REHASENSE SP. Z 0.0. | SULEJOWSKA 45G | 97-300 PIOTRKÓW TRYBUNALSKI | POLAND

Compliance with MDR 2017/745 and sub standards

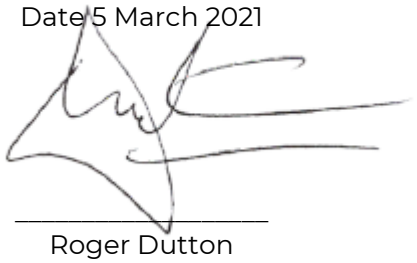
We,
Rehasense Sp. z o.o.
registered place of business
Sulejowska 45 G
97-300 Piotrków Trybunalski, Poland

as manufacturer of medical devices, parts and accessories, hereby declare on our sole responsibility that we meet 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.

Our products are classified as Medical Devices as Class 1 technical aid for disabled person.
Classification is made according to Annex VIII of MDR regulation.
We declare that we have implemented quality management system according to ISO 9001:2015 & ISO 13485:2016.

Risk analysis of our products follows the requirements of the norm ISO 14971:2019.
Following harmonized norms were used during the conformity estimation:
PN-EN ISO 11199-2:2005, PN-EN ISO 11199-3:2005, PN-EN 12182:2012, PN-EN 12183:2014, PN-EN 12184:2014, ISO 7176 (PARTS 1, 2, 3, 4, 5, 6, 7, 8, 9, 10), PN-EN 1021-1:2014, ISO 20417:2021, PN-EN 60601-1-12:2015-07/A1:2021-04, PN-EN 60601-2-52:2010/ A1:2015-07, PN-EN 60601-1-2:2015-11;

Date 5 March 2021



Roger Dutton
CEO Rehasense Group