DECLARATION OF CONFORMITY EC

No. 57/D/EN/3

MANUFACTURER

REH4MAT

PRODUCT

ANKLE ORTHOSIS

MODEL: 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

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

QUALITY SYSTEM CERTIFICATION DNV·GL ISO 13485

COMPANY OWNER
Sławomir Wroński

Głogów Małopolski 27.09.2019