



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 TRIO 4W / BAFFIN TRIO

size: 1 and 2

intended purpose: stand-up electric chair with lying position function – electrical stander

bearing CE mark is a Class I medical device, Rule 13 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 in 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
- EN 60601-1-2:2015

Basic UDI-DI: 5904384015BAFFINTRIO4WS6

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

On behalf of the manufacturer:

Signature:

Tomasz Chmielecki, CEO

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: