

DECLARATION OF CONFORMITY

No. 70/D/EN/2

COMPANY

REH4MAT Sławomir Wroński

DECLARES

that 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 (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:

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|---------------------------|--|
| 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 COMPANY
REH4MAT Sławomir Wroński, 36-060 Głogów Małopolski, ul. Piaski 47, POLAND

Country of origin: **POLAND**

Company owner

Sławomir Wroński