DECLARATION OF CE CONFORMITY

Akces-Med Ltd.

DECLARE

that special needs stroller

URSUS

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 devises (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 13485:2016** - 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

Sławomir Wroński

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

Country of origin: POLAND

Jasionka; 08 March 2019