



REHASENSE

## EU DECLARATION OF CONFORMITY

### COUNCIL DIRECTIVE 93/42 CONCERNING MEDICAL DEVICES

We,

Rehasense sp. z o. o.

registered place of business

Ul. Sulejowska 45 G

97-400 Piotrków Trybunalski

Poland

as manufacturer of medical devices, an electric drive for a wheelchair with a trade name:

### PAWS

**Product family consists following types: PAWS CITY, PAWS CRUISER, PAWS TOURER**

we hereby declare on our sole responsibility that it meets the essential requirements and it is in conformance with the provision of the COUNCIL DIRECTIVE 93/42/EEC annex 7 implemented in Poland on bases of the REGULATION ABOUT MEDICAL DEVICE FROM MAY 20<sup>TH</sup> 2010 (Dz. U.no 107 from 2010, pos. 679) with further changes

Our product is classified as Medical Device as Class 1 "Walking aid manipulated by both arm". The classification is based on the requirements of Rule 1 of annex IX of the Council Directive 93/42/EEC

The CE marking has been affixed on the product according to article 17 of the Council Directive 93/42/EEC.

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

Following harmonized norms were used during the conformity estimation:

PN-EN 12184 :2014, PN-EN 12182 :2012, ISO 7176- PART 1,2,3,4,5,6,8,9,10 ; PN-EN 1041 :2001 ; PN-EN 14971 :2012



Rehasense Sp. z o.o.  
Prezes Zarządu

Roger Spencer Dutton

2020/09/21 CEO Roger Spencer Dutton



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