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

Baffin neoSIT RS
size S, size M, size L
intended purpose: assistive ergonomic chair for children, manually-adjusted

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 following harmonized standards:

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

Basic UDI-DI: 5904384015NEOSITRS9K

EU declaration of conformity is issued under the sole responsibility of the manufacturer.

On behalf of the manufacturer:

Signature:

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

Tomasz Chmielecki, CEO
Łódź, 15th of November 2024

Manufacturer's seal