



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 wheelchair ramps for the disabled with a trade name:

### **BROADBAND**

Product family consists following types:

#### **Broadband Spectrum**

#### **Broadband Defrag**

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 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 ISO14971:2012; PN-EN 1041:2001; PN-EN 12182:2012;



2020/08/11 CEO Roger Spencer Dutton

Rehasense Sp. z o.o.  
Prezes Zarządu

Roger Spencer Dutton

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