

# DECLARATION

## OF EC CONFORMITY

MANUFACTURER REH4MAT LTD. DECLARE, THAT  
PRODUCT: FOOT ORTHOSIS  
LIST OF ITEMS IN APPENDIX NO. 1

of intended use: to reduce instability in the ankle joint and foot and improve the patient's gait pattern and the functionality of the entire limb.

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.

The above product to which this declaration applies complies with Regulation (EU) 2017/745 of the European Parliament and of the Council.

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 ISO 20417:2021-10

Medical devices -- Information to be supplied by the manufacturer.

PN-EN ISO 21856:2023-01

Assistive products -- General requirements and test methods.

PN-EN ISO 15223-1:2022-01

Medical devices -- Symbols to be used with information to be supplied by the manufacturer  
-- Part 1: General requirements.

PN-EN ISO 13485:2016-04

Medical devices -- Quality management systems -- Requirements for regulatory purposes.

PN-EN ISO 14971:2020-05

Medical devices -- Application of risk management to medical devices.



*President of the board*  
A handwritten signature in black ink, appearing to be 'Sławomir Wroński'.  
Sławomir Wroński

THE ABOVE CERTIFICATE WAS ISSUED ON SOLE RESPONSIBILITY OF  
REH4MAT LTD., 35-301 RZESZÓW, UL. ZENITOWA 5A,  
COUNTRY OF ORIGIN: POLAND, SRN: PL-MF-000009271

# APPENDIX NO. 1

## TO DECLARATION OF CONFORMITY

PRODUCT - FOOT ORTHOSIS  
MODELS:

OSS-OS-06	(Basic UDI-DI 59009497OSS-OS-06R8),
OSS-OS-07	(Basic UDI-DI 59009497OSS-OS-07RA),
OSS-OS-08	(Basic UDI-DI 59009497OSS-OS-08RC),
OSS-OS-09	(Basic UDI-DI 59009497OSS-OS-09RE),
OSS-OS-10	(Basic UDI-DI 59009497OSS-OS-10QX),
OSS-OS-11	(Basic UDI-DI 59009497OSS-OS-11QZ),
OSS-OS-12	(Basic UDI-DI 59009497OSS-OS-12R3),
OSS-OS-13	(Basic UDI-DI 59009497OSS-OS-13R5),
OSS-OS-14	(Basic UDI-DI 59009497OSS-OS-14R7),
OSS-OS-15	(Basic UDI-DI 59009497OSS-OS-15R9),
OSS-OS-16	(Basic UDI-DI 59009497OSS-OS-16RB),
OSS-OS-17	(Basic UDI-DI 59009497OSS-OS-17RD),
OSS-OS-18	(Basic UDI-DI 59009497OSS-OS-18RF),
OSS-OS-19	(Basic UDI-DI 59009497OSS-OS-19RH),
OSS-OS-20	(Basic UDI-DI 59009497OSS-OS-20R2).



*President of the board*  
  
Sławomir Wroński

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