

## DECLARATION OF CONFORMITY

## COMPANY REH4MAT Sławomir Wroński

## **DECLARES**

That product:

REFERENCE NUMBER:

AM-WSP-07/TLSO

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 - 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 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