

# DECLARATION OF CONFORMITY EC

## No. 18/D/EN/4

### MANUFACTURER

REH4MAT

### PRODUCT

CRUTCH

Model: AM-KP

marked with the CE sign is Class I medical device, of rule 1, consistent with the requirements of the **Council Directive 93/42/EEC of 14 June 1993 on medical devices** and the **Law of 20 May 2010 on medical devices** as amended. Conformity assessment was carried out on the basis of the **VII Council Directive 93/42/EEC**.

### The product meets the requirements of the harmonized 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 13485:2016

Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes

#### PN-EN ISO 14971:2012

Medical devices. Application of risk management to medical device

#### PN - EN ISO 15223-1:2017-02

Medical devices Symbols to be used with medical device labels, labelling and information to be supplied - Part 1:General requirements

THIS DECLARATION HAS BEEN ISSUED ON THE RESPONSIBILITY  
OF THE MANUFACTURER

REH4MAT, 36-060 Głogów Małopolski, ul. Piaski 47, Poland



rehamat   
COMPANY OWNER  
Sławomir Wronski