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 (wheel wheelchair attachment)

Product name: **Track Wheel**

Models:

Track Wheel C1 (single arm), Track Wheel C2 (double arm) -carbon frame

Track Wheel A1 (single arm), Track Wheel A2 (double arm) – aluminium frame

Intended use: a single front add-on wheel for manual wheelchairs. It has been designed as assistance tool for the disabled people who use wheelchairs.

Basic UDI-DI: 59074678TRA6R

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; EN 12182:2012; ISO 7176 Part 1, 5, 8;

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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05-10-2021/ Piotrków Trybunalski/ CEO Roger Spencer Dutton

REHASENSE
Rehasense Sp. z o. o.
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