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 (manual wheelchair for disabled)

Product name: **ICON**

Model: ICON 10, ICON 20, ICON 30, ICON 40

Item number: RWaaabbcc
(aaa - model; bb - size; cc- configuration)

Intended use : The manual wheelchair is a medical device indicated for use by persons with limited motion abilities who are unable to stand, walk and/or seat independently. It is dedicated for transportation and moving of such people in sitting position.

Basic UDI-DI: 59074678WHE6J

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: EN 12183, EN 12182, EN 1021, ISO 20417, ISO 14971, ISO 7176- PART 1,3,5,7,8, 15,16 and ISO 7176-19 for models ICON 20, ICON 30, ICON 40.

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

REHASENSE
Rehasense Sp. z o. o.
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