

## DECLARATION OF CONFORMITY

## **COMPANY** RFH4MAT

## **DECLARES**

that product:

**FOOT ORTHOSIS** MODEL: FOOT ORTHOSIS AM-OP-02

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

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