REHASENSE

EU DECLARATION OF CONFORMITY

REGULATION (EU) 2017/745OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 05 APRIL 2017 ON MEDICAL DEVICES (MDR)

Manufacturer:

Rehasense Sp. z o.o.
Sulejowska 45G
97-300 Piotrków Trybunalski, Poland
SRN: PL-MF-000004772
Declare with sole responsibility that product (a technical support for the disabled)

Product name: **BACKUP**

Catalog number: **BUWB3001, BUWB3001H, BUAB3001, BUAB3001H**

Intended use: shower chair has been designed as an assistance tool for people who have mobility problems. The device is specifically designed for individuals who require additional support and stability during washing.

Basic UDI-DI: 59074678HIG4E

meet requirements of the Regulation 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices and applicable international standards: ISO 14971:2019; ISO 20417:2021; EN 12182:2012;

Class of the medical device 1, in accordance with rule 1 (technical aid for disabled person). The product classification was carried out in accordance with the rules at Annex VIII of the Regulation 2017/745.

Manufacturer declares that follows conformity assessments procedure described in art. 52 para. 7 of the Regulation 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices after drawing up the technical documentation set out at Annexes II and III of the Regulation 2017/745.

CE

Rehasense Sp. z o.o.
Prezes Zarządu

Roger Spencer Dutton

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06-08-2024/ Piotrków Trybunalski/ CEO Roger Spencer Dutton

REHASENSE
Rehasense Sp. z o. o.
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