

DECLARATION

OF EC CONFORMITY

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

of intended use: to stabilize ankle joint, improve the dynamics walk of patient with dropping foot. Should be applied in cases of: advanced degenerative changes of ankle joint, during rehabilitation after damage of ankle joint and foot.

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 read '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 - ANKLE ORTHOSIS
MODELS:

ANKLE ORTHOSIS AM-OSS-07
ANKLE ORTHOSIS AM-OSS-08
ANKLE ORTHOSIS AM-OSS-09
ANKLE ORTHOSIS AM-OSS-10
ANKLE ORTHOSIS AM-OSS-11
ANKLE ORTHOSIS AM-OSS-12
ANKLE ORTHOSIS AM-OSS-13
ANKLE ORTHOSIS AM-OSS-14
ANKLE ORTHOSIS AM-OSS-15
ANKLE ORTHOSIS AM-OSS-16
ANKLE ORTHOSIS AM-OSS-17
ANKLE ORTHOSIS AM-OSS-18
ANKLE ORTHOSIS AM-OSS-19
ANKLE ORTHOSIS AM-OSS-20
EB-SS
U-SS
U-SS-01
ANKLE ORTHOSIS AM-SX-08
ANKLE ORTHOSIS AM-SX-05
ANKLE ORTHOSIS AM-OSS-05
ANKLE ORTHOSIS AM-SX-01
ANKLE ORTHOSIS AM-SX-02
ANKLE ORTHOSIS AM-SX-03
ANKLE ORTHOSIS AM-SX-04
ANKLE ORTHOSIS AM-SX-06
ANKLE ORTHOSIS AM-SX-07
ANKLE ORTHOSIS AM-OSS-06

(Basic UDI-DI 59009497AM-OSS-076S),
(Basic UDI-DI 59009497AM-OSS-086U),
(Basic UDI-DI 59009497AM-OSS-096W),
(Basic UDI-DI 59009497AM-OSS-106F),
(Basic UDI-DI 59009497AM-OSS-116H),
(Basic UDI-DI 59009497AM-OSS-126K),
(Basic UDI-DI 59009497AM-OSS-136M),
(Basic UDI-DI 59009497AM-OSS-146P),
(Basic UDI-DI 59009497AM-OSS-156R),
(Basic UDI-DI 59009497AM-OSS-166T),
(Basic UDI-DI 59009497AM-OSS-176V),
(Basic UDI-DI 59009497AM-OSS-176V),
(Basic UDI-DI 59009497AM-OSS-196Z),
(Basic UDI-DI 59009497AM-OSS-206J),
(Basic UDI-DI 59009497EB-SSKT),
(Basic UDI-DI 59009497U-SST4),
(Basic UDI-DI 59009497U-SS-01NV),
(Basic UDI-DI 59009497AM-SX-08RU),
(Basic UDI-DI 59009497AM-SX-05RN),
(Basic UDI-DI 59009497AM-OSS-056N),
(Basic UDI-DI 59009497AM-SX-01RE),
(Basic UDI-DI 59009497AM-SX-02RG),
(Basic UDI-DI 59009497AM-SX-03RJ),
(Basic UDI-DI 59009497AM-SX-04RL),
(Basic UDI-DI 59009497AM-SX-06RQ),
(Basic UDI-DI 59009497AM-SX-07RS),
(Basic UDI-DI 59009497AM-OSS-066Q).



President of the board

Sławomir Wroński

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