

DECLARATION OF CONFORMITY
FOR PRODUCTS MANUFACTURED
FROM JANUARY 2024.



DECLARATION

OF EC CONFORMITY

MANUFACTURER REH4MAT LTD. DECLARE, THAT

PRODUCT: FOOT ORTHOSIS

MODELS: AM-OSS-05/CCA (Basic UDI-DI 59009497AM-OSS-05/CCAH4),
AM-OSS-03/CCA (Basic UDI-DI 59009497AM-OSS-03/CCAGE),

of intended use: prevent against deformation of foot and ankle area. Product raise a foot drop, improve dynamic walk and pattern of gait. Product is used prophylactic, after injuries and surgeries.

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

Sławomir Wroński

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

Rzeszów, 08.01.2024 No. 91/D/EN/4

DECLARATION OF CONFORMITY
FOR PRODUCTS MANUFACTURED
BY THE END OF DECEMBER 2023.



DECLARATION

OF EC CONFORMITY

MANUFACTURER REH4MAT SŁAWOMIR WROŃSKI DECLARE, THAT

PRODUCT: FOOT ORTHOSIS

MODELS: AM-OSS-05/CCA (Basic UDI-DI 59009497AM-OSS-05/CCAH4),
AM-OSS-03/CCA (Basic UDI-DI 59009497AM-OSS-03/CCAGE),

of intended use: prevent against deformation of foot and ankle area. Product raise a foot drop, improve dynamic walk and pattern of gait. Product is used prophylactic, after injuries and surgeries.

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.



rehmat COMPANY OWNER
Sławomir Wroński

THE ABOVE CERTIFICATE WAS ISSUED ON SOLE RESPONSIBILITY OF
REH4MAT SŁAWOMIR WROŃSKI, 36-060 GŁOGÓW MAŁOPOLSKI, UL. PIASKI 47,
COUNTRY OF ORIGIN: POLAND, (SRN): PL-MF-000009271

Głogów Małopolski, 19.07.2023r. No. 91/D/EN/3