EU DECLARATION OF CONFORMITY

issued on the basis of Article 19 and Annex IV of Regulation (EU) 2017/745

Manufacturer:

LIW Care Technology Sp. z o.o.
ul. Golfowa 7
94-406 Łódź, Poland

SRN (Single Registration Number): PL-MF-000034242

Hereby declares that products:

BALTO
Size: 1, 2 and 3
intended purpose: assistive pushchair

bearing CE mark is a Class I medical device, Rule 1 in accordance with Annex VIII of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices and fulfills the requirements specified in this Regulation.

The conformity assessment was done according to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

Medical device is in conformity with the harmonized European standards:

- EN 21856:2022
- EN ISO 14971:2019
- EN ISO 20417:2021
- EN ISO 15223-1:2021
- ISO 13485:2016

Basic UDI-DI: 5904384015BALTO28

This declaration is valid for all product versions and accessories described in user manual. EU declaration of conformity is issued under the sole responsibility of the manufacturer.

On behalf of the manufacturer:

Tomasz Chmielecki, CEO
Signature:

LIW CARE TECHNOLOGY Sp. z o.o.
94-406 Łódź, ul. Golfowa 7
NIP: 729-266-53-87, REG. 100715121
KRS:0000333719

Łódź, 15th of November 2024

Manufacturer's seal