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, a technical support for the disabled with a trade name:

GATEWAY Transfer device

we hereby declare 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 20TH 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 ISO14971:2012; PN-EN 1041:2001; PN-EN ISO 11199-2:2008;

CE

2020/08/10 CEO Roger Spencer Dutton

Rehasense Sp. z o.o.
Prezes Zarządu

Roger Spencer Dutton

REHASENSE

Rehasense Sp. z o. o.
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