DECLARATION OF CONFORMITY EC

No. 59/D/EN/3

MANUFACTURER

REH4MAT

PRODUCT

HIP ORTHOSIS

MODEL: AM-SB/1RE; AM-ADS-R; AM-SB/2R; HIP ORTHOSIS AM-SB-01; HIP ORTHOSIS AM-SB-02; HIP ORTHOSIS AM-SB-03; HIP ORTHOSIS AM-SB-04; HIP ORTHOSIS AM-SB-05; HIP ORTHOSIS AM-SB-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