



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 35**

Model: **ICON 35BX, ICON 35LX**

Item number: RWa35bcxy
(a-type, b- cross bar type, c-size, x-colour, y-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, ISO 7176- PART 1,3,5,7,8,15; EN 1021-1, ISO 20417, ISO 14971.

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 Sp. z o.o.
Prezes Zarządu

Roger Spencer Dutton

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