

# DECLARATION OF CONFORMITY EC

## No. 46/D/EN/5

THE REH4MAT MANUFACTURER DECLARES THAT

### PRODUCT: ELBOW ORTHOSIS

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 Wróński

# APPENDIX NO. 1

To declaration of conformity no. 46/D/EN/5

## PRODUCT: ELBOW ORTHOSIS

### MODELS:

ELBOW ORTHOSIS AM-LX-02 (Basic UDI-DI 590128913AM-LX-02F8);  
ELBOW ORTHOSIS AM-SL-02(Basic UDI-DI 590128913AM-SL-02EZ);  
ELBOW ORTHOSIS AM-LX-01 (Basic UDI-DI 590128913AM-LX-01F6);  
ELBOW ORTHOSIS AM-SL-03 (Basic UDI-DI 590128913AM-SL-03F3);  
ELBOW ORTHOSIS MS-L-01 (Basic UDI-DI 590128913MS-L-01A5);  
ELBOW ORTHOSIS MS-L-02 (Basic UDI-DI 590128913MS-L-02A7);  
ELBOW ORTHOSIS R4M-SL (Basic UDI-DI 590743912R4M-SLBE);  
ELBOW ORTHOSIS R4M-SL-01 (Basic UDI-DI 590128913R4M-SL-01VY);  
ELBOW ORTHOSIS AS-PL (Basic UDI-DI 590128913AS-PL7L);  
ELBOW ORTHOSIS AS-L (Basic UDI-DI 590128913AS-LBF);  
ELBOW ORTHOSIS AS-L-01 (Basic UDI-DI 590128913AS-L-013R);  
ELBOW ORTHOSIS AS-L-02 (Basic UDI-DI 590128913AS-L-023T);  
ELBOW ORTHOSIS AM-SL (Basic UDI-DI 590743912AM-SLA7);  
ELBOW ORTHOSIS AM-SL-01 (Basic UDI-DI 590128913AM-SL-01EX);  
AM-KG-AR/1R (Basic UDI-DI 59009497AM-KG-AR/1RSZ);  
AM-KG-AM/1R (Basic UDI-DI 59009497AM-KG-AM/1RRW).