DECLARATION OF CONFORMITY EC

No. 70/D/EN/5

THE REH4MAT MANUFACTURER DECLARES THAT

PRODUCT: FOOT 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. 70/D/EN/5

PRODUCT: FOOT ORTHOSIS

MODELS:

FOOT ORTHOSIS OSS-OS-01 (Basic UDI-DI 59009497OSS-OS-01QW);
FOOT ORTHOSIS OSS-OS-02 (Basic UDI-DI 59009497OSS-OS-02QY);
FOOT ORTHOSIS OSS-OS-03 (Basic UDI-DI 59009497OSS-OS-03R2);
FOOT ORTHOSIS OSS-OS-04 (Basic UDI-DI 59009497OSS-OS-04R4);
FOOT ORTHOSIS OSS-OS-05 (Basic UDI-DI 59009497OSS-OS-05R6);
FOOT ORTHOSIS AM-OP-01 (Basic UDI-DI 59009497AM-OP-01NA);
FOOT ORTHOSIS AM-OP-02 (Basic UDI-DI 59009497AM-OP-02NC).

COMPANY OWNER
Sławomir Wroński

Głogów Małopolski 13.07.2021