

DECLARATION OF CONFORMITY EC

No. 70/D/EN/3

MANUFACTURER

REH4MAT

PRODUCT

FOOT ORTHOSIS

MODEL: FOOT ORTHOSIS OSS-OS-01; FOOT ORTHOSIS OSS-OS-02; FOOT ORTHOSIS OSS-OS-03; FOOT ORTHOSIS OSS-OS-04; FOOT ORTHOSIS OSS-OS-05; FOOT ORTHOSIS AM-OP-01; FOOT ORTHOSIS AM-OP-02

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



reh4mat **COMPANY OWNER**
Sławomir Wronski