REHASENSE

EU DECLARATION OF CONFORMITY

REGULATION (EU) 2017/745 OF 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 (an electric drive for a wheelchair)

Product name: **PAWS**

Model: PAWS CITY 12”/ 14”, PAWS CRUISER 16”, PAWS TOURER 20”

Catalog number: RPabbccdee
(a– model, bb- wheel diameter, cc- clamping and lifting system, d- handle, ee- configuration)
Intended use: an auxiliary drive unit for folding and rigid frame chairs.
Basic UDI-DI: 59074678PAW5W

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 12184:2014; EN 12182:2012; ISO 7176:2014-Part1, 2, 3, 4, 5, 8, 9, 10;

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.

REHASENSE
Rehasense Sp. z o. o.
ul. Sulejowska 45g, 97-300 Piotrków Tryb.
NIP 677-237-14-61, REGON 122658133

Rehasense Sp. z o.o.
Prezes Zarządu

Roger Spencer Dutton

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27-10-2021/ Piotrków Trybunalski/ CEO/ Roger Spencer Dutton