

# DECLARATION OF CONFORMITY EC

## No. 68/D/EN/5

THE REH4MAT MANUFACTURER DECLARES THAT

**PRODUCT: FINGER SPLINT**

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. 68/D/EN/5

## PRODUCT: FINGER SPLINT

### MODELS:

FINGER SPLINT RĘKI AM-D-01 (Basic UDI-DI 590128913AM-D-01XG);  
FINGER SPLINT RĘKI AM-D-02 (Basic UDI-DI 590128913AM-D-02XJ);  
FINGER SPLINT RĘKI AM-D-03 (Basic UDI-DI 590128913AM-D-03XL);  
FINGER SPLINT RĘKI AM-D-04 (Basic UDI-DI 590128913AM-D-04XN);  
FINGER SPLINT RĘKI AM-D-05 (Basic UDI-DI 590128913AM-D-05XQ);  
FINGER SPLINT RĘKI AM-SP-01 (Basic UDI-DI 590128913AM-SP-01FT);  
FINGER SPLINT RĘKI AM-SP-02 (Basic UDI-DI 590128913AM-SP-02FV);  
FINGER SPLINT RĘKI AM-SP-03 (Basic UDI-DI 590128913AM-SP-03FX);  
FINGER SPLINT RĘKI AM-SP-04 (Basic UDI-DI 590128913AM-SP-04F Z);  
FINGER SPLINT RĘKI AM-SP-05 (Basic UDI-DI 590128913AM-SP-05G3);

reh:mat   
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