

DECLARATION OF CONFORMITY

COMPANY REH4MAT DECLARES

that product:

FOOT ORTHOSIS MODEL: FOOT ORTHOSIS OSS-OS-05

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 PN-EN 12182:2012	Information supplied by the manufacturer of medical devices Assistive products for persons with disability. General requirements and test methods
PN-EN ISO 13485:2012	Medical Devices - Quality Management Systems - Requirements for
PN-EN ISO 14971:2012	Regulatory Purposes Medical devices. Application of risk management to medical
PN-EN ISO 15223-1:2012	devices Medical devices. Symbols to be used with medical device labels,
FIN-EIN 130 13223-1.2012	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

Głogów Małopolski., 23.07.2015