DECLARATION OF CE CONFORMITY

Akces-MED Ltd.

DECLARE

that standing frame:

LUNAR

MODELS:
LUNAR 1; LUNAR 2; LUNAR 3

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.

Product in compliance with the Polish law on medical devices of April 7, 2022.

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: 59038165LUN3B 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, 14th June 2022