DECLARATION OF EC CONFORMITY

Akces-MED Ltd.

DECLARE

that stander:

CAT I

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.

President of the board

Sławomir Wroński

BASIC UDI-DI: 59038165KTK2V SINGLE REGISTRATION NUMBER (SRN): PL-MF-000003624

THE ABOVE CERTIFICATE WAS ISSUED ON SOLE RESPONSIBILITY OF

AKCES-MED LTD., JASIONKA 955B, 36-002 JASIONKA

Country of origin: POLAND

Jasionka, 18th May 2021