

DECLARATION OF CE CONFORMITY



Akces-Med Ltd.

DECLARE

that stander

CAT II INVENTO

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 (Journal of Laws of 2015, No. 876, 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 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 13485:2012 - Medical products - Quality management systems - Requirements for law regulations aims
- > PN - EN 14971:2012 - Medical devices - Application of risk management to medical devices

Prezes Zarządu

A handwritten signature in blue ink, appearing to read "Sławomir Wroński", is written over a large, stylized blue oval graphic.

Sławomir Wroński

< THE ABOVE CERTIFICATE WAS ISSUED ON SOLE RESPONSIBILITY OF
AKCES-MED LTD., JASIONKA 955B, 36-002 JASIONKA >

Jasionka; 23 May 2017