DECLARATION OF CONFORMITY EC

No. 84/D/EN/2

MANUFACTURER

REH4MAT

PRODUCT

POSTURAL COMPRESSION ORTHOSES

MODEL: PCO-T-01, PCO-T-02, PCO-T-03, PCO-T-04, PCO-T-05, PCO-T-06, PCO-T-07, PCO-T-08, PCO-T-09, PCO-T-10, PCO-T-11, PCO-T-12, PCO-T-13, PCO-T-14, PCO-T-15, PCO-T-16, PCO-T-17, PCO-T-18, PCO-T-19, PCO-T-20, PCO-T-21, PCO-T-22, PCO-T-23, PCO-T-24, PCO-T-25, PCO-T-26, PCO-T-27, PCO-T-28, PCO-T-29, PCO-L-01, PCO-L-02, PCO-L-03, PCO-L-04, PCO-L-05, PCO-L-06, PCO-L-07, PCO-L-08, PCO-L-09, PCO-L-10, PCO-L-11, PCO-L-12, PCO-L-13, PCO-L-14, PCO-L-15, PCO-L-16, PCO-L-17, PCO-L-18, PCO-A-01, PCO-A-02, PCO-A-03, PCO-A-04, PCO-A-05, PCO-A-06, PCO-A-07, PCO-A-08, PCO-A-09, PCO-A-10, PCO-H-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

QUALITY SYSTEM CERTIFICATION DNV·GL ISO 13485

COMPANY OWNER
Sławomir Wroński

Głogów Małopolski 27.09.2019