DECLARATION
OF EC CONFORMITY

Manufacturer Akces-MED Ltd.

Declare

that special needs stroller

OMBRELO

BASIC UDI-DI: 59038165OMO34
MODELS: OMBRELO 2, OMBRELO 3, OMBRELO 4, OMBRELO 5

of intended use: for people with musculoskeletal diseases/disabilities that prevent or limit their ability to stand upright and/or move independently.

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.

The above product to which this declaration applies complies with Regulation (EU) 2017/745 of the European Parliament and of the Council.

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 ISO 20417:2021-10

Medical devices -- Information to be supplied by the manufacturer.

PN-EN ISO 21856:2023-01

Assistive products -- General requirements and test methods.

PN-EN ISO 15223-1:2022-01

Medical devices -- Symbols to be used with information to be supplied by the manufacturer -- Part 1: General requirements.

PN-EN ISO 13485:2016-04

Medical devices -- Quality management systems -- Requirements for regulatory purposes.

PN-EN ISO 14971:2020-05

Medical devices -- Application of risk management to medical devices.

President of the board

Sławomir Wroński

The above certificate was issued on sole responsibility of Akces-MED Ltd.,
Jasionka 955B, 36-002 Jasionka
Country of origin: POLAND, (SRN): PL-MF-000003624
Jasionka, 30th October 2023 NO. 21/D/EN/3