG-35(Basic UDI-DI 59009497OKG-35M3);  
OKG-36(Basic UDI-DI 59009497OKG-36M5 );  
OKG-37(Basic UDI-DI 59009497OKG-37M7 );  
OKG-38(Basic UDI-DI 59009497OKG-38M9 );  
OKG-39(Basic UDI-DI 59009497OKG-39MB );  
OKG-40(Basic UDI-DI 59009497OKG-40LU );  
OKG-41(Basic UDI-DI 59009497OKG-41LW );  
OKG-42(Basic UDI-DI 59009497OKG-42LY );  
OKG-43(Basic UDI-DI 59009497OKG-43M2 );  
OKG-44(Basic UDI-DI 59009497OKG-44M4 );  
OKG-45(Basic UDI-DI 59009497OKG-45M6 );  
OKG-46(Basic UDI-DI 59009497OKG-46M8);  
OKG-47(Basic UDI-DI 59009497OKG-47MA );  
OKG-48(Basic UDI-DI 59009497OKG-48MC );  
OKG-49(Basic UDI-DI 59009497OKG-49ME );  
OKG-50(Basic UDI-DI 59009497OKG-50LX );  
OKG-51(Basic UDI-DI 59009497OKG-51LZ );  
OKG-52(Basic UDI-DI 59009497OKG-52M3 );  
OKG-53(Basic UDI-DI 59009497OKG-53M5 );  
OKG-54(Basic UDI-DI 59009497OKG-54M7 );  
OKG-55(Basic UDI-DI 59009497OKG-55M9 );  
OKG-56(Basic UDI-DI 59009497OKG-56MB );  
OKG-57(Basic UDI-DI 59009497OKG-57MD);  
OKG-58(Basic UDI-DI 59009497OKG-58MF );  
OKG-59(Basic UDI-DI 59009497OKG-59MH );  
OKG-60(Basic UDI-DI 59009497OKG-60M2 );  
OKG-61(Basic UDI-DI 59009497OKG-61M4 );  
OKG-62(Basic UDI-DI 59009497OKG-62M6 );  
OKG-63(Basic UDI-DI 59009497OKG-63M8 );  
OKG-64(Basic UDI-DI 59009497OKG-64MA );  
OKG-65(Basic UDI-DI 59009497OKG-65MC );  
OKG-66(Basic UDI-DI 59009497OKG-66ME );  
OKG-67(Basic UDI-DI 59009497OKG-67MG );  
OKG-68(Basic UDI-DI 59009497OKG-68MJ );  
OKG-69(Basic UDI-DI 59009497OKG-69ML );  
OKG-70(Basic UDI-DI 59009497OKG-70M5 );  
OKG-71(Basic UDI-DI 59009497OKG-71M7 );  
OKG-72(Basic UDI-DI 59009497OKG-72M9 );  
OKG-73(Basic UDI-DI 59009497OKG-73MB );  
OKG-74(Basic UDI-DI 59009497OKG-74MD );  
OKG-75(Basic UDI-DI 59009497OKG-75MF );  
OKG-76(Basic UDI-DI 59009497OKG-76MH );  
OKG-77(Basic UDI-DI 59009497OKG-77MK).

  
COMPANY OWNER  
Sławomir Wroński