



REHASENSE

EU DECLARATION OF CONFORMITY

We,

Rehasense sp. z o. o.

registered place of business

Ul. Sulejowska 45 G

97-400 Piotrków Trybunalski

Poland

as manufacturer of devices with a trade name:

Track Wheel – Single Arm

Item number/Catalogue number : RTW12SC

(TW=Track Wheel, 00-99: wheel size (12", 14", etc.), AA-ZZ: S=Single Arm, D=Double Arms, A=Alu, C=Carbon Fiber, 000-ZZZ: Configuration, color, etc.)

We hereby declare on our sole responsibility that it meets the essential requirements of Annex I and complies with the requirements of Regulation of the European Parliament and of the Council of the EU 2017/745 on medical devices of April 5, 2017, with all changes.

The accessory listed above is intended to be used together with medical device Class 1 technical aid for disabled person. Classification is made according to Annex VII of MDR regulation.

Medical Device as Class 1 technical aid for disabled person. Classification is made according to Annex VII of MDR regulation

Risk analysis follows the requirements of the norms: ISO 14971:2012 & ISO 13485:2016

Following harmonized norms were used during the conformity estimation:

ISO 14971:2012; ISO 13485:2016, EN 12182:2012; ISO 7176-1; ISO 7176-5; ISO 7176-8



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**ul. Sulejowska 45g, 97-300 Piotrków Tryb.
NIP 677-237-14-61, REGON 122658133**

**Rehasense Sp. z o.o.
Prezes Zarządu**

Roger Spencer Dutton

2020/03/27 CEO Roger Spencer Dutton