DECLARATION OF CONFORMITY EC

No. 58/D/EN/5

THE REH4MAT MANUFACTURER DECLARES THAT

PRODUCT: FOOT AND 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

COMPANY OWNER
Sławomir Wroński

Głogów Małopolski 13.07.2021

APPENDIX NO. 1

To declaration of conformity no. 58/D/EN/5

PRODUCT: FOOT AND ANKLE ORTHOSIS

MODELS:

AM-OSS-01 (Basic UDI-DI 59009497AM-OSS-016E);
AM-OSS-02 (Basic UDI-DI 59009497AM-OSS-026G);
AM-OSS-03 (Basic UDI-DI 59009497AM-OSS-036J);
AM-ASS-OS (Basic UDI-DI 59009497AM-OSS-OSBA);
AM-OSS-04 (Basic UDI-DI 59009497AM-OSS-046L);
R4M-SS (Basic UDI-DI 59009497R4M-SSLR);
R4M-SS-01 (Basic UDI-DI 59009497R4M-SS-017F);
AS-S (Basic UDI-DI 59009497AS-SSN6);
AS-SS-01 (Basic UDI-DI 59009497AS-SS-01TH).

COMPANY OWNER
Sławomir Wroński

Głogów Małopolski 13.07.2021