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 four-wheeled support for the disabled)

Product name: **SENSOR**

Item numbers: RRSENaabbb

(aa- color; bbb- sizes)

Intended use: The rollator has been designed as a tool to assist walking for people who have mobility problems.

Basic UDI-DI: 59074678ROL6U

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: ISO14971:2019; ISO 20417:2021; ISO 11199-2:2021;

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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01-09-2023/ Piotrków Trybunalski/ CEO Roger Spencer Dutton

REHASENSE
Rehasense Sp. z o. o.
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