

# DECLARATION OF CONFORMITY

COMPANY  
REH4MAT

## DECLARES

that product:

**ANKLE ORTHOSIS**  
**MODEL: ANKLE ORTHOSIS AM-SX-03**

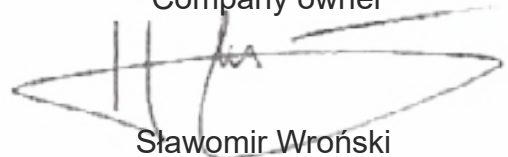
is in conformity with Council Directive 93/42 / EEC of 14 June 1993  
concerning medical devices and harmonized with its standards:

|                        |  |
|------------------------|--|
| 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 devices   |
| PN-EN ISO 15223-1:2012 | Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements |

and with the Act of Law of 20 May 2010 on Medical Devices  
(Dz. U. 2010 nr 107 poz 679)

THIS DECLARATION HAS BEEN ISSUED ON THE RESPONSIBILITY  
OF THE COMPANY REH4MAT, 36-060 Głogów Małopolski, ul. Piaski 47.

Company owner



Sławomir Wroński