

DECLARATION OF CONFORMITY EC

No. 57/D/EN/5

THE REH4MAT MANUFACTURER DECLARES THAT

PRODUCT: ANKLE 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


reimat COMPANY OWNER
Sławomir Wroński

APPENDIX NO. 1

To declaration of conformity no. 57/D/EN/5

PRODUCT: ANKLE ORTHOSIS

MODELS:

ANKLE ORTHOSIS AM-OSS-07 (Basic UDI-DI 59009497AM-OSS-076S);
ANKLE ORTHOSIS AM-OSS-08 (Basic UDI-DI 59009497AM-OSS-086U);
ANKLE ORTHOSIS AM-OSS-09 (Basic UDI-DI 59009497AM-OSS-096W);
ANKLE ORTHOSIS AM-OSS-10 (Basic UDI-DI 59009497AM-OSS-106F);
ANKLE ORTHOSIS AM-OSS-11 (Basic UDI-DI 59009497AM-OSS-116H);
ANKLE ORTHOSIS AM-OSS-12 (Basic UDI-DI 59009497AM-OSS-126K);
ANKLE ORTHOSIS AM-OSS-13 (Basic UDI-DI 59009497AM-OSS-136M);
ANKLE ORTHOSIS AM-OSS-14 (Basic UDI-DI 59009497AM-OSS-146P);
ANKLE ORTHOSIS AM-OSS-15 (Basic UDI-DI 59009497AM-OSS-156R);
ANKLE ORTHOSIS AM-OSS-16 (Basic UDI-DI 59009497AM-OSS-166T);
ANKLE ORTHOSIS AM-OSS-17 (Basic UDI-DI 59009497AM-OSS-176V);
ANKLE ORTHOSIS AM-OSS-18 (Basic UDI-DI 59009497AM-OSS-176V);
ANKLE ORTHOSIS AM-OSS-19 (Basic UDI-DI 59009497AM-OSS-196Z);
ANKLE ORTHOSIS AM-OSS-20 (Basic UDI-DI 59009497AM-OSS-206J);
EB-SS (Basic UDI-DI 59009497EB-SSKT);
U-SS (Basic UDI-DI 59009497U-SST4);
U-SS-01 (Basic UDI-DI 59009497U-SS-01NV);
ANKLE ORTHOSIS AM-SX-08 (Basic UDI-DI 59009497AM-SX-08RU);
ANKLE ORTHOSIS AM-SX-05 (Basic UDI-DI 59009497AM-SX-05RN);
ANKLE ORTHOSIS AM-OSS-05 (Basic UDI-DI 59009497AM-OSS-056N);
ANKLE ORTHOSIS AM-SX-01 (Basic UDI-DI 59009497AM-SX-01RE);
ANKLE ORTHOSIS AM-SX-02 (Basic UDI-DI 59009497AM-SX-02RG);
ANKLE ORTHOSIS AM-SX-03 (Basic UDI-DI 59009497AM-SX-03RJ);
ANKLE ORTHOSIS AM-SX-04 (Basic UDI-DI 59009497AM-SX-04RL);
ANKLE ORTHOSIS AM-SX-06 (Basic UDI-DI 59009497AM-SX-06RQ);
ANKLE ORTHOSIS AM-SX-07 (Basic UDI-DI 59009497AM-SX-07RS);
ANKLE ORTHOSIS AM-OSS-06 (Basic UDI-DI 59009497AM-OSS-066Q)


COMPANY OWNER
Sławomir Wroński