

DECLARATION OF CONFORMITY

COMPANY REH4MAT Sławomir Wroński

DECLARES

that orthoses:

Cat. nr.: AS-LK-01

It conforms the requirements of the Instruction of the Council 93/42/EWG from 14 June 1993 regarding medical products and associated with it norms:

PN-EN 1041:2010 - 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 14971:2011 - Medical products - Application of risk management to

medical products

PN-EN ISO 15223-1:2012 - Medical devices - Symbols to be used with medical device labels,

labelling and information to be supplied - Part 1: General requirements

and with the act of law from 20 May 2010 regarding medical products (Law gazette from 2010 Year no 107 pos.679).

The Company REH4MAT SŁAWOMIR WROŃSKI, 36-660 Głogów Małopolski, ul. Piaski 47 takes full responsibility for issuing the herby declaration.

Declaration is in compliance with the attachment No VII

President of the board

Sławomir Wroński