

# DECLARATION OF CONFORMITY EC

## No. 58/D/EN/3

**MANUFACTURER**

REH4MAT

**PRODUCT**

FOOT AND ANKLE ORTHOSIS

Model: AM-OSS-01; AM-OSS-02; AM-OSS-03; AM-ASS-OS; AM-OSS-04;  
R4M-SS; R4M-SS-01; AS-S; AS-SS-01

marked with the CE sign is Class I medical device, of rule 1, consistent with the requirements of the **Council Directive 93/42/EEC of 14 June 1993 on medical devices** and the **Law of 20 May 2010 on medical devices** as amended. Conformity assessment was carried out on the basis of the **VII Council Directive 93/42/EEC**.

**The product meets the requirements of the harmonized standards**

**PN-EN 1041+A1:2013-12**

Information supplied by the manufacturer of medical devices

**PN-EN 12182:2012**

Assistive products for persons with disability. General requirements and test methods

**PN-EN ISO 13485:2016**

Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes

**PN-EN ISO 14971:2012**

Medical devices. Application of risk management to medical device

**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

THIS DECLARATION HAS BEEN ISSUED ON THE RESPONSIBILITY  
OF THE MANUFACTURER

REH4MAT, 36-060 Głogów Małopolski, ul. Piaski 47, Poland

