REH4MAT
MANUFACTURER OF MODERN ORTHOPAEDIC BRACES

DECLARATION OF CONFORMITY

No. 57/D/EN/1

COMPANY

REH4MAT

DECLARES

that 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 MayN2010 on medical devises (Journal of Laws of 2015, No. 876, 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 13485:2012	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 COMPANY
REH4MAT, 36-060 Głogów Małopolski, ul. Piaski 47, POLAND

Country of origin: **POLAND**

Company owner
Sławomir Wroński

Głogów Małopolski., 08.06.2018