

# DECLARATION

## OF EC CONFORMITY

MANUFACTURER REH4MAT LTD. DECLARE, THAT  
PRODUCT: BACK ORTHOSIS  
MODELS: AM-PES-01 (Basic UDI-DI 59009497AM-PES-01ZW),  
AM-PES-02 (Basic UDI-DI 59009497AM-PES-0223),

of intended use: maintains the patient's correct posture and stabilizes the joints of the shoulder girdle.  
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

Rzeszów, 27.03.2024 No. 11/D/EN/9