

# DECLARATION OF CONFORMITY EC

## No. 61/D/EN/5

THE REH4MAT MANUFACTURER DECLARES THAT

**PRODUCT: KNEE 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 Wroński

# APPENDIX NO. 1

To declaration of conformity no. 61/D/EN/5

**PRODUCT:** KNEE ORTHOSIS

**MODELS:**

- AM-OSK-Z** (Basic UDI-DI 59009497AM-OSK-ZVP);
- AM-OSK-Z/P** (Basic UDI-DI 59009497AM-OSK-Z/PS6);
- AM-OSK-Z/S** (Basic UDI-DI 59009497AM-OSK-Z/SSC);
- AM-OSK-Z/S-P.** (Basic UDI-DI 59009497AM-OSK-Z/S-P4T);
- AM-OSK-Z/S-X** (Basic UDI-DI 59009497AM-OSK-Z/S-X5B);
- R4M-SK** (Basic UDI-DI 59009497R4M-SKL9);
- R4M-SK/F** (Basic UDI-DI 59009497R4M-SK/FT8);
- AS-SK** (Basic UDI-DI 59009497AS-SKMN);
- AS-SK-01** (Basic UDI-DI 59009497AS-SK-01RR);
- AS-SK-02** (Basic UDI-DI 59009497AS-SK-02RT);
- AS-SK/F** (Basic UDI-DI 59009497AS-SK/FL9).

rehamat  COMPANY OWNER  
Sławomir Wroński