

DECLARATION OF CONFORMITY EC

No. 51/D/EN/4

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. 51/D/EN/4

PRODUCT: KNEE ORTHOSIS

MODELS:

KNEE ORTHOSIS AS-KX-06 (Basic UDI-DI 59009497AS-KX-06S6);

KNEE ORTHOSIS AS-KX-05 (Basic UDI-DI 59009497AS-KX-05S4);

KNEE ORTHOSIS AS-KX-04 (Basic UDI-DI 59009497AS-KX-04S2);

KNEE ORTHOSIS AS-KX-08 (Basic UDI-DI 59009497AS-KX-08SA);

KNEE ORTHOSIS AS-KX-07 (Basic UDI-DI 59009497AS-KX-07S8);

KNEE ORTHOSIS AS-P/RZ (Basic UDI-DI 59009497AS-P/RZKT);

KNEE ORTHOSIS AS-KX-01 (Basic UDI-DI 59009497AS-KX-01RU);

KNEE ORTHOSIS AS-KX-02 (Basic UDI-DI 59009497AS-KX-02RW);

KNEE ORTHOSIS AS-KX-03 (Basic UDI-DI 59009497AS-KX-03RY);

EB-P/RZ (Basic UDI-DI 59009497EB-P/RZF2);

U-SK (Basic UDI-DI 59009497U-SKSL);

U-SK-01 (Basic UDI-DI 59009497U-SK-01M5);

U-SK-02 (Basic UDI-DI 59009497U-SK-02M7);

 **COMPANY OWNER**

Sławomir Wroński