

# DECLARATION OF CONFORMITY EC

## No. 74/D/EN/4

THE REH4MAT MANUFACTURER DECLARES THAT

### **PRODUCT: BATH DECKCHAIR AKVOLITO**

(Basic UDI-DI 59009497AKVOLITODZ);

marked with the CE sign is Class I medical device, of rule 1, consistent with the requirements of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

Conformity assessment was carried out in accordance with the requirements of the Regulation (EU) 2017/745 of the European Parliament and of the Council.

In order to demonstrate the safety and effectiveness of the medical device, the following standards were used to assess conformity:

#### **PN-EN 1041+A1:2013-12**

Information provided by the producer together with the medical product.

#### **PN-EN 12182:2012**

Assistive products for persons with disability - General requirements and research methods.

#### **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.

#### **PN-EN ISO 13485:2016**

Medical products - Quality management systems - Requirements for law regulations aims.

#### **PN-EN ISO 14971:2020**

Medical devices - Application of risk management to medical devices.

THIS DECLARATION HAS BEEN ISSUED ON THE RESPONSIBILITY  
OF THE MANUFACTURER

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

  
COMPANY OWNER  
Sławomir Wroński