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 13 (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

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Rehasense Sp. z o.o.
Prezes Zarządu

Roger Spencer Dutton

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