

## **DECLARATION OF CONFORMITY**

## COMPANY REH4MAT Sławomir Wroński

## DECLARES

That product:

**REFERENCE NUMBER:** 

AM-PES-04

It conforms the requirements of the Council Directive 93/42/EEC of 14 June 1993 (Annex VII), as amended by Medical Device Directive 2007/47/EEC regarding medical products belong to the 1 Class Of Medical Devices without measuring function, non-sterile 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	<ul> <li>Medical devices - Quality management systems - Requirements for regulatory purposes</li> </ul>
PN-EN ISO 14971:2011	<ul> <li>Medical products - Application of risk management to medical products</li> </ul>
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 of 20 May 2010 on Medical Devices (Dz.U. 2010 nr 107 poz. 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

Głogów Młp. 01.01.2014 r.