

# DECLARATION OF CONFORMITY EC

## No. 28/D/EN/6

THE REH4MAT MANUFACTURER DECLARES THAT

### PRODUCT: CALF ORTHOSIS

**MODEL:** AS-PU (Basic UDI-DI 59009497AS-PUMZ);  
AS-PU-01 (Basic UDI-DI 59009497AS-PU-01SW);  
R4M-PU (Basic UDI-DI 59009497R4M-PULL);  
R4M-PU-01 (Basic UDI-DI 59009497R4M-PU-016U).

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

reh4mat   
COMPANY OWNER  
Sławomir Wroński